216-RICR-30-05-4

Laurie Gaddis Barrett <lauriegaddis@gmail.com>

Sat 2/3/2024 3:48 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Mr. Garceau,

The ANPR for the adoption of Masking in School (216-RICR-30-05-4) for the purpose of publicly setting forth the rationale for a masking requirement in K-12 states that for the the full regulatory analysis and supporting documentation the person to contact is yourself.

Please consider this a formal request under APRA for an electronic copy of those documents, to be returned by email to this address.

"Regulatory Analysis Summary and Supporting Documentation:
In development of this rule, consideration was given to:
1. Alternative approaches;
2. Overlap or duplication with other statutory and regulatory provisions; and
3. Significant economic impact on small business
No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs. **For full regulatory analysis or supporting documentation contact the agency staffperson listed above."**

Thank you.

Masking in School

Cheryl Almeida <angelw3150@aol.com>

Mon 2/5/2024 2:11 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Mr. Garceau,

Respectfully, after hearing of the proposed adoption by the Dept. of Health of Masking in School (216-RICR-30-05-4), I was infuriated. As a grandmother with a now 11 year old grandson who was deeply affected by the school masking, I could not believe, after all the science that has proven that it was never necessary to mask our kids! Not one child died from COVID in this state. Masks do not work. If they did, why did people who wore them get COVID? This article, https://thefederalist.com/2023/12/20/rhode-island-parents-score-major-legal-win-against-the-states-school-mask-mandates/ [thefederalist.com], as well as many others, show that this is all nothing more than a grasp at trying to control out children. It affects their social skills, emotions, learning, self esteem. It sounds like the State is anticipating something we do not know and wants to be ready to push it on us when the time comes. I personally do not think people will fall for this again. This portion of the above article touches on what many in the medical field have now stated is true, MASKS DO NOTHING! They are used to make you submissive and take away your voice. Our failing schools are showing now, the results of what all of this caused.

I hope and pray that thousands of parents and grandparents reject this proposed adoption and make their voices heard LOUD & CLEAR!

The Science Is In

Despite so-called "experts," like Dr. Anthony Fauci, flip-flopping [thefederalist.com] on the subject, forced masking has proven to be ineffective at stopping the spread of Covid. Earlier this year, for example, a study published [reason.com] by the Cochrane Library — which is considered [thefederalist.com] to be the "gold standard for health care data review" — found that wearing masks "makes little or no difference to influenza-like or COVID-19-like illness transmission."

The study came roughly a year after the Centers for Disease Control and Prevention tacitly admitted [thefederalist.com] that cloth masks "provide the least protection" against Covid.

[**RELATED: Emails Show Fauci Knew From A 2020 Federalist Article That Masking Was Ineffective But Demanded It Anyway [thefederalist.com]**]

Mandatory masking in schools is even more ludicrous when considering that children are the least at-risk [thefederalist.com] age demographic with respect to Covid. In addition to children not being super-spreaders [pubmed.ncbi.nlm.nih.gov] of the virus, research shows [static1.squarespace.com] the majority of American children already recovered from Covid by early 2022 and therefore possess immunity to reinfection.

As part of their efforts to dispel Rhode Island's baseless school masking policy, plaintiffs in *Southwell v. McKee* relied upon the expertise of Dr. Andrew Bostom, an epidemiologist and retired Brown University associate professor of internal and family medicine. In his capacity as an expert witness, Bostom presented [andrewbostom.org] data documenting the grossly inaccurate modeling used to justify tyrannical Covid policies such as forced masking. He also referenced data from the RIDOH's own Covid information hub [ri-department-of-health-covid-19-response-severity-rihealth.hub.arcgis.com] showing *zero* Rhode Island children died from Covid since the outbreak began.



"There is no justification" for masking, Bostom told The Federalist. "We have to rely on randomized controlled trials when it comes to questions like community masking, that's the highest form of evidence. If there's no other evidence, so be it. But we had a lot of evidence before Covid [that this policy doesn't work in stopping the spread of respiratory disease.]"

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2 *TRENDING:* Washington Post Blames Grocery Stores For High Prices To Cover For Biden In Election Year

*** BREAKING ***
Obscure Statute Could Disqualify States Like Colorado From Kicking Trump Off The Ballot

MEDICAL ETHICS

Rhode Island Parents Score Major Legal Win Against The State's School Mask Mandates

BY: SHAWN FLEETWOOD

DECEMBER 20, 2023

7 MIN READ



KETUT SUBIYANTO/PEXELS

Rhode Island parents and the state government agreed to a settlement committing the state's health agency to hold public hearings 'on whether masking in schools is efficacious and safe.'



SHAWN FLEETWOOD
@SHAWNFLEETWOOD

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Parents challenging Rhode Island's school mask mandate scored a major court victory last week that will greatly impact how the state handles potential future public health outbreaks.

The legal saga began in September 2021, when several Rhode Island parents filed a complaint in Providence County Superior Court against Democrat Gov. Daniel McKee and Nicole Alexander-Scott, the director of Rhode Island's Department of Health (RIDOH), over the state's then-enacted school mask mandate. In response to the Covid outbreak, then-Democrat Gov. Gina Raimondo issued an executive order on March 9, 2020, declaring a state of emergency. From that date until July 2, 2021, Raimondo and McKee — who took office in March 2021 — issued a combined 78 executive orders related to Covid.

On July 6, 2021, the Rhode Island legislature passed a measure terminating the governor's authority to issue Covid orders, prompting McKee to rescind all existing and related directives that same day. This, however, did not stop McKee from issuing a pair of Covid-linked executive orders on Aug. 19, 2021, one of which required Rhode Island public schools "to abide by a universal indoor masking protocol developed by the [RIDOH]" mandating "masking by all students (age 2 and older), staff, teachers, and visitors to K-12 schools."

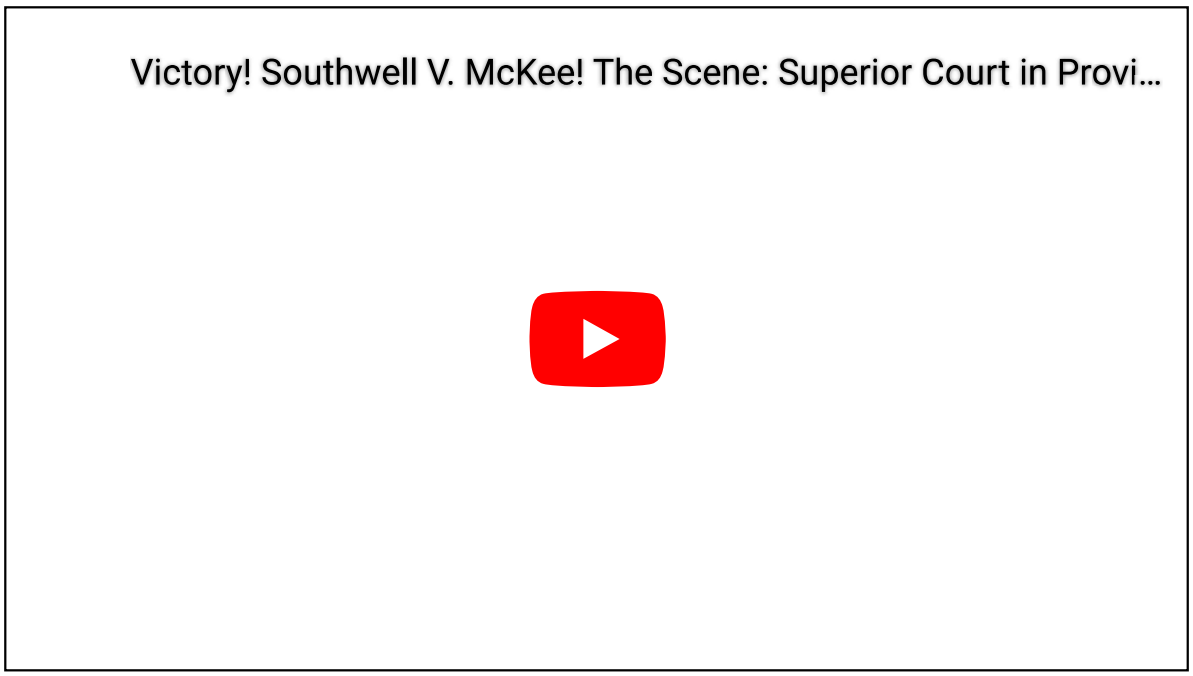
On June 29, 2021, the state's education department, "in conjunction with the RIDOH and the Governor," announced back-to-school guidance for the upcoming academic year, allowing local districts to decide whether masks should be mandatory or optional. Many localities subsequently adopted a policy of "strongly recommending," but not mandating, masks for students, faculty, and visitors.

McKee's August 2021 order prompted Rhode Island parents to file the aforementioned complaint, documenting the lack of evidence supporting universal masking and requesting the court declare the directive unlawful. Plaintiffs also requested the court issue a temporary restraining order and preliminary and permanent injunction prohibiting McKee from issuing additional Covid-related executive orders and declaring the governor's standing orders and RIDOH's school masking guidance as void.

While McKee and RIDOH lifted the school mask mandate in March 2022, parties in the case continued to engage in litigation for the next year and a half. On Dec. 12, they agreed to a settlement that commits RIDOH to follow the normal regulatory process and hold public hearings "on whether masking in schools is efficacious and safe."

According to the plaintiffs' press release, RIDOH has agreed to provide Notice of a Public Hearing "within 30 days of the entry of a dismissal stipulation" in compliance with the regulatory process as specified by the state's Administrative Procedures Act that will determine "whether, in the future, forced masking in a public

school setting is appropriate." The dismissal stipulation is expected to be submitted before the end of this year.



Plaintiffs intend to call medical specialists to discuss the inefficacy and harms associated with forced masking during the aforementioned hearing, which will be open to the public. Following the hearing, RIDOH has agreed to produce a "cost-benefit analysis of the forced masking of schoolchildren," which the state has declined to do until now. Greg Piccirilli, the plaintiffs' lawyer, told The Federalist he expects the hearing to occur in spring 2024.

Furthermore, Rhode Island health officials agreed to alter guidance to public schools, clarifying that "there is not now and will not be a 'mask mandate' for students, even those who test positive for COVID," who were exposed to the virus, or show Covid-like

symptoms. In exchange for these actions, the plaintiffs have agreed to drop their lawsuit.

"This was never a case about parents looking for money. We just wanted the state to follow the regular normal regulatory procedure," Piccirilli told The Federalist. "We're hoping to really create a record that people will be able to look to in the future, so if they ever try to do something like this again, we'll be able to say, 'No, the evidence shows that [mandatory masking] doesn't work.'"

Amended Complaint, Southwel… by The Federalist

The Science Is In

Despite so-called "experts," like Dr. Anthony Fauci, flip-flopping on the subject, forced masking has proven to be ineffective at stopping the spread of Covid. Earlier this year, for example, a study published by the Cochrane Library — which is considered to be the "gold standard for health care data review" — found that wearing masks "makes little or no difference to influenza-like or COVID-19-like illness transmission."

The study came roughly a year after the Centers for Disease Control and Prevention tacitly admitted that cloth masks "provide the least protection" against Covid.

[**RELATED: Emails Show Fauci Knew From A 2020 Federalist Article That Masking Was Ineffective But Demanded It Anyway**]

Mandatory masking in schools is even more ludicrous when considering that children are the least at-risk age demographic with respect to Covid. In addition to children not being super-spreaders of the virus, research shows the majority of American children already recovered from Covid by early 2022 and therefore possess immunity to reinfection.

As part of their efforts to dispel Rhode Island's baseless school masking policy, plaintiffs in *Southwell v. McKee* relied upon the

expertise of Dr. Andrew Bostom, an epidemiologist and retired Brown University associate professor of internal and family medicine. In his capacity as an expert witness, Bostom presented data documenting the grossly inaccurate modeling used to justify tyrannical Covid policies such as forced masking. He also referenced data from the RIDOH's own Covid information hub showing *zero* Rhode Island children died from Covid since the outbreak began.

"There is no justification" for masking, Bostom told The Federalist. "We have to rely on randomized controlled trials when it comes to questions like community masking, that's the highest form of evidence. If there's no other evidence, so be it. But we had a lot of evidence before Covid [that this policy doesn't work in stopping the spread of respiratory disease.]"

Similar to their attacks against other doctors who refused to accept government narratives on Covid without question, legacy media have attempted to discredit Bostom as a credible voice on the issue. In its October 2021 report on *Southwell v. McKee*, for instance, The Providence Journal tried to delegitimize Bostom's medical expertise by referencing his appearances in conservative media and prior scholarly writings on Islam.

"Some television viewers might recognize Dr. Andrew Bostom for his television appearances on Fox News and C-SPAN, where he has made appearances as an author with much to say about Islamic jihad," the article reads. Another local outlet advanced claims questioning Bostom's ties to Brown.

"I was just trying to get people to calm down and behave in a rational, evidence-based way, and these people were out" to destroy me, Bostom said. "It was shocking."

The Road Ahead

In his closing remarks, Piccirilli expressed hope that last week's court settlement will set a standard compelling other states and the federal government to follow the regulatory process and hold public hearings when issuing public health edicts that greatly impact people's lives.

"If the evidence is so clear, have a public hearing. Have the debate. … That's the way the law has been for decades," Piccirilli said. This wasn't done with Covid "because the evidence didn't support what they were doing, and they were afraid to have public hearings. So, not only should every state be doing this like they do with every regulation they pass, but the federal government should be doing it [as well]."

Bostom voiced similar optimism, suggesting the exposure of health officials' lies during the Covid pandemic will prompt more Americans to support evidentiary-based hearings on issues related to public health.

"Evidence needs to be needs to be presented and debated openly and fairly," Bostom said.

Shawn Fleetwood is a staff writer for The Federalist and a graduate of the University of Mary Washington. He previously served as a state content writer for Convention of States Action and his work has been featured in numerous outlets, including RealClearPpolitics, RealClearHealth, and Conservative Review. Follow him on Twitter @ShawnFleetwood

ANDREW BOSTOM COURT SETTLEMENT COVID COVID MANDATES

GREGORY PICCIRILLI MASKING CHILDREN RHODE ISLAND

More from Medical Ethics

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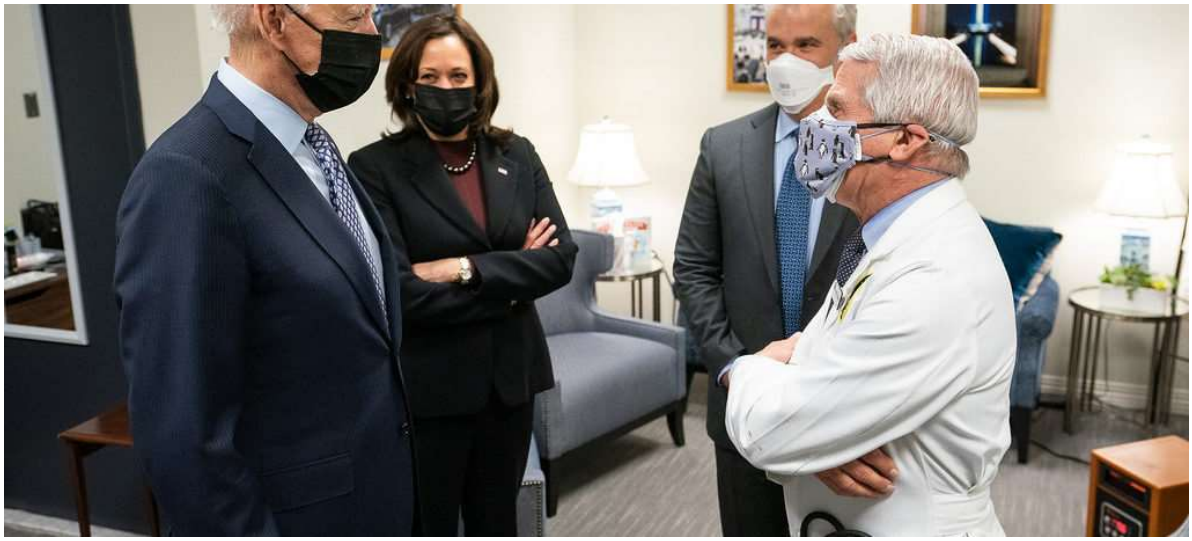
WUHAN VIRUS

Emails Show Fauci Knew Masks Weren't Very Effective Before Pushing Universal Masking

BY: JORDAN BOYD

JUNE 02, 2021

3 MIN READ



In Fauci's newsly released emails, he confidently responded to inquiries that wearing a mask wasn't necessarily effective at stopping the spread of COVID.



JORDAN BOYD
@JORDANBOYDTX

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Dr. Anthony Fauci pushed Americans to mask up even when he knew masks weren't very effective. In a batch of emails recovered and published by Buzzfeed News and the Washington Post through the Freedom of Information Act this week, Fauci confidently responded to inquiries that wearing a mask wasn't necessarily effective at stopping the spread of the new virus.

"Masks are really for infected people to prevent them from spreading infection to people who are not infected rather than protecting uninfected people from acquiring infection," he replied to Sylvia Burwell, possibly the same woman who served as former President Barack Obama's Health and Human Services secretary, on Feb. 5, 2020. "The typical mask you buy in the drug store is not really effective in keeping out virus, which is small enough to pass through material. It might, however, provide some slight benefit in keep out gross droplets if someone coughs or sneezes on you."

Fauci's final recommendation for Burwell was not to wear a mask "particularly since you are going to a very low-risk location."

The White House Coronavirus Task Force member continued to warn the public against wearing a mask and even said "there's no reason to be walking around with a mask," on March 8, 2020, but by the end of the month, he changed his tune. Despite acknowledging that the masks available to most Americans only offered a "slight benefit" to users, it wasn't long before Fauci began to push for widespread masking.

"The idea of getting a much more broad, community-wide use of masks outside of the health care setting is under very active discussion at the task force. The CDC group is looking at that very carefully," Fauci told CNN on March 31, 2020.

Unlike the way he portrayed the non-efficacy of masking in the email to Burwell, Fauci later pushed for widespread masking under the guise of accidental asymptomatic transmission — a phenomenon that studies and even the World Health Organization's technical lead have said is "very rare."

"Because if, in fact, a person who may or may not be infected wants to prevent infecting someone else, one of the best ways to do that is with a mask. So perhaps that's the way to go," Fauci continued to CNN.

Fauci carried this masking narrative for more than a year, even encouraging people to begin wearing layers of masks because it is just "common sense."

Fauci knows and has even admitted that science doesn't drive the Centers for Disease Control and Prevention's decisions, but that hasn't stopped him from repeatedly engaging in political theater by masking beyond what the health agency recommends and even after he received both doses of his COVID-19 vaccine.

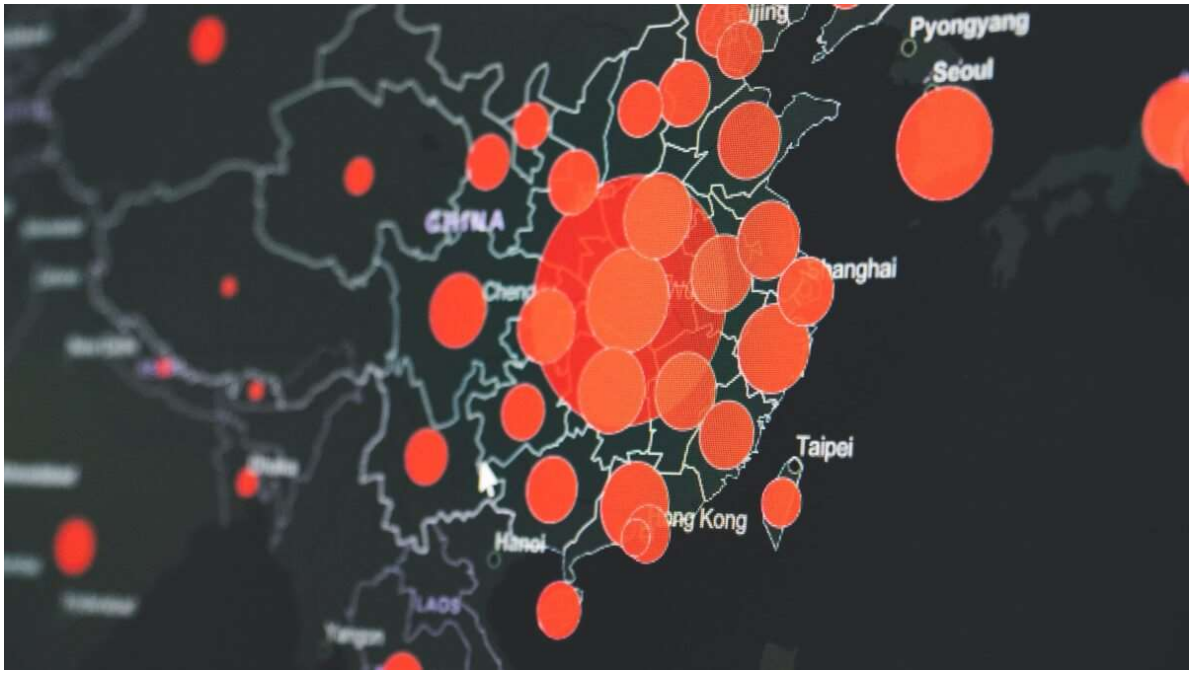
Jordan Boyd is a staff writer at The Federalist and co-producer of The Federalist Radio Hour. Her work has also been featured in The Daily

Wire, Fox News, and RealClearPolitics. Jordan graduated from Baylor University where she majored in political science and minored in journalism. Follow her on Twitter @jordanboydtx.

ANTHONY FAUCI COVID-19 FACE MASKS MASKS

More from Wuhan Virus

VIEW ALL



WUHAN VIRUS

More Evidence Emerges Confirming Covid Lab-Leak Theory, But Corporate Media Stay Silent

HELEN RALEIGH
JANUARY 2, 2024

MASK MANDATES

Masks Make 'Little or No Difference' on COVID-19, Flu Rates: New Study

The Cochrane Library's review of masking trials should sound the death knell for mask mandates everywhere.

ROBBY SOAVE | 2.7.2023 9:52 AM



Mask mandates (Julian Wan)

The wearing of masks to prevent the spread of COVID-19 and other respiratory illnesses had almost no effect at the societal level, according to a rigorous new review of the available research.

"Interestingly, 12 trials in the review, ten in the community and two among healthcare workers, found that wearing masks in the community probably makes little or no difference to influenza-like or COVID-19-like illness transmission," writes Tom Jefferson, a British epidemiologist and co-author of the Cochrane Library's new report on masking trials. "Equally, the review found that masks had no effect on laboratory-confirmed influenza or SARS-CoV-2 outcomes. Five other trials showed no difference between one type of mask over another."

That finding is significant, given how comprehensive Cochrane's review was. The randomized control trials had hundreds of thousands of participants, and made useful comparisons: people who received masks—and, according to self-reporting, actually wore them—versus people who did not. Other studies that have tried to uncover the efficacy of mask requirements have tended to compare one municipality with another, without taking into account relevant differences between the groups. This was true of an infamous study of masking in Arizona schools conducted at the county level; the findings were cited by the Centers for Disease Control and Prevention (CDC) as reason to keep mask mandates in place.

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"Comparing Pima and Maricopa counties is a pointless way to study masks—because the people are fundamentally different—apart from masking," noted Vinay Prasad, an epidemiologist who has opposed COVID-19 mandates. "They have different rates of vaccination and different levels of caution."

Cochrane employed randomized control trials (RCTs), which are considered the gold standard for review. And the results are inarguable: Zoom out to the population level, and masks had a scarcely discernible impact on COVID-19 cases.

"The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks," write the authors. "There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection."

David Zweig, a writer who helped call attention to the flaws in the Arizona study, noted that these negative findings reflect basic reality: While individual mask wearers might get some benefit for a while if they consistently, *perfectly* wear masks, this does not comport with the aggregate experience. According to Zweig:

> Even the most ardent mask supporters, who want to wear them properly, fail to do so. And, as this study and others illustrate, even when masks are required they are either not worn properly, or not worn at all by a significant number of people. These images from a *NY Times* article comically show that children are no exception to this problem. And nor are teachers — this study, published by the CDC, on a school outbreak encapsulates the problem quite well: "the teacher read aloud unmasked to the class despite school requirements to mask while indoors."
>
> Succinctly, Benjamin Recht, a statistician at UC Berkeley, who co-authored a re-analysis of the Bangladesh RCT, which negated that trial's findings, said: "At this point, I doubt any study will change anyone's mind about masking. But the one consistent finding of all of the randomized studies is that the effect of this intervention at the population level is vanishingly small."

The findings have yet to penetrate the mainstream media's bubble: Whereas flawed studies like the Arizona one received rave reviews in the pages of *The New York Times* and *The Washington Post*, so far the Cochrane review has not attracted coverage from these outlets. Nor has it garnered commentary from the CDC—an agency that has routinely seized on less compelling evidence in order to recommend the maintenance of intrusive COVID-19 interventions like mask mandates and lockdowns.

Indeed, while mask mandates are no longer a typical part of American life, there are still enclaves that require masking. Some U.S. schools have kept mask mandates in place, or brought them back during flu season. Within the nation's capital, George Washington University still requires masks in classrooms.

If *following the science* means updating one's priors when new evidence becomes available, then institutions that require masks should finally concede—three years into the pandemic—that indefinitely forcing them on unwilling people, especially children, is not a defensible strategy. As for any lingering government requirements, let this be the final and long overdue word: no more mandates.

ROBBY SOAVE is a senior editor at *Reason*.

MASK MANDATES MASKS CORONAVIRUS PANDEMIC GOVERNMENT MANDATES CDC SCIENCE PUBLIC HEALTH HEALTH POLITICS

Children, COVID, and the Urgency of Normal: The Under Age 5 Edition

A tool kit for parents, teachers, administrators, and child advocates.

Version 5-18-2022. This Toolkit is updated to include new studies and responses from the field to ensure that the information and guidance reflects the latest, most accurate understanding. Please check our website, https://www.urgencyofnormal.com to download the latest version.

Our Team



Dr. Kristen Walsh is a board-certified pediatrician in northern NJ. She has over 20 years of clinical experience in both academic and private practice settings. For the past 10 years, she has volunteered at a school for special needs children and been involved in early childhood advocacy on both the state and national levels.



Dr. Ram Duriseti received his MD from the University of Michigan and his medical training and PhD in Computational Decision Modeling from Stanford University. He has been practicing clinical Emergency Medicine in both community and academic settings for over 20 years. At Stanford, he primarily works in the Pediatric Emergency Department.



Dr. Jennifer Grant is a Clinical Associate Professor at University of British Columbia. She practices as a medical microbiologist and infectious disease physician in Vancouver with research interests in quality improvement, infection control and occupational health.



Karen Vaites is an elementary literacy curriculum expert and children's advocate based in New York. As the founder of Eduvaites, she serves as consultant and advisor to multiple literacy nonprofits as well as states on efforts to improve reading instruction in the United States. As the founding Chief Marketing Officer at Open Up Resources, she has been a pioneer in the effort to improve literacy and math curriculum in the United States.



Dr. Eliza Holland is a pediatric hospitalist practicing in Charlottesville, VA. She spent several years as a volunteer in elementary school libraries and is an advocate for early literacy. Since 2020, she has been supporting COVID response to enable in-person activities for children in schools in Virginia and at camps in North Carolina.



Dr. Nicole Johnson is board certified in pediatric critical care and specializes in pediatric procedural sedation. She is active in many grassroots organizations advocating for restoring the patient-physician relationship and delivery of safe, quality, low-cost medical care to all Americans. She has been outspoken about the potential impact of US COVID19 policies on children since 2020.



Dr. Todd Porter received his MD from the University of Virginia School of Medicine and MSPH from the University of Colorado. He is a community pediatrician in Illinois whose interests include literacy instruction and dyslexia. He has been advocating for the importance of in-person learning and return to normalcy for our children since 2020.



Dr. J. Thomas Megerian is a board-certified pediatrician and child neurologist specializing in Autistic spectrum and other neurodevelopmental disorders. He is currently the medical director of the Thompson Autism Center and attending neurologist at Children's Health Orange County, as well as an Associate Professor (volunteer faculty) at CHOC and University of California, Irvine.

About This Toolkit

This toolkit summarizes the most important data regarding COVID19 infection for children under age 5. It is intended for parents, teachers, administrators, and everyone invested in taking care of children, and serves as a supplement to our first Toolkit on COVID-19 in schools.[1]

Our goal is to inform you about the risks of COVID specifically to children under 5 and how the measures we are using to prevent the transmission of COVID affect them. As physicians, our role is to inform you with accurate data, give it context you can understand, and provide guidance about confusing issues. We want to empower you to make evidence-based decisions to take the best possible care of children under age 5 years.

Impacts from COVID vary among different communities, schools, families, and individual children. We humbly acknowledge this, and provide these data **to support every community in making their own decisions.**

1 Urgency of Normal Toolkit available at: https://www.urgencyofnormal.com/

About This Toolkit cont.

In this toolkit we discuss the risk of COVID infection to children under 5 and compare it to other common respiratory viruses. We then discuss the effects of COVID prevention measures with a focus on masking children in this age group. We close with our recommendations based on this evidence.

We urge everyone to have discussions with openness and mutual respect. The job of being a teacher, school administrator, parent, or child has been exceptionally difficult these last two years. Understand that if you're frayed, so is the person you're talking to. **Compassion and accurate information will move us forward.**

Please share and discuss with your communities, and use this information to help inform and focus discussions with your school or daycare.

RSV Bronchiolitis is More Severe Than COVID for Children Under Age 5

Respiratory syncytial virus (RSV) bronchiolitis is a seasonal illness that primarily affects children under the age of 5. Approximately 58,000 children per year are hospitalized for RSV bronchiolitis according to the CDC.[1]

The US has 20 million children under 5, so the RSV hospitalization rate is **290** hospitalizations per 100,000 children in this age group every year.

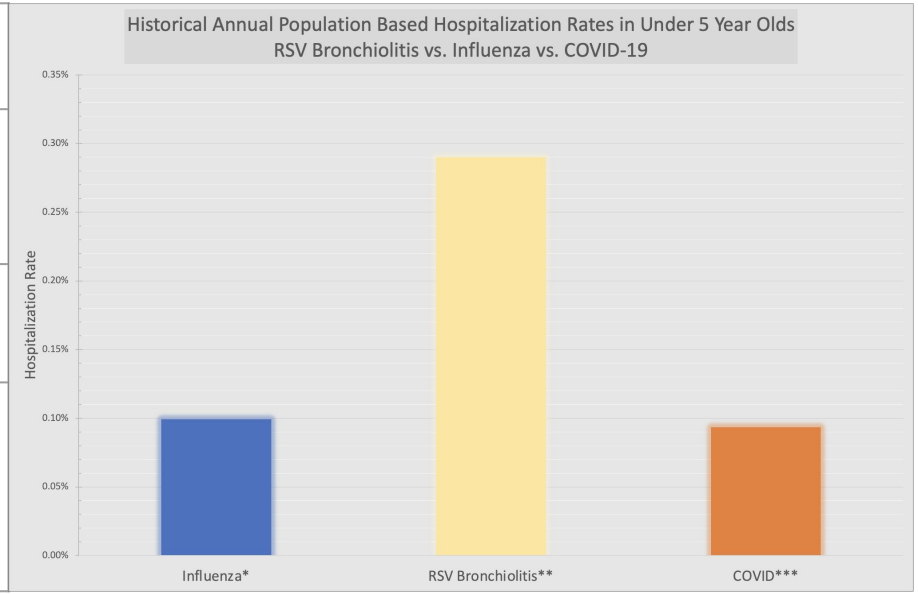
By comparison, **the *two* years of COVID pandemic has caused fewer hospitalizations of kids under age 5 than a single typical year of RSV: 186** hospitalizations per 100,000 children in the same age group.[2]

In addition, children **with RSV are more likely to have longer hospital stays and need oxygen support compared to children with COVID.**[3,4]

1 https://www.cdc.gov/rsv/research/us-surveillance.html
2 https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network
3 https://www.tandfonline.com/doi/full/10.1080/14767058.2020.1849125
4 https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiac052/6529705

Hospitalization Risk from COVID is Similar to Other Respiratory Viruses in Children Under 5

ANNUAL HOSPITALIZATIONS, CHILDREN UNDER 5	
Influenza, average annual hospitalizations (2010-2020).*	19,451
RSV, average annual hospitalizations (2000-16).**	58,000
COVID, 24,000-36,000 hospitalizations*** estimated over **two** years of the pandemic (from COVID-Net rate of 186 per 100,000 under 5 year olds).	18,000



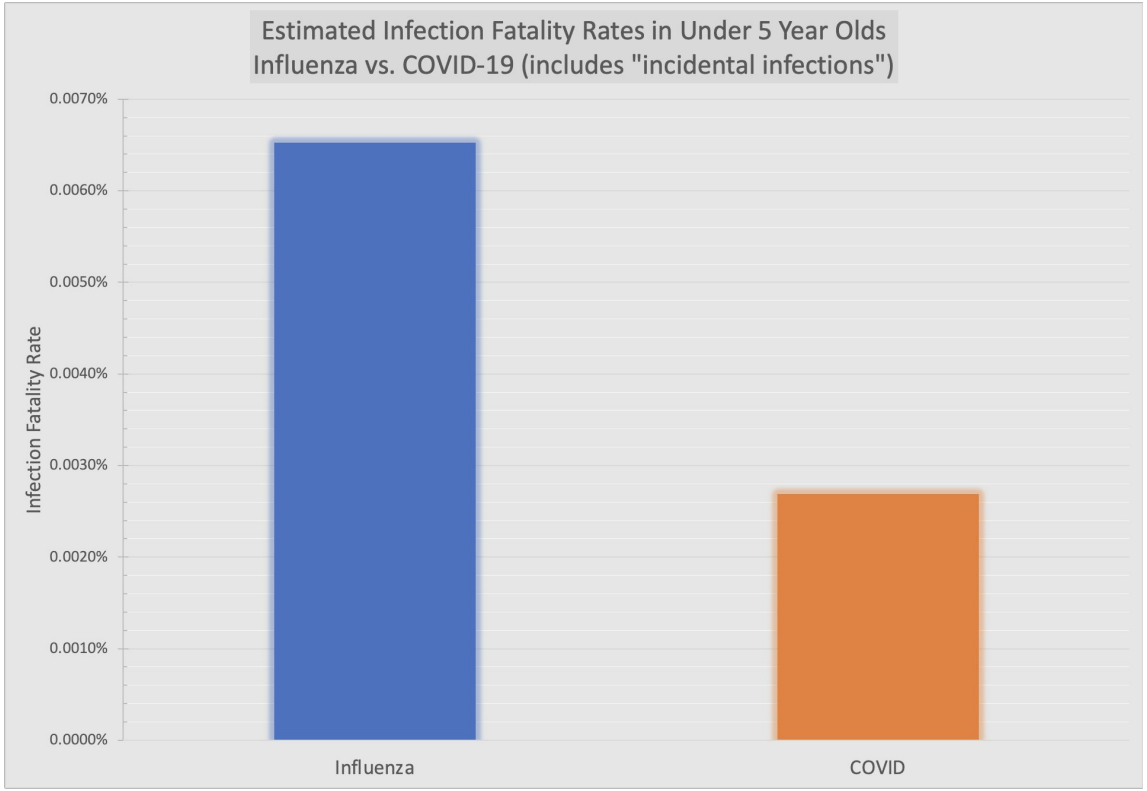
*CDC average annual hospitalizations are divided by population to yield the hospitalization rates shown at right.

**The Burden of RSV in Young Children

***These are "uncorrected" hospitalizations. We test every admission for COVID which leads to positive tests not connected to the reason for admission. This has happened globally in 35%-60% of Pediatric hospitalizations. In the US, it counts as a COVID admission. Incidental positives were even more common with Omicron (50-70%). Therefore, hospitalizations truly attributable to COVID are lower than reflected in these figures and chart.

Other sources for this slide are listed on slide 22

Influenza Has a Higher Fatality Rate Per Infection Than COVID in Young Children



Infection Fatality Rates Calculated from CDC Data

For influenza, the 2010-20 seasonal average used.[1] The 2020-21 Influenza burden was too low to be estimated, so was not included here.

For COVID, there have been 396 deaths in the under-5 age group[2], out of approximately 15 million infections. (There are 20 million under-5s in the US[3], and CDC data shows that 73.5% of children have had COVID[4])

[1] CDC: Estimated Flu Burden from Past Seasons
[2] CDC: Provisional COVID-19 Pediatric Deaths
[3] US Census Data
[4] CDC Seroprevalence data

Summary: Fatality and Hospitalization Rates in Children Under 5 with COVID, RSV, and Influenza

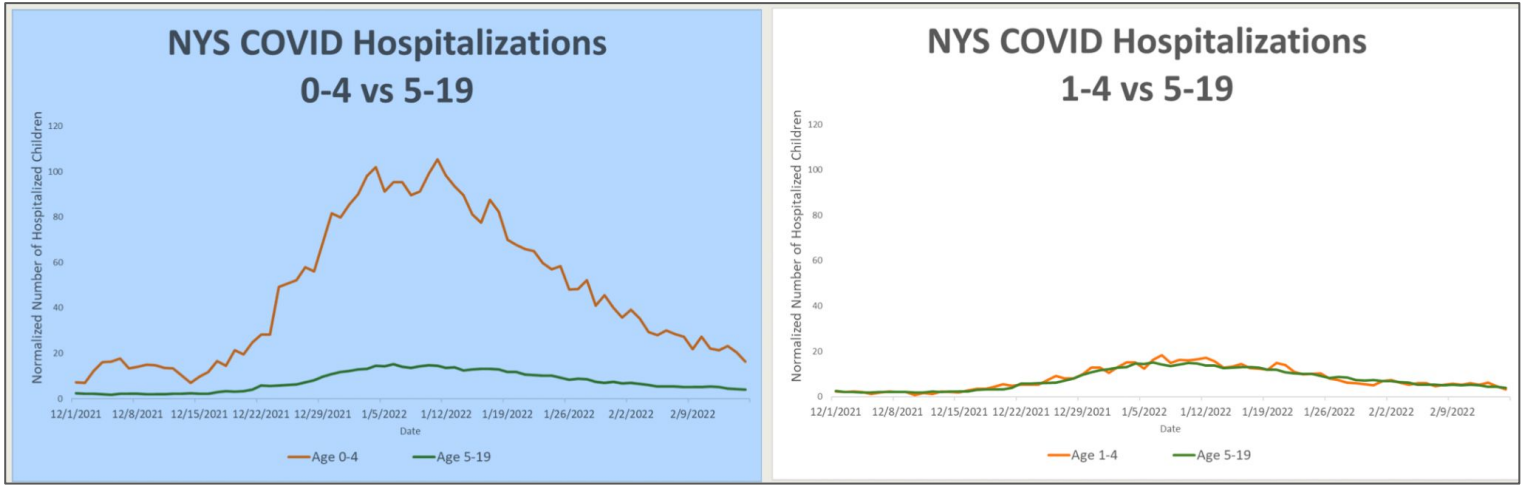
Virus	Annual Hospitalizations (CDC estimates)	Percentage Annual Hospitalization	Average annual Deaths
COVID	18,000	0.09%	198 (396 in two years of pandemic)[1]
Influenza	19,451	0.10%	216[2]
RSV	58,000	0.29%	100-500[3]

Fortunately, the risk of serious disease and death from COVID in the under-5 age group is similar to that from common respiratory illnesses for which we do not implement special policies.

[1] CDC pediatric COVID data
[2] CDC Estimated Flu Burden from Past Seasons
[3] CDC RSV report

Children Age 1-4 Do Not Have Higher COVID Hospitalization Rates Than Older Children

Some have suggested that children under 5 are high-risk because they are hospitalized at outsized rates; in fact, **hospitalization rates for children 1-4 are similar to that of children ages 5-19**.[1,2] Infants under 1 year old are the group at highest risk, as is the case with other respiratory viruses, including precautionary admissions for fever in very young infants. New York State data provides a helpful illustration:



1 https://gis.cdc.gov/grasp/covidnet/covid19_5.html
2 https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e4.htm#F1_down)

The Majority of US Children Have Immunity to COVID

In blood sampling taken through the month of February 2022 in the US, 75% in the under-11 year old group has evidence of a prior infection.[1,2] UK estimates 82% in the 5-11yo age group through March 2022.[3]

Immunity gained from a previous infection is protective against re-infection, and more importantly, severe disease, with efficacy similar to that of vaccines.[4]

This protection has been shown to be robust against variants[5] and durable, with antibody responses lasting at least 20 months.[6]

1 https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm?s_cid=mm7117e3_w
2 https://covid.cdc.gov/covid-data-tracker/#national-lab
3https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/coronaviruscovid19latestinsights/antibodies
4 https://journals.sagepub.com/doi/10.1177/01632787211047932
5 https://www.medrxiv.org/content/10.1101/2022.01.05.22268782v1.full
6 https://jamanetwork.com/journals/jama/fullarticle/2788894

The World Health Organization Recommends Against Masking Toddlers

"Children aged **5 years and under** should not be required to wear masks. This is based on the safety and overall interest of the child and the capacity to appropriately use a mask with minimal assistance."

"Children with cognitive or respiratory impairments, developmental disorders, disabilities or other specific health conditions who experience difficulties wearing a mask should not be required to do so."

https://www.who.int/news-room/questions-and-answers/item/q-a-children-and-masks-related-to-covid-19

The European Centre for Disease Prevention and Control Does Not Recommend School Masking Under the Age of 12

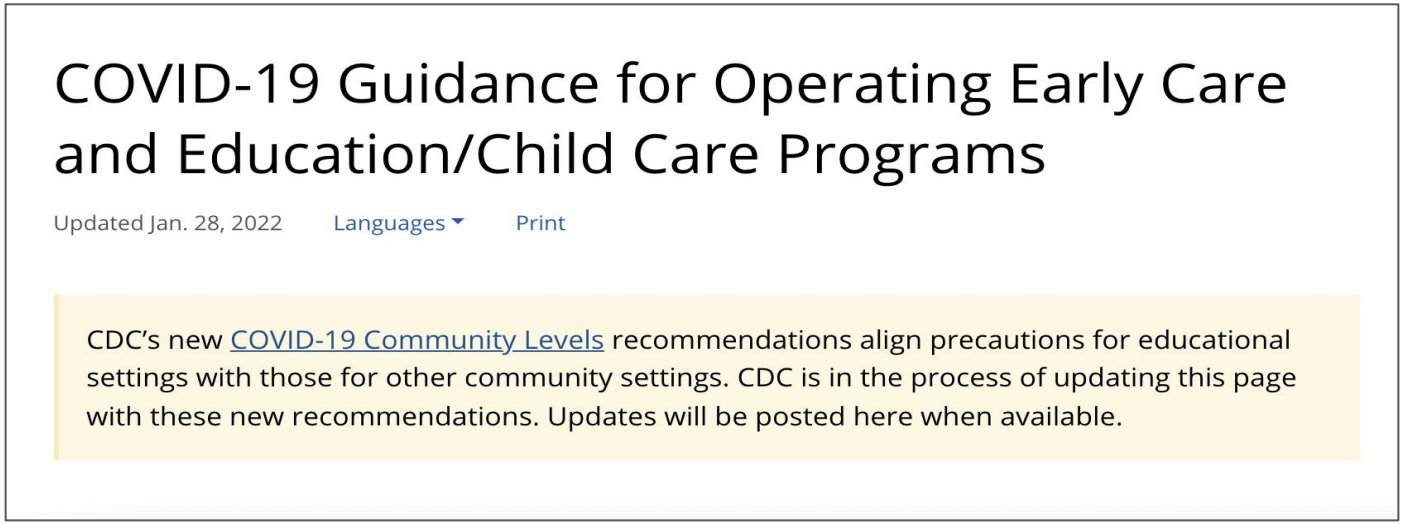
"[The use of face masks] in school settings is challenging, as children younger than 12 years old may have a lower tolerance to wearing masks for extended periods of time and may fail to wear them properly.

In primary schools, the use of face masks is recommended for teachers and other adults when physical distancing cannot be guaranteed, but it is not recommended for students."

https://www.ecdc.europa.eu/en/covid-19/questions-answers/questions-answers-school-transmission

The CDC No Longer Recommends Different Masking Rules for Children and Adults

The CDC updated its K–12 guidance and no longer recommends universal masking in “low” or “medium” risk areas.[1] The CDC indicates on its website[2] and representatives[3] confirmed that these changes apply to early education settings.



COVID-19 Guidance for Operating Early Care and Education/Child Care Programs

Updated Jan. 28, 2022 Languages Print

CDC’s new COVID-19 Community Levels recommendations align precautions for educational settings with those for other community settings. CDC is in the process of updating this page with these new recommendations. Updates will be posted here when available.

1 https://covid.cdc.gov/covid-data-tracker/#county-view?list_select_state=all_states&list_select_county=all_counties&data-type=CommunityLevels&null=CommunityLevels
2 https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html
3 https://www.the74million.org/article/an-outdated-website-an-atlantic-article-an-instagram-story-how-the-cdc-botched-revising-its-mask-guidance-for-preschoolers/

Masking Young Children Has Little to No Effect on COVID Transmission

A rigorous study of over 1 million children compared in-school COVID transmission rates between unmasked 3-5 year olds and masked 6-11 year olds in the fall of 2020. **There was no difference in transmission rates between unmasked 5 year olds and masked 6 year olds.**[1]

During the fall 2021 Delta surge, both infection and transmission rates were again measured between unmasked 5 year olds and masked 6 year olds. The results were the same: **"mask mandates in schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective."**[2]

One frequently cited study concluded that "masking young children is associated with fewer childcare program closures, enabling in-person education."[3] **However the study did not specifically evaluate the effect of masking on transmission, it was only looking at closures.** Even then, the claimed benefit was very small: only 14%.

Every well-controlled real-world study shows the same result: little to no benefit to mask use in children under the age of 5.

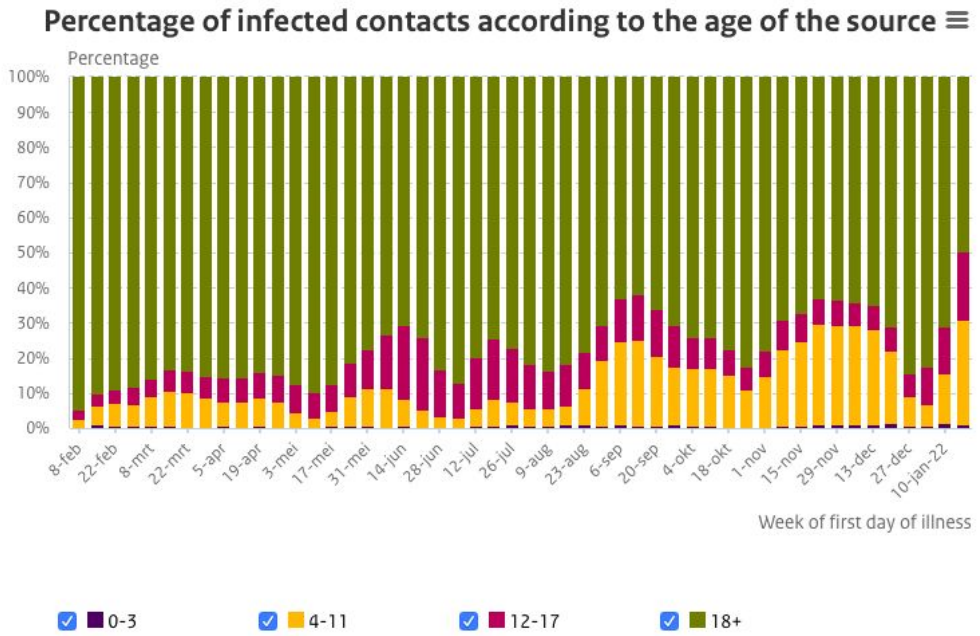
1 https://journals.lww.com/pidj/fulltext/2021/11000/age_dependency_of_the_propagation_rate_of.2.aspx
2 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4046809
3 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2788457

We Do Not Need to Mask Young Children to Protect Adults

Transmission data from the Netherlands shows that children in this age group are less likely to spread COVID than any other age group.

The figure shows the percentages of people (in source and contact tracing) who tested positive for SARS-CoV-2 and infected another person, per age group, per week

Children aged 0 to 3 years represent the lowest percentage (see thin black bars at far bottom of each column). Adults (≥18) represent a significant majority as the most likely source of infection.



https://www.rivm.nl/en/coronavirus-covid-19/children-and-covid-19/research-results-ggd-data

Unfortunately, We Have Limited Research on the Effects of Long-Term Masking

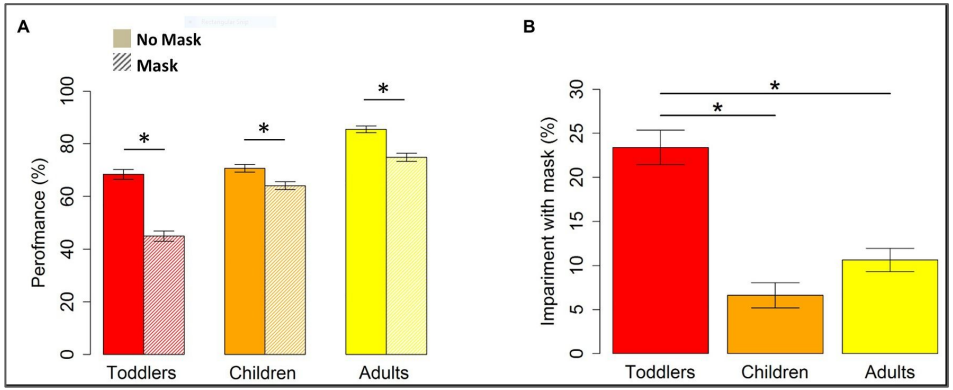
There is little research on the effects of masking children for long periods of time. Therefore, **we do not know if masking young children for years is benign.**

What we do know about children's development in the first 5 years gives us cause for concern about potential impacts of long-term masking on children's speech, language, and literacy learning.

This section highlights evidence and research that we would encourage leaders to consider with regards to risks for young children.

Masking Impairs the Recognition of Emotions

An Italian study looked at the impact of masking on correctly reading emotions across different age groups. All age groups struggled, but toddlers had the most difficulty.[1]



Studies have shown that children with autism are especially affected by emotional recognition challenges.[2]

A recently-published study found that masks “led to a profound deficit in face perception abilities” that was more pronounced in children than adults.[3]

1 https://www.frontiersin.org/articles/10.3389/fpsyg.2021.669432/full
2 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0257740
3 https://cognitiveresearchjournal.springeropen.com/articles/10.1186/s41235-022-00360-2

Masking Impairs Understanding in Both Hearing and Hearing-Impaired People

A study looked at the impact of masking and ambient noise on word recognition in children and adults. Especially with classroom noise and 2 people talking, children had a harder time with word recognition when masks were used.[1]

Face masks lower the volume of a person's speech and slightly garble it. Depending on the type of face mask, they may reduce the clarity of speech and lower it from anywhere to 5 to 15 decibels (dB). In other words, **speech is not just quieter, it's more muffled**.[2]

The CDC recommends clear masks when working with hearing-impaired people.[3] However, ClearMasks are expensive, costing $77 for 24 masks. They are marketed as single use and for “use indoors at room-temperature in ventilated, low-humidity environments.”[4]

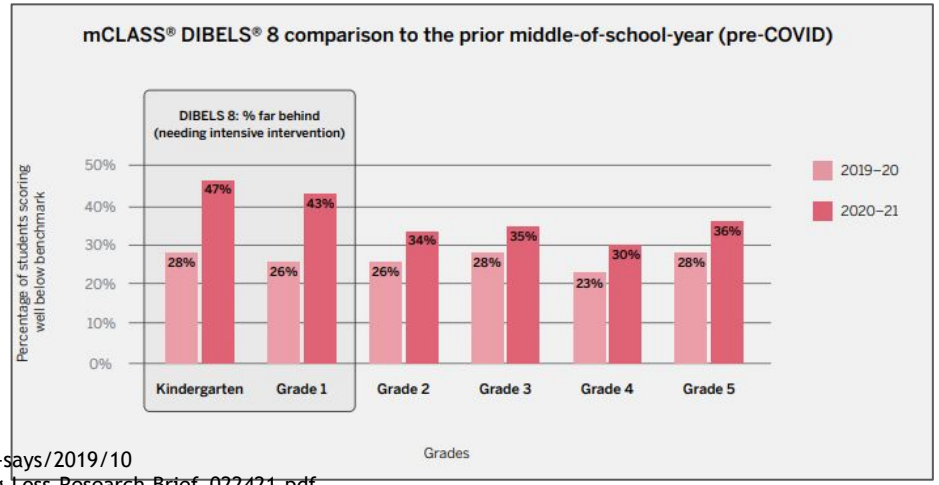
Recent interviews with speech pathologists revealed frustrations and difficulties around masking during therapy, including clear masks. “[Despite] a number of tricks to prevent [clear masks] from fogging up, they inevitably do. Fogging aside, even clear masks prevent therapists from using tactile cues, such as straws or tongue depressors to push patients’ tongues into place, or bite plates to keep the jaw in alignment.”[5]

1 https://exlingsociety.com/images/ExLing-2021/ExLing_2021_preliminary_proceedings.pdf#page=207
2 https://www.healthyhearing.com/report/53084-Face-masks-and-hearing-aids
3 https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html
4 www.theclearmask.com
5 https://www.theatlantic.com/family/archive/2022/03/how-masks-get-way-speech-therapy-kids/623332/

Potential Impact on Early Reading Skills

Phonics instruction, in which “teachers explicitly tell students what sounds correspond to what letter patterns,” is an essential part of learning to read[1]. Students in early grades (K-2) learn that the English language has 26 letters which combine to make 44 sounds (e.g., S and H combine to make the “sh” sound), which empowers kids to decode new words. In phonics lessons, teachers regularly model sounds for students, and ask students to practice these sounds in classrooms.

While we lack studies to isolate the effect of masking on reading outcomes in early grades, screeners for early reading skills (ex. DIBELS[2]) have shown the most pronounced declines in reading proficiency in early grades during the pandemic, raising concerns that masks may be impeding the teaching and learning of reading skills.



1 https://www.edweek.org/teaching-learning/how-do-kids-learn-to-read-what-the-science-says/2019/10
2 https://amplify.com/wp-content/uploads/2021/02/Amplify-mCLASS_MOY-COVID-Learning-Loss-Research-Brief_022421.pdf

Recommendations

Maintain in-person learning regardless of case counts and vaccination rates. Students' overall health is best supported by keeping daycares, pre-schools, and schools open.

De-escalate fear around getting COVID.

- For healthy young children, COVID is similar to other seasonal respiratory viruses
- Encourage children, parents, and staff to see mild COVID infections as inevitable and not alarming.
- Encourage a booster dose for parents, caregivers and school employees if older or in higher-risk groups.

Change the focus to supporting students' developmental, emotional, and social health.

- Avoid escalating mask rules or other COVID policies. More restrictive policies increase fear and falsely convey that preschools and daycares are unsafe.
- Restore fully normal life and preschool/daycare for all children.
- Encourage extracurricular activities and social events without fear.

Well-Being is About More Than the Mere Absence of COVID

It is time to appropriately balance risks to children's health

- Disruptions to normal living can never be harm-free
- Coronavirus is here to stay
- We cannot eliminate risk, but we *can* reduce it to levels we've always known how to live with

There is no reason to wait for a vaccine for young children to return to normal

- The vast majority of healthy children are at low risk for serious illness or for spreading COVID to others
- Three quarters of all children already have had naturally acquired COVID infection

Reclaiming normal life for our kids is the best way to support and protect them

- Masking has little to no benefit and poses poorly understood risks to learning and development
- Other countries have never masked this age group, with no adverse consequences to health
- Restrictions on physical activity, social interaction, and barriers to learning could have lasting impacts on young children

All analyses and recommendations presented here represent the authors' combined perspective, and do not represent the view of any of our employers or institutions.

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Data Sources Used for Calculations and Charts for this Toolkit:

CDC: Summer 2021 RSV Surge Advisory
Trends in Bronchiolitis Hospitalizations 2000-2016
The Burden of RSV in Young Children
RSV Associated Hospitalizations in Young Children
UK 2021 Pediatric COVID Hospitalization Chart Review
CDC: Provisional COVID-19 Pediatric Deaths*
CDC: COVID Data-tracker*
CDC: IFR Estimates by Age
CDC:Disease Burden Estimates
CDC: COVID-19 Hospitalization Data**
CDC: COVID-19 Seroprevalence Hub***
CDC: By Age Post-Infection Seroprevalence through February 2022
UK COVID-19 Seroprevalence Estimates by Age
CDC: Estimated Flu Burden from Past Seasons
South African Study of Pediatric Omicron Hospitalizations
UK 2022 COVID Pediatric Hospitalization Chart Review
CDC: Weekly COVID-19 Hospitalizations
Bronchiolitis and RSV Associated Deaths
RSV Fatality Rates in At-Risk and Otherwise Healthy Children
RSV Associated Mortality American Academy of Pediatrics
Estimates of RSV Disease Burden Relative to Influenza
US Census Data
Mechanisms Underlying Decreased COVID-19 Severity in Children

*Data pulled through February 12, 2022
**Data pulled through April 2, 2022
***Data available through January 29, 2022

CDC Finally Admits Cloth Masks Were Always Political Theater

thefederalist.com/2022/01/17/cdc-finally-admits-cloth-masks-were-always-political-theater/

January 17, 2022

Wuhan Virus
By: Elle Purnell
January 17, 2022

4 min read



Image CreditMaxPixel

Mask mandates have always been more about showing compliance than keeping people safe, and the CDC's latest embarrassing disclosure further proves it.



Elle Purnell

Visit on Twitter @_etreynolds

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For two years now, to walk into a grocery store barefaced has been to risk soliciting dirty stares, at least in some parts of the country. But walk in with your face covered by a thin piece of fabric, preferably with some vaguely woke slogan, that you got overpriced on Etsy? You're golden.

Masks have been obvious political theater from the start, back when Anthony Fauci et al. promised we didn't need them and then flip-flopped and promised we did. But when sensible observers tried to point that out, the Big Tech-media cabal gleefully slapped them with "fact" "checks."

When The Federalist ran the headline "Many Studies Find That Cloth Masks Do Not Stop Viruses Like COVID" in November 2020, Lead Stories attempted to "fact-check" the piece, slapping a red "masks work" label over a screenshot of the original article.

The "fact-check" even cited data from the Centers for Disease Control and Prevention (CDC) about the effectiveness of masks against COVID-19, where the CDC insisted, "Cloth masks not only effectively block most large droplets (i.e., 20-30 microns and larger), but they can also block the exhalation of fine droplets and particles," and "cloth mask materials can also reduce wearers' exposure to infectious droplets through filtration."

Yet the same CDC quietly admitted on Friday that the thin cloth masks the agency and its corporate media allies spent the last two years cheering actually "provide the least protection" against COVID-19. It was "the first time the C.D.C. has explicitly addressed" the relative ineffectiveness of cloth masks, according to The New York Times.

The agency's concession comes on the heels of admissions from people like CNN's Leana Wen that "cloth masks are not appropriate for this pandemic."

This latest reversal in a long line of trust-eroding flip-flops means a victory lap is well deserved by people like Kentucky Republican Sen. Rand Paul, who was censored by Google-owned YouTube for suggesting that cloth masks don't work and N95s do. It's also deserved by everyone who refused to hang a piece of useless fabric from their ears at every restaurant, store, and airport for the sole purpose of fitting into the popular political narrative.

> Does this mean snot-nosed censors at YouTube will come to my office and kiss my … and admit I was right?https://t.co/0BZ2HZHiZW
>
> — Senator Rand Paul (@RandPaul) January 15, 2022

But taking a deserved victory lap shouldn't keep us from anticipating the reason the CDC, CNN, and others are quietly shifting the talking points and hoping we'll forget their track record. We can't let them memory-hole their old narrative, but we also can't afford to be fooled into the coming narrative that everyone from kindergarteners to marching bands must now strap on a medical-grade N95 mask until this never-ending pandemic ends.

It's already happening in Los Angeles County, where the Los Angeles Times noted a "big push for Californians to switch to N95 or KN95 masks" as an updated county health order that went into effect Monday requires employers to provide not just masks for their employees but "a well-fitting medical grade mask, surgical mask or higher-level respirator, such as an N95 filtering facepiece respirator or KN95."

Yes, N95s are more effective than cloth masks, and we've been saying that from the beginning. Hazmat suits are more effective too, but that doesn't mean we should all walk around the grocery store like we're in a post-apocalyptic world of toxic fumes.

Nor does it mean we should let the COVID bureaucrats get away with mandating N95s, considering every other COVID mandate handed down for the past two years has proven ineffective. Extended, state-mandated lockdowns did more harm than good, the mandated vaccine doesn't prevent transmission or infection, and the CDC just admitted many of those masks they forced people to wear for two years were more or less pointless.

COVID demands a risk-benefit analysis that varies widely from situation to situation and person to person. If you're in a particularly high-risk situation — say, you have the sniffles but you're going to visit your immuno-compromised grandmother in an assisted living facility — and you want to take extra precaution, you can stay home or wear an N95. If you're young and healthy and going out to eat with a group of friends — or sitting in a classroom, or going on a jog, or anything else — and you don't want to wear a mask, don't.

But mandating N95 masks for every activity of normal life, to ward off a mild variant of a virus that poses little risk to many Americans by the CDC's own admission, is just as senseless as lugging around the useless cloth muzzles we've been told to keep in our cars

and pockets for 22 months. Mask mandates have always been more about showing compliance than keeping people safe, and the CDC's latest embarrassing disclosure further proves it.

Elle Purnell is the elections editor at The Federalist. Her work has been featured by Fox Business, RealClearPolitics, the Tampa Bay Times, and the Independent Women's Forum. She received her B.A. in government from Patrick Henry College with a minor in journalism. Follow her on Twitter @_etreynolds.

CDC
cloth masks
mask mandates
masks
N95

Don't Let Petty Covid Tyrants Bring Back Mask Mandates

thefederalist.com/2023/09/06/petty-covid-tyrants-want-to-bring-back-masks-and-lockdowns-dont-let-them/

September 6, 2023



Image CreditWhite House/Flickr

Government

Petty Covid Tyrants Want To Bring Back Masks And Lockdowns. Don’t Let Them

By: John Daniel Davidson
September 06, 2023

5 min read

The new mask mandates will not be about science or data or public health. They’ll be about the raw exercise of power, nothing more.



John Daniel Davidson

Visit on Twitter @johnddavidson

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A day after First Lady Jill Biden tested positive for Covid with mild symptoms, the White House announced that President Joe Biden will once again be wearing a mask indoors and will only remove it “when sufficiently distanced from others.”

The news comes as health officials in major urban centers, including New York City and Los Angeles, are urging Americans to wear masks again, citing a new strain of Covid spreading through the country. Some colleges and universities, too, are bringing back mask mandates, as are large employers like Kaiser Permanente at its Santa Rosa, California, campus, along with a group of hospitals in New York.

An elementary school near Washington, D.C., on Tuesday imposed a mask mandate — stressing that it would be passing out KN95s, no less — on *third graders* after a handful of kids tested positive for Covid.

Here we go again.

Having gotten a taste of what unlimited power and authority they could wield under the pretext of pandemic management, the American public health bureaucracy — aided and encouraged by Democrats at every level of government — is gearing up to reassert control over our lives, dictating what we can and can’t do, where we can and can’t go, and what counts, or doesn’t count, as an “essential business.” The reemergence of mask mandates is simply the first sign of what’s to come.

And it doesn’t matter *at all* to them that masks have been more or less conclusively shown not to work. Over the weekend, CNN’s Michael Smerconish confronted Anthony Fauci with a study from earlier this year, the most comprehensive and rigorous analysis of the efficacy of masking during Covid, which found that masking made no difference.

The study's lead author, Tom Jefferson of Oxford University, said in an interview in February that there's no evidence that masks, whether N95s or the plain cloth types, had any effect, "Full stop." Asked about other preventative measures like hand-washing and social distancing, Jefferson said, "There's no evidence that many of these things make any difference."

This wasn't some woefully flawed, nonrandomized study of the sort that too often informed slapdash policymaking during the pandemic. It was conducted by a dozen experts for a British nonprofit called Cochrane, which is considered the gold standard for health care data review and analysis. The study's conclusions were based on the results of 78 randomized controlled trials involving more than 610,000 people in multiple countries. Areas with mask mandates, the authors found, fared no better than areas without them. As the pandemic ran its course in the U.S., this became obvious, as different states (and often cities) had different masking rules. The mandates made no difference.

Asked about this study, Fauci's response was abject nonsense. He simply waved it off with a bit of legerdemain saying, "Yeah but there are other studies" that show masking protects at the "individual level," even if the data show no effect of masking at the "pandemic level."

> Fauci admits that masks don't work for the public at large but still absurdly claims masks work on an individual basis. More subterfuge. pic.twitter.com/UcjOa8flkr
>
> — Rand Paul (@RandPaul) September 3, 2023

This of course misses the point. Whatever benefits masking might offer to a specific person, there is absolutely no scientific case for masking as a matter of public policy, let alone as a coercive tactic with penalties attached to it.

The same goes for lockdowns, Covid shots, and the entire slew of pandemic-related policies that were foisted on us by a self-righteous rabble of pundits and so-called experts. They were all wrong, and those who questioned and resisted draconian Covid measures were right. Time and data analysis have left little doubt of that.

And yet calls for masking — and, just wait for it, lockdowns — are coming around again, zombielike, as if the past three years never happened, as if we don't know what we all clearly know by now: None of it made any difference.

The reason these ideas and policies are coming around again has nothing to do with science or data or public health or epidemiology, just like the first time around. It's not a question of science but of power.

Covid and its ever-changing variants are never going away. Like the seasonal flu, we're always going to have some new strain of Covid around now. Public health "experts" and the Democrats who enable them will try to use these variants, however harmless they might be,

as a pretext to exert control and trample the rights of law-abiding Americans. Don't let them.

When they suggest you wear a mask, don't do it. When they demand you wear a mask (to fly, for example) just do the bare minimum. If they try to force your kids to wear masks in school, challenge them. Insist they back up their masking policy with data that show it's justified.

Many Americans were forced to wear masks and get the Covid shots just to keep their jobs. This was a huge violation of basic civil rights, for which we have not had a reckoning. None of the people who imposed these harmful mandates and policies on the American people have been held accountable (which is why you can still see Fauci bloviating on national TV). Remember that as you begin to see news stories about school districts and employers and local health officials floating the idea of a new mask mandate or a booster shot requirement.

Don't ever give these people the benefit of the doubt. They aren't interested in keeping you healthy, they're interested in controlling you. It's not more complicated than that.

John Daniel Davidson is a senior editor at The Federalist. His writing has appeared in the Wall Street Journal, the Claremont Review of Books, The New York Post, and elsewhere. He is the author of the forthcoming book, *Pagan America: the Decline of Christianity and the Dark Age to Come*, to be published in March 2024. Follow him on Twitter, @johnddavidson.

Anthony Fauci
covid lockdowns
covid vaccine mandates
Covid-19
Joe Biden
mask mandates

Fauci Knew From A 2020 Federalist Piece That Masks Didn't Work

thefederalist.com/2023/07/25/emails-show-fauci-knew-from-a-2020-federalist-article-that-masking-was-ineffective-but-demanded-it-anyway/

July 25, 2023



Image CreditAndrea Hanks/Trump White House Archived/Flickr/Edited with Canva

Wuhan Virus

Emails Show Fauci Knew From A 2020 Federalist Article That Masking Was Ineffective But Demanded It Anyway

By: Jordan Boyd
July 25, 2023

7 min read

Mere weeks after seeing The Federalist's reporting, Fauci published a paper that made no mention of masks' shortcomings.



Jordan Boyd

Visit on Twitter @jordanboydtx

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Former Director of the National Institute of Allergy and Infectious Diseases Anthony Fauci knew as early as October 2020 that masking was ineffective at preventing the transmission of Covid-19 after he read a Federalist article about it, emails obtained by the Functional Government Initiative (FGI) and shared with The Federalist reveal.

Despite showing awareness of a Centers for Disease Control and Prevention (CDC) study — which showed a majority of Covid patients in the study became ill despite always wearing face coverings — and The Federalist's reporting on it, Fauci published a paper weeks after the story that made no mention of masks' shortcomings. In fact, for two more years, Fauci demanded universal masking and encouraged mandates requiring face coverings despite their uselessness.

The Federalist article in question was published on On Oct. 12, 2020, under the headline "CDC Study Finds Overwhelming Majority Of People Getting Coronavirus Wore Masks." The story featured the CDC study, which was conducted in July 2020 but not released until that September, that compared 154 "case-patients" who tested positive for Covid-19 to 160 "control participants" who were symptomatic but ultimately tested negative for the virus.

Researchers tried to use the data to convince the public that "Exposures and activities where mask use and social distancing are difficult to maintain, including going to places that offer on-site eating or drinking, might be important risk factors for acquiring COVID-19." Yet a majority of case patients (71 percent) and control participants (74 percent) "reported always using cloth face coverings or other mask types when in public" in the weeks leading up to their illness.

The CDC was forced to concede that, despite its best efforts to blame the spread of the virus on those who maintained public participation with little-to-no masking, "direction, ventilation, and intensity of airflow might affect virus transmission, even if social distancing measures and mask use are implemented according to current guidance."

The same day The Federalist published the article outlining the damning evidence against masks, Fauci's Chief of Staff Greg Folkers emailed the story's text to the NIAID director.

From: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Sent: Monday, October 12, 2020 2:17 PM
Subject: The Federalist: CDC Study Finds Overwhelming Majority Of People Getting Coronavirus Wore Masks

- Wuhan Virus



CDC Study Finds Overwhelming Majority Of People Getting Coronavirus Wore Masks

October 12, 2020 By Jordan Davidson

A Centers for Disease Control report released in September shows that masks and face coverings are not effective in preventing the spread of COVID-19, even for those people who consistently wear them.

A study conducted in the United States in July found that when they compared 154 "case-patients," who tested positive for COVID-19, to a control group of 160 participants from the same health care facility who were symptomatic but tested negative, over 70 percent of the case-patients were contaminated with the virus and fell ill despite "always" wearing a mask.

"Not good for our paper," Fauci admitted in his reply, which looped in NIAID staffer Andrea Lerner.

From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-(b)(6)
Sent: 10/12/2020 6:34:36 PM
To: Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b41887-(b)(6); Greg Folkers (b)(6) [/o=NIH/ou=NIHEXCHANGE/cn=NIAID/cn=(b)(6)
Subject: FW: The Federalist: CDC Study Finds Overwhelming Majority Of People Getting Coronavirus Wore Masks

Not good for our paper……,

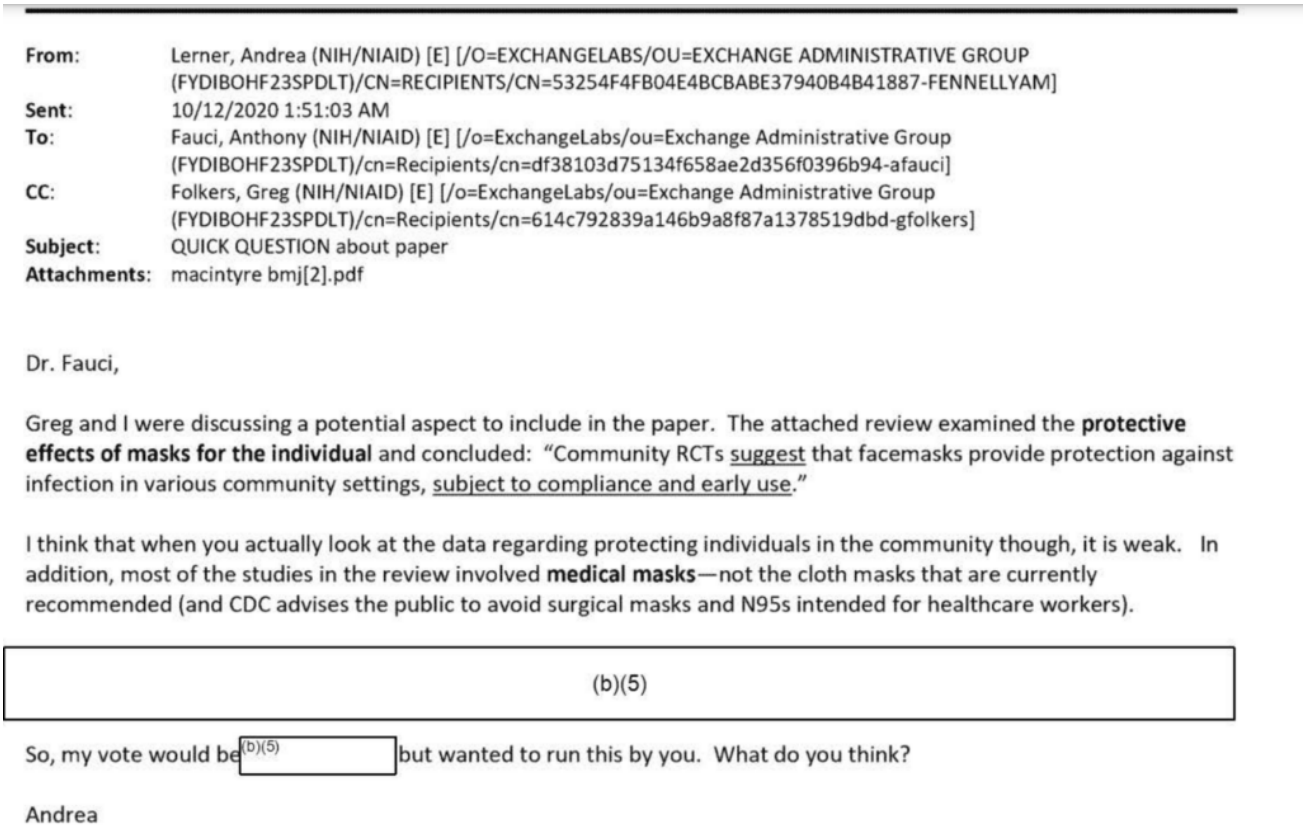
During this time, Fauci and his NIAID team couldn't get their story straight on masking — telling the public masking was essential but acknowledging in private that the science didn't support their narrative. For instance, days before he was sent The Federalist article, Fauci

publicly declared that the data on masks "speak for themselves."

"We had a super-spreader event in the White House and it was in a situation where people were crowded together and were not wearing masks. So the data speak for themselves," he told CBS.

Yet on Oct. 12, even before Fauci's staff flagged The Federalist story, Lerner warned her colleagues that the research data they wanted to include in their paper about masks "protecting individuals in the community" was actually "weak."

"In addition, most of the studies in the review involved medical masks–not the cloth masks that are currently recommended (and CDC advises the public to avoid surgical masks and N95s intended for healthcare workers)," Lerner wrote.



From: Lerner, Andrea (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53254F4FB04E4BCBABE37940B4B41887-FENNELLYAM]
Sent: 10/12/2020 1:51:03 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]
CC: Folkers, Greg (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=614c792839a146b9a8f87a1378519dbd-gfolkers]
Subject: QUICK QUESTION about paper
Attachments: macintyre bmj[2].pdf

Dr. Fauci,

Greg and I were discussing a potential aspect to include in the paper. The attached review examined the **protective effects of masks for the individual** and concluded: "Community RCTs suggest that facemasks provide protection against infection in various community settings, subject to compliance and early use."

I think that when you actually look at the data regarding protecting individuals in the community though, it is weak. In addition, most of the studies in the review involved **medical masks**—not the cloth masks that are currently recommended (and CDC advises the public to avoid surgical masks and N95s intended for healthcare workers).

(b)(5)

So, my vote would be (b)(5) but wanted to run this by you. What do you think?

Andrea

Paper Trail

Around the same time the Federalist article was published, Fauci, Folkers, and Lerner were busy working on their aforementioned "viewpoint" paper that claimed the nation's "return to normalcy" was contingent upon the "widespread acceptance and adoption of mask wearing and other inexpensive and effective interventions as part of the COVID-19 prevention toolbox."

Emails reveal the paper was solicited by Howard Bauchner, the then-editor-in-chief of the *Journal of the American Medical Association* and its network.

“A request has come in to have ‘Dr. Fauci write a VP about the importance of masking’ — for the record. Obviously aware of the tug and war ongoing. Your call. The twist could be that masking will be important even after vaccination begins,” Bauchner wrote in an Oct. 1, 2020 email to Fauci.

From: Howard Bauchner <(b)(6)
Sent: Thursday, October 1, 2020 8:08 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b)(6); Conrad, Patricia (NIH/NIAID) [E] (b)(6)
Cc: Phil Fontanarosa (b)(6)
Subject: JAMA

Tony

A request has come in to have “Dr. Fauci write a VP about the importance of masking” – for the record.

Obviously aware of the tug and war ongoing.

Your call.

The twist could be that masking will be important even after vaccination begins.

Let me know if it is something you would like to do.

Patty – copied you – might want to print out and give Tony a copy. Know his inbox quite filled.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

When The Federalist article came across his desk, Fauci acknowledged the CDC’s findings ran counter to his mask push. Yet exactly two weeks after admitting the data threatened his preferred narrative, *JAMA* published Fauci’s article titled, “Preventing the Spread of SARS-CoV-2 With Masks and Other ‘Low-tech’ Interventions.”

Fauci would have had plenty of time to update the paper with the latest masking findings since *JAMA* did not send him his page proof until Oct. 21.

From: (b)(6) (b)(6)
Sent: Wednesday, October 21, 2020 1:04 AM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6)
Subject: Page proofs for JVP200233 for JAMA

10-21-2020

Dear Dr Fauci,

A page proof for your article JVP200233, "Preventing the Spread of SARS-CoV-2 With Masks and Other "Low-tech" Interventions," is available for you to review and provide feedback. Please complete your review (using the link below) within 24 hours.

Your article has been edited for content, consistency, and JAMA Network style. Please read these page proofs carefully. At this stage, only changes to correct typographical or factual errors should be made.

Please submit your response using the form provided no later than 10-22-2020, with any changes or with your approval. Click here to access the proof and the form for reviewing and approving your proof.

The information in your article is confidential. You should not distribute copies of the proof to anyone, except coauthors, without our approval. Your article is tentatively scheduled for publication on October 26, 2020. The news media should not release any information about your article until the embargo date. If you have questions about the embargo date or need help coordinating press conferences or releases, please contact the JAMA Network Media Relations Department at (b)(6) or (b)(6)

Instead of acknowledging the critical information undermining his previously held masking narrative, however, Fauci doubled down.

In the published paper, he insisted that "to safely reopen businesses, schools, and other facets of society, mask use in the community to prevent the spread of SARS-CoV-2, in conjunction with other low-cost, low-tech, commonsense public health practices, is and will remain critical." To bolster his point, Fauci touted now-debunked data to suggest that mask mandates "have been associated with a decline in the daily growth rate of COVID-19 cases in the US."

"During the pandemic, Dr. Fauci was the face of the United States' medical and scientific struggle against COVID-19. So it should be extremely concerning to the American public that he cherry-picked research on the efficacy of masks in preventing the spread of the virus," Peter McGinnis, spokesman for FGI, said in a statement. "He clearly knew about the CDC study showing masks didn't work as we were told, but he chose neither to address nor even mention it and instead pushed forward his paper saying the exact opposite. At best, this is poor scientific ethics. If Dr. Fauci was so quick to ignore science so early in the pandemic, why should the American public trust anything else he said or did over the last few years?"

To Mask or to Double Mask

Even before the CDC study, Fauci privately admitted at the beginning of the Covid pandemic that masking was not the effective solution he later claimed it would be. Fauci's February 2020 emails obtained in 2021 by Buzzfeed News and The Washington Post showed the director confidently stating that wearing a mask did not stop the spread of the new virus. He publicly repeated the sentiment that "there's no reason to be walking around with a mask" in a "60 Minutes" interview in March 2020.

As the corporate media and Covid regime's panic ramped up, however, Fauci changed his tune and began pushing for widespread masking under the guise of protecting against accidental asymptomatic transmission — a phenomenon that studies and the World Health Organization's technical lead admitted is "very rare."

When Howard Zucker, the commissioner of the New York State Department of Health appointed by disgraced former Gov. Andrew Cuomo, asked Fauci in July 2020 for "information backing the efficacy of masks at prevention acquisition and spread of SARS-CoV-2," Fauci obliged with a list of several studies that called for "Universal Masking," emails reviewed by The Federalist showed.

"You are doing a terrific job in New York," Fauci wrote. "Hang in there."

From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-(b)(6)
Sent: 7/21/2020 12:06:07 AM
To: Zucker, Howard A (HEALTH) (b)(6)
Subject: RE: JAMA/Brooks et al : Universal Masking to Prevent SARS-CoV-2 Transmission—The Time Is Now / will send mmwr articles separately

Thanks, Howard. I hope that all is well with you. You are doing a terrific job in New York. Hang in there.

From: Zucker, Howard A (HEALTH) (b)(6)
Sent: Monday, July 20, 2020 6:47 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6)
Subject: Re: JAMA/Brooks et al : Universal Masking to Prevent SARS-CoV-2 Transmission—The Time Is Now / will send mmwr articles separately

Tony,

Thank you very much for this information! I just saw you on the national news a minute ago and my friend in Philadelphia was on the phone singing your praises.

Will read the information provided. Much appreciated. Did not realize that Patty Conrad was your assistant. I do recall that after Tommy Thompson left she was interested in working at NIH - if I recall correctly. She's awesome!

Speak soon. Let me know if there is anything you need me to do.

Best wishes,
Howard

By January 2021, Fauci declared one mask wasn't enough and encouraged "common sense" measures like wearing two face coverings at once. At least one scientist emailed him to explain that double masking caused an increase in "unavoidable leakage between the mask and the face [that] carries significant air flow with no filtration."

"I am very concerned that general public may (1) begin to use 2-3 masks and become more vulnerable or (2) not use mask at all since breathing through 2 masks is much harder and uncomfortable," the scientist wrote.

It does not appear Fauci replied. Days after that email, the CDC announced it would investigate whether double masking was effective. Folkers forwarded Fauci a CNN article highlighting that decision.

Jordan Boyd is a staff writer at The Federalist and co-producer of The Federalist Radio Hour. Her work has also been featured in The Daily Wire, Fox News, and RealClearPolitics. Jordan graduated from Baylor University where she majored in political science and minored in journalism. Follow her on Twitter @jordanboydtx.

Why Aren't More Republicans Noting Risks Of Infant Covid Shots?

thefederalist.com/2022/06/28/why-arent-more-republicans-highlighting-the-risks-of-giving-infants-covid-shots/

June 28, 2022



Image CreditGovernor Ron DeSantis

Medical Ethics

Why Aren’t More Republicans Highlighting The Risks Of Giving Infants Covid Shots?

By: Shawn Fleetwood
June 28, 2022

5 min read

The willingness of DeSantis to stand up and raise questions over the CDC and FDA’s decision-making process is a much-needed breath of fresh air.



Shawn Fleetwood

Visit on Twitter @ShawnFleetwood

More Articles

A little over a week ago, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) authorized the first round of Pfizer and Moderna Covid-19 shots for infants as young as 6 months old. The decision came following a unanimous agreement among members of the FDA's advisory panel, who recommended the jabs for children under the age of five.

"Together, with science leading the charge, we have taken another important step forward in our nation's fight against COVID-19," said CDC Director Rochelle Walensky in a statement on the matter. "We know millions of parents and caregivers are eager to get their young children vaccinated, and with today's decision, they can."

Walensky would later go on to falsely claim during a Thursday press conference that Covid-19 has been one of the top five causes of death for children since the beginning of its outbreak, making her the third CDC official this month to make this assertion.

In greenlighting the use of Covid jabs for infants, the CDC and FDA also officially made the United States the first country in the world to do so. U.S. President Joe Biden took to Twitter to celebrate the decision, saying that "For the first time in our fight against this pandemic, nearly every American can now have access to life-saving vaccines."

Similar sentiments were also echoed by White House Chief of Staff Ron Klain, who repeatedly emphasized how America would be "the first country on earth to give mRNA vaccines to its youngest children."

What Does the Science Say?

As has long been established, children are the least at-risk age demographic with respect to Covid-19. As of June 2, 2022, for instance, 0-to 17-year-olds comprised approximately 0.1 percent of the total Covid-related deaths in the United States. Recent studies conducted in Sweden and Germany have also documented similar trends, with both analyses finding Covid fatalities among healthy children in each European country to be nearly nonexistent.

In addition to children not being super-spreaders of the virus, research shows the majority of American children have already recovered from Covid and therefore possess immunity to reinfection. According to the CDC's own data, approximately 75 percent of children in the United States have recovered from Covid. Numerous scientific studies have shown individuals previously infected with the virus possess robust natural immunity.

In light of such minimal risk to children and that the jabs don't stop individuals from getting or spreading the virus, medical professionals have begun to raise concerns about the U.S. government's push to vaccinate infants against Covid, given the risk of harmful side effects balanced against the potential benefits. While speaking with radio host Dan Bongino on Fox News, renowned cardiologist Dr. Peter McCullough expressed dismay at the FDA's decision and noted the effects of the virus are "characteristically a mild syndrome in children" when compared to the elderly.

"We know even if [the vaccines are] used in kids, there won't be any differences in rates of Covid-19 serious outcomes," he said, referencing two studies on the subject. "There's no reductions in hospitalizations and deaths in the randomized trials. And, Dan, we have no assurances that these are safe over the long term."

Dr. Marty Makary, a surgeon and public policy researcher at Johns Hopkins University, also voiced concerns about the FDA and CDC's actions and criticized the data the health agencies cited as justification for their position.

"There was NO STATISTICAL SIGNIFICANCE in the vaccine study cited by FDA &CDC to recommend the vax in babies through kids<5," Makary said in a tweet. "Any respected medical journal would normally reject this study for publication. How does the CDC so vigorously recommend this with such strong language?"

Makary later expanded upon his assessment in a recent Fox News op-ed, saying the studies cited by the federal government "were too small to achieve statistical significance when evaluating efficacy against mild or severe COVID-19 infection."

DeSantis Courageously Says the Truth

Florida Gov. Ron DeSantis a recent press conference also highlighted the medical concerns about giving healthy babies Covid shots.

“We are not gonna have any [state] programs where we’re trying to jab 6-month-old babies with mRNA. That’s just the reality,” he said, while referencing several data points on the subject. “The White House is bragging that we’re the only country that is trying to do mRNA shots for infants … There’s nothing wrong with being the lone ranger if you’re right, but the other countries in Europe that are going a different direction, similar to the direction Florida’s gone, they have been right on Covid way more than [Dr. Anthony] Fauci and his crew have been throughout this whole thing.”

Germany and France, along with Denmark, Finland, Sweden, and Norway, have all restricted the distribution of the Moderna Covid shots for individuals under the age of 30, all citing the documented risk of heart inflammation among young people as justification. Florida has also taken similar actions, with the state’s Department of Health becoming the first in the nation to recommend against the use of Covid shots for children back in March.

> Gov. Ron DeSAVAGE goes FULL-BLAST on Biden White House, legacy media over vaccines for BABIES pic.twitter.com/QVB6sMnozM
>
> — Benny Johnson (@bennyjohnson) June 21, 2022

The willingness of DeSantis to listen to medical professionals who courageously raise questions about the CDC and FDA’s decision-making process is a much-needed breath of fresh air. For too long, America’s health bureaucracy has operated with little oversight, with agencies like the CDC and FDA apparently functioning as rubber stamps for Big Pharma rather than legitimate scientific institutions.

While the decision to vaccinate one’s child is an individual choice for parents, the blanket authorization from the CDC and FDA to jab infants against scientific evidence accepted by many scientists and peer nations deserves far greater scrutiny and investigation. Doing so, however, would mean acting in the best interests of their voters and the public, something Republicans frequently fail to do.

Shawn Fleetwood is a staff writer for The Federalist and a graduate of the University of Mary Washington. He previously served as a state content writer for Convention of States Action and his work has been featured in numerous outlets, including RealClearPolitics, RealClearHealth, and Conservative Review. Follow him on Twitter @ShawnFleetwood

Dr. Andrew Bostom
Uncreated, Uncreative Words

My Certified Rhode Island Superior Court Testimony in Southwell v. McKee on Randomized, Controlled Trial Disproven Community Masking for Respiratory Virus Infection, the Overwhelmingly Mild Nature of Covid-19 in Children, and the Absence of "Dangerous Hospital Over-Utilization" During the "Delta Wave"

Posted on 15th October 2021 | Comments Off

Certified Expert Witness Testimony: Slides Merged

Dr. Andrew Bostom CV as certified expert witness: AB CV 10.21

Dr. Bostom clinical trial in Circulation: FAVORIT 2011

Dr. Bostom grant award announcement: Brown FAVORIT award announcement short version

Dr. Bostom study of rtPCR cycle threshold data from Rhode Island Department of Health testing during the first SARS-CoV-2 wave Bostom Kenyon Eaton Covid-19 positive test cycle threshold trends predict covid-19 mortality in Rhode

CV of Dr. James McDonald, defense/RIDOH expert witness

McDonald CV

This entry was posted in Essays. Bookmark the permalink.

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Dr. Andrew Bostom

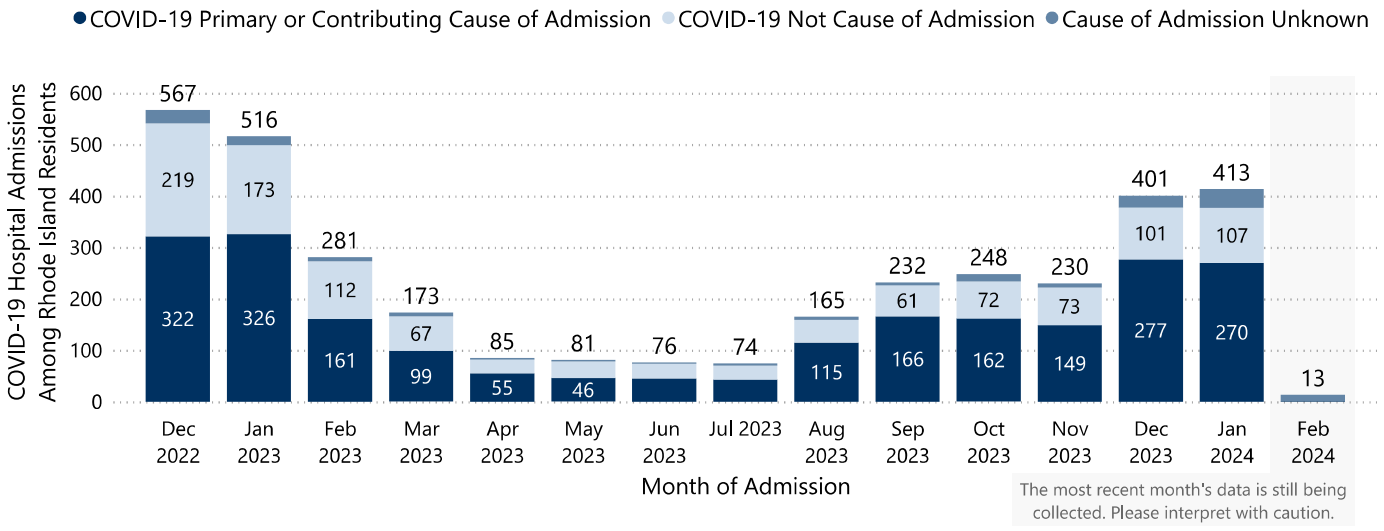
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Rhode Island COVID-19 Hospitalizatio...

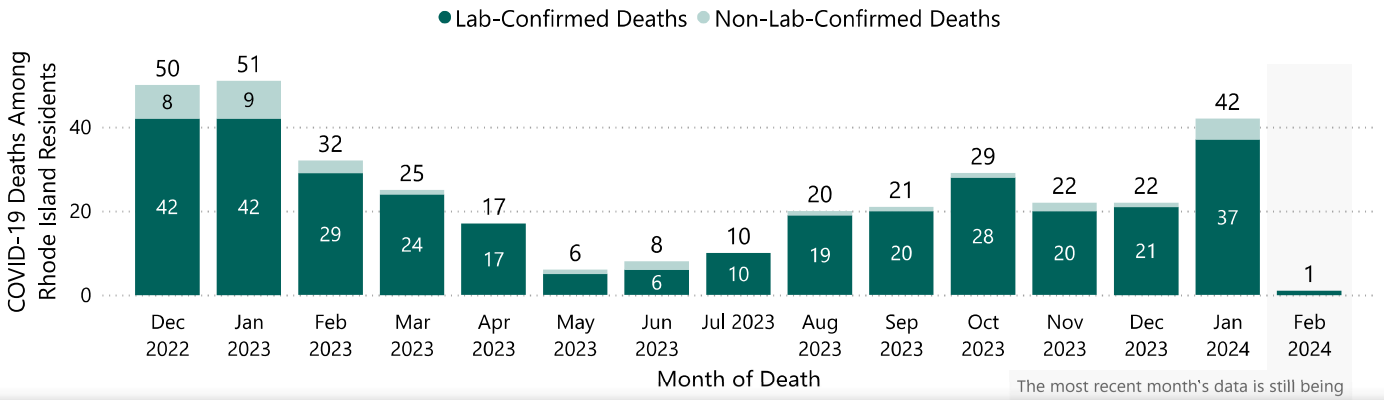
Data Hub Home | Population Specific Data | Vaccination | Variants | CO

Rhode Island COVID-19 Hospital Admissions & COVID-19 Deaths

COVID-19 Hospital Admission Counts

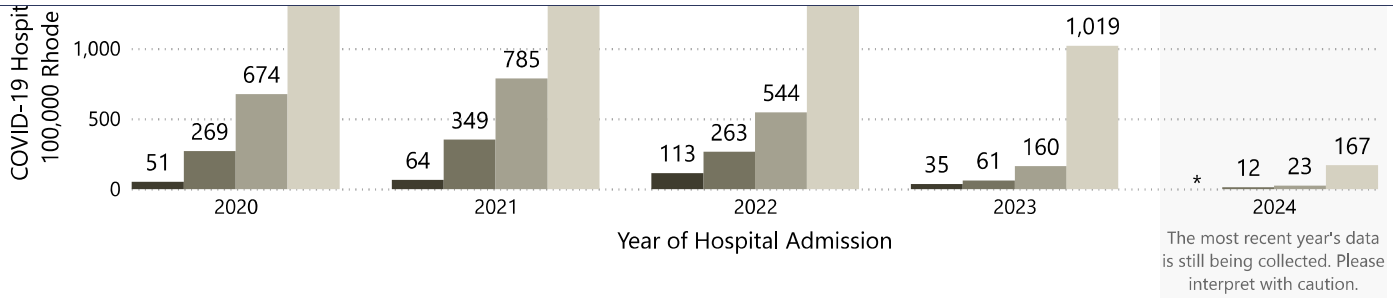


COVID-19 Death Counts



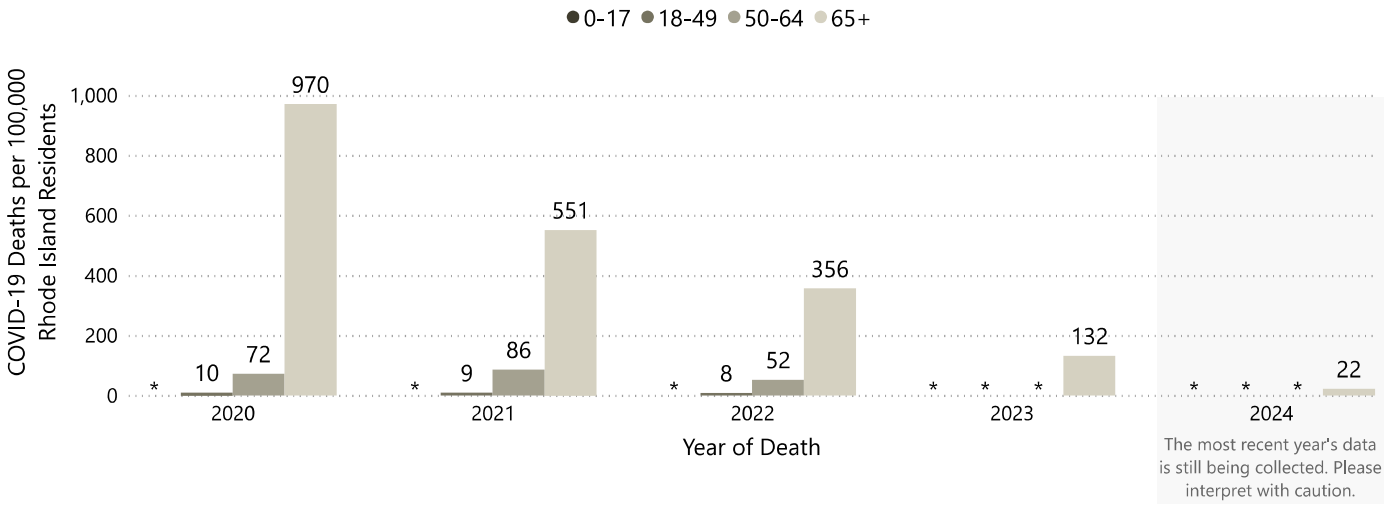
Sign In

Rhode Island COVID-19 Hospitalizatio...



Select demographic breakdown here: Age | Race/Ethnicity (Age-Adjusted) | Sex (Not Age-Adjusted)

COVID-19 Death Rates by Age



Please see below for data notes.

Viewpoint

Children are not COVID-19 super spreaders: time to go back to school

Alasdair P S Munro [1, 2], Saul N Faust [1, 2]

Correspondence to Dr Alasdair P S Munro, NIHR Southampton Clinical Research Facility and NIHR Southampton Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Southampton SO16 6YD, UK; a.munro@soton.ac.uk

https://doi.org/10.1136/archdischild-2020-319474

Statistics from Altmetric.com



See more details

Picked up by **60** news outlets
Blogged by **8**
Referenced in **1** policy sources
Posted by **5995** X users
On **9** Facebook pages
Reddited by **3**
On **1** videos

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Since the first reports of SARS-CoV-2 infections in China, doctors, parents and policy-makers have been aware that COVID-19 is 'not just another respiratory virus' in children. There is a large discrepancy in case rate and prognosis between young children and older adults that has caught everyone by surprise, and for which the mechanisms remain unknown. As community testing has demonstrated a significant number of children with no or subclinical symptoms,[1] key questions needs answering: are there low rates of confirmed infection in children because children are not becoming infected and/or infectious, or is COVID-19 in children usually such a benign upper respiratory illness that does not even cause infants or immune suppressed children to need hospital admission? If children are infected, are they infectious to each other and/or to adults? If so, how long for?

The implications of asymptomatic but potentially infectious children in the community are important. If, as for influenza,[2] children are the primary drivers of household SARS-CoV-2 transmission, then silent spread from children who did not alert anyone to their infection could be a serious driver of community transmission. On this presumption but without evidence, school closures were implemented almost ubiquitously around the world to try and halt the potential spread of disease despite early modelling that suggested this would have less impact than most other non-pharmacological interventions.[3]

Early contact tracing data from Shenzhen, China, appeared to confirm a role for children in transmission. Although apparently presenting with more benign disease or even without symptoms, similar attack rates were found in children and adults in individual households.[4] However, the story has subsequently evolved.

Some regions have implemented widespread community testing, such as South Korea and Iceland. Both countries found children were significantly underrepresented. In Iceland, this is true both in ...

View Full Text

Footnotes

Twitter: @apsmunro

Correction notice: This paper has been amended since it was published Online First. The digital object identifiers were missing from some of the references. Also, we have removed the 'accessed date' for reference 11 because this was added by the publisher and was not the date accessed by the authors. The article states 'In New South Wales, Australia none of 735 students and 128 staff contracted COVID-19 from nine child and nine adult initial school cases despite close contact.' This paragraph has been rewritten to provide more clarity. The publisher has also updated references which cite preprints to make it clearer that these are preprints. In paragraph four, starting 'In some regions...' it should have been clearer that the data from Japan was also reported in a preprint.

Contributors: APSM and SNF both conceived the paper. APSM wrote the first draft of the manuscript, and SNF and APSM both edited and agreed on the final manuscript.

Funding: The salaries of APSM and SNF are funded in part by the NIHR Southampton Clinical Research Facility and NIHR Southampton Biomedical Research Centre.

Competing interests: None declared.

Patient consent for publication: Not required.

Provenance and peer review: Not commissioned; internally peer reviewed.

Linked Articles

Atoms
Highlights from this issue
Nick Brown
Archives of Disease in Childhood 2020; **105** i-i Published Online First: 19 Jun 2020. doi: 10.1136/archdischild-2020-319866

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Help

questions regarding 216-RICR-30-05-4 - RIDOH's March 15th hearing for its proposal of a mask mandate regulation

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Mon 2/5/2024 2:16 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (4 KB)

Notice of Proposed Rulemaking_Masking Regs (1).pdf;

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

Good afternoon Zachary,

I have a number of questions regarding RIDOH's March 15th hearing for its proposal of a mask mandate regulation (see attached). According to the public notice, the hearing will take place in conference Rooms A, B, and C. The public notice states that seating capacity will be enforced but does not specify what that capacity is. What is the capacity of each room individually? How close are these conference rooms to one another? In which room will the hearing actually take place? How will members of the public be notified of their turn to speak if they are not in the primary conference room? Will the hearing be projected into the other rooms or will the public be left in the dark as to what is occurring? Will an overflow room be provided in the event that we exceed the capacity of the three conference rooms or will the public be turned away once capacity is reached? How does RIDOH intend to organize public comment? Will there be a sign-up sheet? If so, where will it be located? What technological equipment be available for expert witnesses who wish to provide a visual presentation?

Additionally, I request a full regulatory analysis of the supporting documentation used in the development of this rule.

Thank you for taking the time to respond to my inquiry.

Maddalena Cirignotta

347-860-0789

Follow up email and and additional question

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Tue 2/6/2024 2:17 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good afternoon again Zack,

I emailed you yesterday with a number of questions regarding RIDOH's March 15th hearing for its proposal of a mask mandate regulation and I requested a full regulatory analysis of the supporting documentation used in the development of this rule, which I hope to receive from you soon.
I have an additional question. It's come to my attention that RIDOH is not accepting online public comments for this filing (see screenshot below). Why? Is this common practice for all filings of regulation proposals? If public comments cannot be submitted online, how will the public ensure accurate record keeping on the part of RIDOH?

Again, thank you for taking the time to address my questions and requests. I hope to hear from you soon.

Sincerely,
Maddalena Cirignotta
347-860-0789

March 15th hearing on masks

Alexandra Lepore <humanwondrs@gmail.com>

Thu 2/8/2024 2:51 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:sen-morgan@rilegislature.gov <sen-morgan@rilegislature.gov>;Senator Tony DeLuca <Td2082@yahoo.com>

1 attachments (397 KB)

Screenshot_20240208_121355_Rumble.jpg;

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Report Suspicious

Good afternoon, Zachary:

I AM a RI resident and very concerned about this hearing on mask wearing in our k-12 schools. There are multiple studies that are conclusive that masks harm people.

You are risking the health and lives of our Rhode Island families. As it IS written on your website in your mission statement:

The Department's mission is: "to prevent disease and protect and promote the health and safety of the people of Rhode Island."

You are, all, derelict in your duties by even considering masking our children with the plethora of available studies on this subject.

I ask that you halt any moving forward on this matter and promote the health and safety of the people of RI.

Please see below for links on such studies and articles.

Thank you for your time. Looking forward to hearing from you soon and will see you on the 15th of March!

Kind Regards,

Alexandra Lepore
(401) 318-3226

"Patience IS a stepping stone to Wisdom." -- Joanne Sacred Scribe

Here are links to articles and scientific studies.

https://principia-scientific.com/65-studies-reveals-face-masks-do-cause-physical-harm/ [principia-scientific.com]

https://ratical.org/PandemicParallaxView/MasksAreHarmful-Meehan2020.html [ratical.org]

https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/ [brownstone.org]

65 Studies Reveals Face Masks DO Cause Physical Harm

Published on April 29, 2021

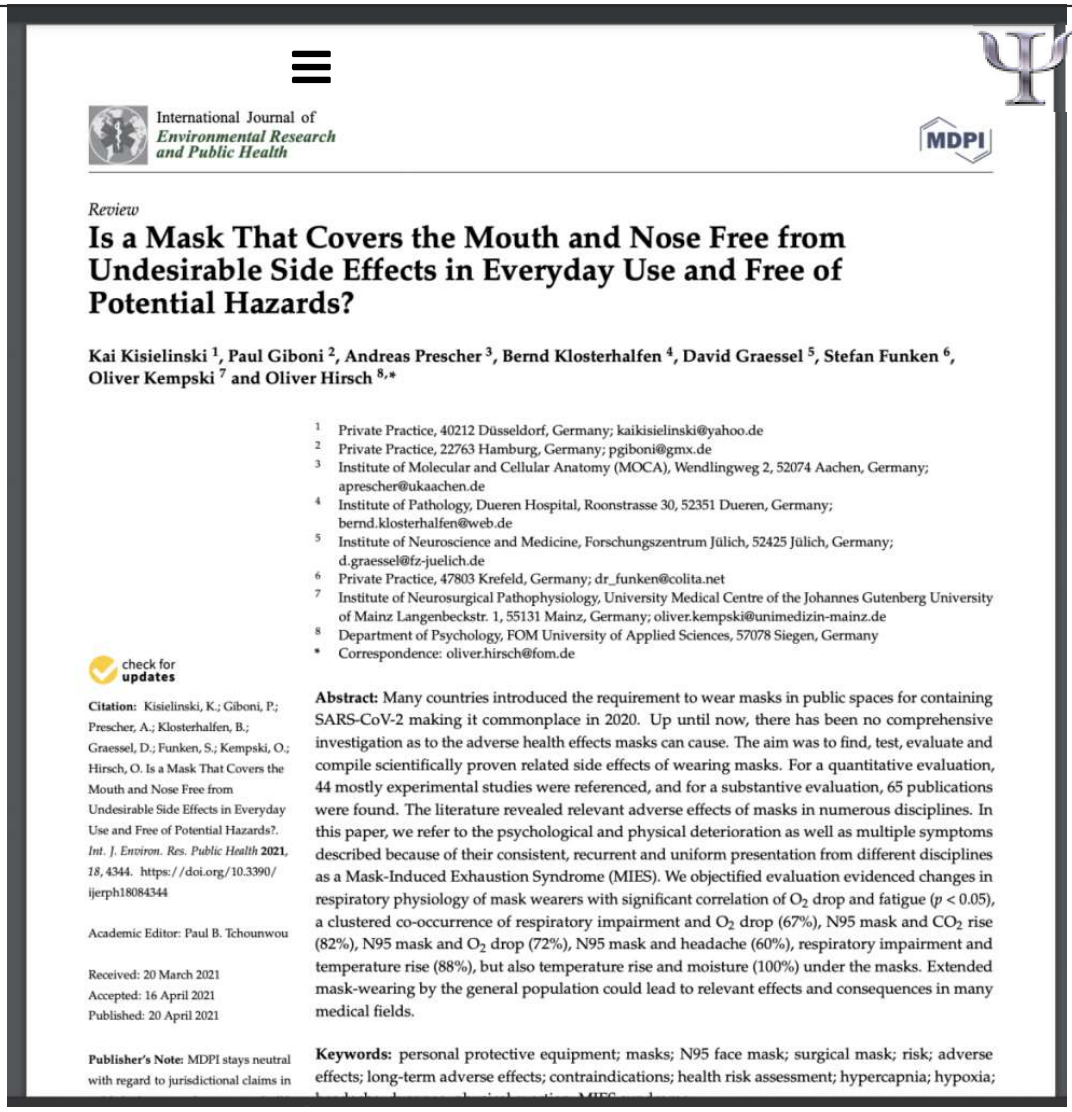
Written by greenmedinfo.com



Image: DW

Meta-Analysis of 65 Studies Reveals Face Masks Induce Mask-Induced Exhaustion Syndrome (MIES).





International Journal of *Environmental Research and Public Health*

MDPI

Review

Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?

Kai Kisielinski [1], Paul Giboni [2], Andreas Prescher [3], Bernd Klosterhalfen [4], David Graessel [5], Stefan Funken [6], Oliver Kempski [7] and Oliver Hirsch [8,*]

1 Private Practice, 40212 Düsseldorf, Germany; kaikisielinski@yahoo.de
2 Private Practice, 22763 Hamburg, Germany; pgiboni@gmx.de
3 Institute of Molecular and Cellular Anatomy (MOCA), Wendlingweg 2, 52074 Aachen, Germany; aprescher@ukaachen.de
4 Institute of Pathology, Dueren Hospital, Roonstrasse 30, 52351 Dueren, Germany; bernd.klosterhalfen@web.de
5 Institute of Neuroscience and Medicine, Forschungszentrum Jülich, 52425 Jülich, Germany; d.graessel@fz-juelich.de
6 Private Practice, 47803 Krefeld, Germany; dr_funken@colita.net
7 Institute of Neurosurgical Pathophysiology, University Medical Centre of the Johannes Gutenberg University of Mainz Langenbeckstr. 1, 55131 Mainz, Germany; oliver.kempski@unimedizin-mainz.de
8 Department of Psychology, FOM University of Applied Sciences, 57078 Siegen, Germany
* Correspondence: oliver.hirsch@fom.de

check for updates

Citation: Kisielinski, K.; Giboni, P.; Prescher, A.; Klosterhalfen, B.; Graessel, D.; Funken, S.; Kempski, O.; Hirsch, O. Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?. *Int. J. Environ. Res. Public Health* **2021**, *18*, 4344. https://doi.org/10.3390/ijerph18084344

Academic Editor: Paul B. Tchounwou

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Abstract: Many countries introduced the requirement to wear masks in public spaces for containing SARS-CoV-2 making it commonplace in 2020. Up until now, there has been no comprehensive investigation as to the adverse health effects masks can cause. The aim was to find, test, evaluate and compile scientifically proven related side effects of wearing masks. For a quantitative evaluation, 44 mostly experimental studies were referenced, and for a substantive evaluation, 65 publications were found. The literature revealed relevant adverse effects of masks in numerous disciplines. In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES). We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.

Keywords: personal protective equipment; masks; N95 face mask; surgical mask; risk; adverse effects; long-term adverse effects; contraindications; health risk assessment; hypercapnia; hypoxia;

A first-of-its-kind literature review on the adverse effects of face masks, titled "Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?," reveals there are clear, scientifically demonstrable adverse effects for mask wearers, both on psychological, social and physical levels.

Newly published in the **International Journal of Environmental Research and Public Health**, a team of German researchers acknowledge that theirs is the first comprehensive investigation into the adverse health effects that masks can cause — a surprising fact considering that many countries around the world introduced universal mask wearing in public spaces for containing SARS-CoV-2 in 2020 as a mandatory health policy without investigating nor communicating to their citizens the true risks of masks, **hence violating informed consent**.

According to the German research team, their work is designed to "provide a first, rapid, scientific presentation of the risks of general mandatory mask use by focusing on the possible adverse medical effects of masks, especially in certain diagnostic, patient and user groups."

The researchers summarize their study as follows:

"The aim was to find, test, evaluate and compile scientifically proven related side effects of wearing masks. For a quantitative evaluation, 44 mostly experimental studies were referenced, and for a substantive evaluation, 65 publications were found. The literature revealed relevant adverse effects of masks in numerous disciplines.

In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES).

We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O2 drop (67%), N95 mask and CO2 rise (82%), N95 mask and O2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks.

Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields."

The researchers provided the following important context for their work:

"The potential drastic and undesirable effects found in multidisciplinary areas illustrate the general scope of global decisions on masks in general public in the light of combating the pandemic. According to the literature found, there are clear, scientifically recorded adverse effects for the mask wearer, both on a psychological and on a social and physical level.

Neither higher level institutions such as the WHO or the European Centre for Disease Prevention and Control (ECDC) nor national ones, such as the Centers for Disease Control and Prevention, GA, USA (CDC) or the German RKI, substantiate with sound scientific data a positive effect of masks in the public (in terms of a reduced rate of spread of COVID-19 in the population) [2,4,5]

Contrary to the scientifically established standard of evidence-based medicine, national and international health authorities have issued their theoretical assessments on the masks in public places, even though the compulsory wearing of masks gives a deceptive feeling of safety [5,112,143]."

The authors provided the following summary of the problem with the widely disseminated narrative that masks are a priori "safe and effective."

"From an infection epidemiological point of view, masks in everyday use offer the risk of self-contamination by the wearer from both inside and outside, including via contaminated hands [5,16,88]. In addition, masks are soaked by exhaled air, which potentially accumulates infectious agents from the nasopharynx and also from the ambient air on the outside and inside of the mask.

In particular, serious infection-causing bacteria and fungi should be mentioned here [86,88,89], but also viruses [87]. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be an indication of this phenomenon. Clarification through further investigations would therefore be desirable.

Masks, when used by the general public, are considered by scientists to pose a risk of infection because the standardized hygiene rules of hospitals cannot be followed by the general public [5]. On top of that, mask wearers (surgical, N95, fabric masks) exhale relatively smaller particles (size 0.3 to 0.5 μm) than mask-less people and the louder speech under masks further amplifies this increased fine aerosol production by the mask wearer (nebulizer effect) [98].

The history of modern times shows that already in the influenza pandemics of 1918-1919, 1957-58, 1968, 2002, in SARS 2004-2005 as well as with the influenza in 2009, masks in everyday use could not achieve the hoped-for success in the fight against viral infection scenarios [67,144]. The experiences led to scientific studies describing as early as 2009 that masks do not show any significant effect with regard to viruses in an everyday scenario [129,145].

Even later, scientists and institutions rated the masks as unsuitable to protect the user safely from viral respiratory infections [137,146,147]. Even in hospital use, surgical masks lack strong evidence of protection against viruses [67]. Originally born out of the useful knowledge of protecting wounds from surgeons' breath and predominantly bacterial droplet contamination [144,148,149], the mask has been visibly misused with largely incorrect popular everyday use, particularly in Asia in recent years [150].

Significantly, the sociologist Beck described the mask as a cosmetic of risk as early as 1992 [151]. Unfortunately, the mask is inherent in a vicious circle: strictly speaking, it only protects

reinforced by the collective fear mongering, which is constantly nurtured by main stream media [137].

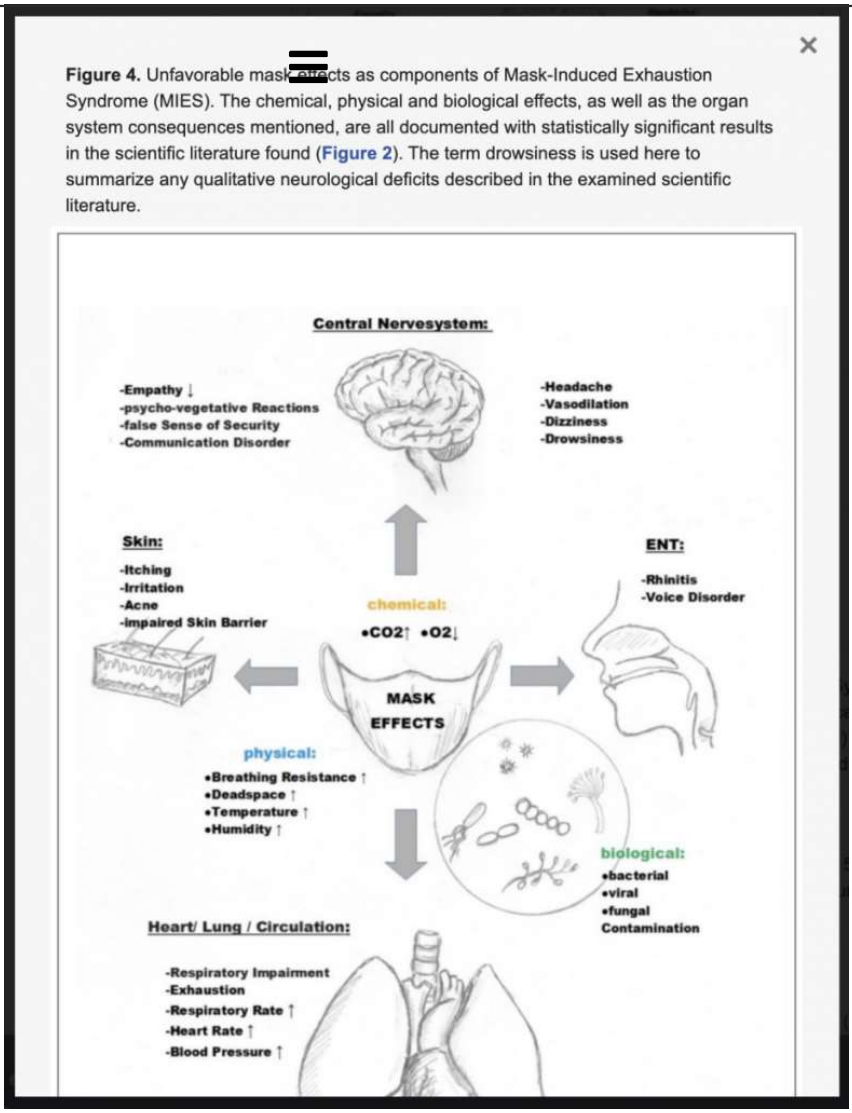
Nowadays, the mask represents a kind of psychological support for the general population during the virus pandemic, promising them additional anxiety-reduced freedom of movement. The recommendation to use masks in the sense of "source control" not out of self-protection but out of "altruism" [152] is also very popular with the regulators as well as the population of many countries.

The WHO's recommendation of the mask in the current pandemic is not only a purely infectiological approach, but is also clear on the possible advantages for healthy people in the general public. In particular, a reduced potential stigmatization of mask wearers, the feeling of a contribution made to preventing the spread of the virus, as well as the reminder to adhere to other measures are mentioned [2].

Morever, the researchers pointed out that there are recurring patterns of related health issues associated with mask wearing, leading them to coin the term mask-induced exhaustion syndrome (MIES), which encompasses the following pathophysioloical changes and subjective complaints:

- *Increase in dead space volume [22,24,58,59] (Figure 3, Section 3.1 and Section 3.2)*
- *Increase in breathing resistance [31,35,61,118] (Figure 3, Figure 2: Column 8)*
- *Increase in blood carbon dioxide [13,15,19,21,22,23,24,25,26,27,28] (Figure 2: Column 5)*
- *Decrease in blood oxygen saturation [18,19,21,23,28,29,30,31,32,33,34] (Figure 2: Column 4)*
- *Increase in heart rate [15,19,23,29,30,35] (Figure 2: Column 12)*
- *Decrease in cardiopulmonary capacity [31] (Section 3.2)*
- *Feeling of exhaustion [15,19,21,29,31,32,33,34,35,69] (Figure 2: Column 14)*
- *Increase in respiratory rate [15,21,23,34] (Figure 2: Column 9)*
- *Difficulty breathing and shortness of breath [15,19,21,23,25,29,31,34,35,71,85,101,133] (Figure 2: Column 13)*
- *Headache [19,27,37,66,67,68,83] (Figure 2: Column 17)*
- *Dizziness [23,29] (Figure 2: Column 16)*
- *Feeling of dampness and heat [15,16,22,29,31,35,85,133] (Figure 2: Column 7)*
- *Drowsiness (qualitative neurological deficits) [19,29,32,36,37] (Figure 2: Column 15)*
- *Decrease in empathy perception [99] (Figure 2: Column 19)*
- *Impaired skin barrier function with acne, itching and skin lesions [37,72,73] (Figure 2: Column 20-22)*

The researchers point out that the effects described above have been observed in studies of healthy people, implying that sick people will have even more pronounced effects from wearing masks. Also, they pointed out that these effects observed in previous studies involved exposure times significantly lower than what is presently expected to be the case in the general public under current pandemic regulations and ordinances.



The study goes into great depth on the harms of mask wearing and adds to a growing body of underreported, if not outright censored and suppressed, biomedical literature that has accumulated that refutes the widely disseminated narrative that masks are both safe and effective, and that their recommendations for use by agencies like the CDC are evidence-based, which clearly they are not. Learn more by visiting the GreenMedInfo.com database **Face Masks (Lack of Safety and Ineffectiveness Research)**.

Also, let your voice be heard and use the Stand for Health Freedom digital advocacy portal to tell your elected officials that you will only support voluntary mask wearing. **ACT NOW: Mandatory Masks Endanger Your Health and Your Liberties. Tell Your State and Local Officials to Make Mask-Wearing Voluntary.**

See more here: greenmedinfo.com

back to Pandemic Parallax View | rat haus | Index | Search | tree

Editor's Note: This is section 4 of Jim Meehan, MD, An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful, 10 October 2020, *meehanmd.com* with the 17 points linked for direct access and sourcing.

Masks are Harmful: 17 Ways That Masks Can Cause Harm

As a physician and former medical journal editor, I've carefully read the scientific literature regarding the use of face masks to mitigate viral transmission. I believe the public health experts have community wearing of masks all wrong. Here are a few of the mechanisms by which medical masks can be harmful to their wearers and community wearing of face masks is a very bad idea:

> **Wearing masks for extended periods increased incidences of headaches and negatively affected work performance.**

See Jonathan J.Y. Ong, et al., Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19, Headache, the Journal of Head and Face Pain (May 2020). https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.13811

1. Medical masks adversely affect respiratory physiology and function
2. Medical masks lower oxygen levels in the blood
3. Medical masks raise carbon dioxide levels in the blood
4. SARS CoV-2 is armed with a "furin cleavage site" that makes it more pathogenic
5. Medical masks trap exhaled viral (and other) pathogens in the mouth/mask interspace, increase viral/infectious load, and increase the severity of disease
6. SARS CoV-2 Becomes More Dangerous When Blood Oxygen Levels Decline
7. The furin cleavage site of SARS CoV-2 increases cellular invasion, especially during hypoxia (low blood oxygen levels)
8. Cloth masks may increase the risk of contracting Covid-19 and other respiratory infections
9. Wearing a face mask may give a false sense of security
10. Masks compromise communications and reduce social distancing

11. Untrained and inappropriate management of face masks
12. Masks Worn Imperfectly Are Dangerous
13. Masks collect and colonize viruses, bacteria, and mold
14. Wearing a face mask makes the exhaled air (respiratory plumes) go into the eyes
15. Contact tracing studies show that asymptomatic carrier transmission is very rare
16. Face masks and stay at home orders prevent the development of herd immunity
17. Face masks are dangerous and contraindicated for a large number of people with pre-existing medical conditions and disabilities

1. Medical masks adversely affect respiratory physiology and function.

- **Masks inhibit air flow into and out of the lungs.**
    - For people with asthma, chronic obstructive pulmonary disease (COPD), and many other chronic lung diseases, face masks are intolerable to wear as they worsen breathlessness.[R]
- Medical masks lower blood oxygen and raise carbon dioxide such that respiratory rate and depth of breaths are increased.[R]
    - Decreasing oxygen and increasing carbon dioxide in the bloodstream stimulates a compensatory response in the respiratory centers of the brain. These changes in blood gases result in **increases in both frequency and depth of breaths.**
    - As masks Increase both the frequency and depth of respirations (breaths), they increase the likelihood that each respiration will contain a larger amount of infectious viral particles. This may worsen the community transmission of CoVID-19 as infected people wearing masks exhale respiratory plumes loaded with greater levels of infectious viral particles. These infectious plumes readily move around the sides, bottom, and top of masks.
    - This may also increase the severity of CoVID-19 as the **increased tidal volume delivers the viral particles deeper into the lungs.**
    - These effects are amplified if face masks are contaminated with the viruses, bacteria, or fungi that find their way or opportunistically grow in the warm,

moist environment that medical masks quickly become.

2. Medical masks lower oxygen levels in the blood.[R]

Wearing a mask for more than a few minutes causes a significant reduction in a person's blood oxygen level.

- Beder, A., U. Büyükkoçak, H. Sabuncuoğlu, Z. A. Keskil, and S. Keskil. 2008. "Preliminary Report on Surgical Mask Induced Deoxygenation during Major Surgery." Neurocirugia 19 (2): 121-26. DOI: 10.1016/s1130-1473(08)70235-5
    - This study of 53 surgeons evaluated the effect of surgical masks on oxygen saturation of hemoglobin in surgeons performing surgery.
    - The study revealed the surgeons experienced a significant decrease in the oxygen saturation of arterial pulsations (SpO2) and a slight increase in pulse rates after one hour. The decrease was more prominent in the surgeons over the age of 35.
    - Given that **a small decrease in SpO2 reflects a large decrease in partial pressure of oxygen in the arterial blood (PaO2)**[R], the findings of this study suggests that surgical masks worn more than one hour may lower arterial oxygen enough to induce physiologically detrimental effects.
- Here are two cases of the tragic consequences of forcing children to wear masks: Two Chinese boys drop dead while wearing face masks during physical exercise classes.[R][R]

  Two boys from two Chinese cities died of sudden cardiac arrest within a week. The first boy, 15, collapsed after jogging in PE class while wearing a face mask on April 24. The other boy, 14, reportedly died during a running exam while wearing a mask.

  Why would healthy boys drop dead while wearing masks and running in gym class?! To answer this question, we must consider how mask induced deoxygenation and increased oxygen demands of heart muscle during exercise could have precipitated heart attacks in otherwise healthy teenagers:

    - **Point #1**: Heart muscle needs oxygen to survive. And the harder the heart works, the more oxygen it requires. The American Heart Association says this about heart attacks:
    - "Your **heart muscle needs oxygen to survive.** A heart attack occurs when the blood flow that brings **oxygen to the heart muscle is severely reduced** or cut

off completely."[R]

- **Point #2**: Masks block air intake and decrease arterial oxygen.

Studies of masked individuals have shown that mask wear decreases arterial oxygen. For example, the effects of surgical masks worn by surgeons in the operating room (an environment in which the oxygen blocking effects of masks are minimized by the high air flow, increased oxygen levels, and cool temperature of the operating suite) during major surgery showed a significant decrease in arterial oxygen.[R]

The lesson here is that medical masks should not be worn during intense exercise. As described above and shown in the study of surgeons wearing surgical masks, medical masks block oxygen intake. Depriving the heart of oxygen while exercising, especially intense exercise, could precipitate an acute heart attack.

Any questions? Wait...there's more...

- Jogger's lung collapses after he ran for 2.5 miles while wearing a face mask [R]

  Mr Zhang's left lung was punctured due to high pressure caused by running. The 26-year-old became breathless whiling jogging with a mask on in China. Doctors said his punctured lung was caused by jogging with a face covering. He is now in stable condition after undergoing an operation, the hospital said.

- Hypoxia increases the risk of blood clot formation.[R]
- Lowering arterial oxygen suppresses the immune system, thus increasing the susceptibility of mask wearers to infectious disease.

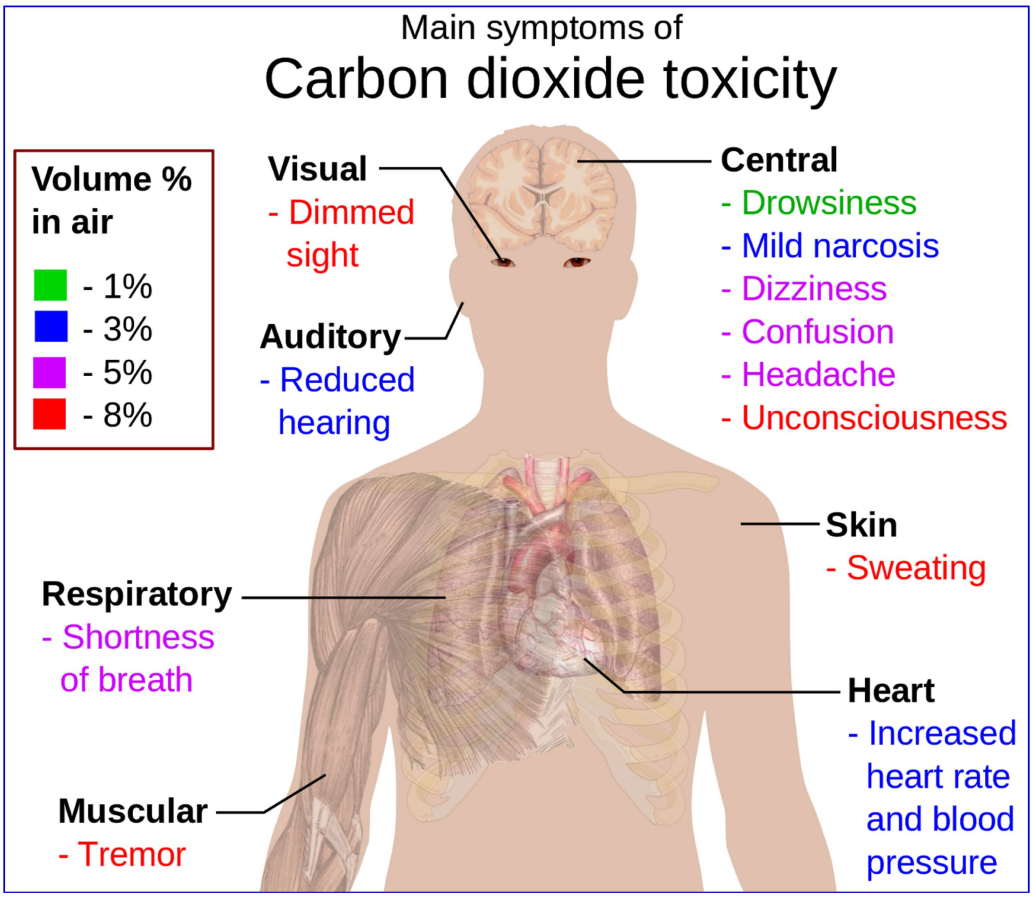
3. Medical masks raise carbon dioxide levels in the blood.

Although the body has robust mechanisms for mitigating transient and minor elevations of CO2 in the air we breathe, these mechanisms can easily be overwhelmed by chronic exposure to significant elevations in CO2, such as occurs with prolonged wearing of a medical mask.

- The science clearly demonstrates that **face masks cause carbon dioxide rebreathing and hypercapnia** [R]

  - Fletcher, S. J., M. Clark, and P. J. Stanley. 2006. "Carbon Dioxide Re-Breathing with Close Fitting Face Respirator Masks." Anaesthesia 61 (9): 910. https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2044.2006.04767.x

- Exhaled air is rich in carbon dioxide, a waste product of cellular respiration.
- A portion of carbon dioxide previously exhaled is inspired (breathed) at each respiratory cycle.
- **Masks trap CO2 rich respiratory exhalations at the mask-mouth interface, force re-breathing of CO2 rich exhalations, raise carbon dioxide blood (CO2) levels.** [R]



- Objective evidence demonstrating how masks increase blood carbon dioxide levels and negatively impact health and function.
    - **Transcranial Ultrasound Doppler (TCUD)** is a noninvasive means of assessing blood flow in the cerebral vasculature. The increase in carbon dioxide partial pressures (PCO2) caused by medical masks can be assessed by TCUD.[R]
    - Elevation of PCO2 causes vasodilation of the arteriolar channels leading to a decrease in peripheral vascular resistance. The decrease in peripheral vascular resistance is responsible for the changes in cerebrovascular circulation time, CBF, and the velocity of flow (V) in cerebral arteries.
    - Medical masks force the wearer to inspire (re-breathe) air that is a mix of air from the local environment and the respiratory waste products from the mask

wearer's previous exhalations.

- Respiratory exhalations contain significantly higher levels of carbon dioxide (CO2), one of the waste products of respiration.
- The pulmonary system is designed to collect oxygen and remove CO2 from the body. Masks trap CO2 rich exhalations at the mask-mouth interface.
- Changes in arterial PCO2 considerably influence cranial blood flow (CBF).[R]

- Transcranial Ultrasound Doppler (TCUD) studies on masked and unmasked individuals demonstrate the changes in blood flow in the brain the result from the arterial CO2 elevation that occurs within seconds of donning a mask.

  This video demonstrates the use of TCUD and heart rate variability to measure the adverse effects of masking a healthy nine year old child: https://bit.ly/2GGQWiZ

4. SARS CoV-2 is armed with a "furin cleavage site" that makes it more pathogenic.

- The furin cleavage site makes the virus more capable of invading human cells.
- The furin cleavage site makes the virus even more capable of invading cells when arterial oxygen levels decline.[R]
- Therefore, wearing a medical mask may increase the severity of CoVID-19.

5. Medical masks trap exhaled viral (and other) pathogens in the mouth/mask interspace, increase viral/infectious load, and increase the severity of disease.

- Face masks trap exhaled viral particles in the mouth/mask interspace. The trapped viral particles are prevented from removal from the airways. The mask wearer is then forced to re-breathe the viral particles, thus increasing infectious viral particles in the airways and lungs.
- In this way, surgical masks cause self-inoculation, increase viral load, and increase the severity of disease.

- Neurosurgeon, Russell Blaylock, MD, raises additional concerns:

  "By wearing a mask, the exhaled viruses will not be able to escape and will concentrate in the nasal passages, enter the lungs, olfactory nerves, and travel into the brain."[R]

- Face masks **trap exhaled viral particles** in the mouth/mask interspace.[R] The trapped viral particles are prevented from removal from the airways. The mask wearer is thus forced to **re-breathe** the viral particles, increasing infectious viral particles in the airways and lungs. In this way, Medical masks cause self-inoculation, increase viral load, and increase the severity of disease.

- Asymptomatic or mild cases of CoVID-19 become more severe when the infected is masked, oxygen lowers, viral load increases from particle re-breathing, and the disease **overwhelms the innate immune system.**

    - The main purpose of the innate immune response is to immediately prevent the spread and movement of foreign pathogens throughout the body.[R]
    - The innate immune system plays a crucial role in destroying the virus, preventing infection, or decreasing the viral load to decrease the severity of infection.
    - The innate immunity's effectiveness is highly dependent on the viral load. If face masks increase viral particle re-breathing at the same time they create a humid habitat where SARS-CoV-2 remains actively infectious, the mask increases the viral load and can overwhelm the innate immune system.
- This trapping, re-breathing, and increasing pathogen load delivered to the lungs becomes dramatically more dangerous when the medical mask becomes contaminated with the opportunistic viruses, bacteria, and fungi that can grow in the warm, moist environment of the mask.
- "By wearing a mask, the exhaled viruses will not be able to escape and will concentrate in the nasal passages, enter the olfactory nerves and travel into the brain." - Russell Blaylock, MD

6. SARS CoV-2 Becomes More Dangerous When Blood Oxygen Levels Decline

- Arterial oxygen desaturation is a critical issue in CoVID-19. The virus' ability to infect cells is markedly enhanced by oxygen desaturation, which has been shown to occur even in the ideal operating room environment in which surgeons operate: high air flow/exchange systems, cool temperature, and higher room oxygen levels. when wearing a surgical mask.[R]
- One of the features that make SARS CoV-2 uniquely infectious is the "furin" sequence in the virus that activates increased ACE2 receptor attack and cellular invasion in low oxygen environments.[R]

7. The furin cleavage site of SARS CoV-2 increases cellular invasion, especially during hypoxia (low blood oxygen levels)[R]

- The furin cleavage site found in SARS CoV-2 is the likely result of the bioengineering "gain of function" (which means increasing the virulence of a pathogen) research conducted at the Wuhan Institute of Virology. This unethical, dangerous, and illegal-in-most-countries research is alleged to have been funded by Dr. Anthony Fauci (with $7.4 million taxpayer dollars) and Bill Gates.
- Furin cleavage sites are found in some of the most pathogenic forms of influenza, which can be acted upon by furin and other cellular proteases. The ubiquitous expression of cellular proteases across cell types increases the potential for the virus to successfully infiltrate the host.
- Furin is a membrane-bound protease that is expressed in multiple tissues throughout the human body. Furin is expressed in significant concentrations in the lungs. Thus, viruses in the respiratory tract can make use of this enzyme to convert and activate their own surface glycoproteins. This makes their role in viral protein processing noteworthy.[R]
- Some of the most pathogenic forms of influenza and HIV have similar furin cleavage sites. It is not present in other bat beta coronaviruses. (By the way, Fauci built his career researching and failing to create a vaccine for HIV). The furin cleavage site is NOT present in SARS CoV-1 or MERS, or any of the other known "bat coronaviruses."
- Let me say it again, the SARS-CoV (aka, SARS-CoV-1), which is closely related to the newest SARS-CoV-2 strain, does not bear the furin cleavage site.

So, the question we should all be asking is how did the genetic sequence that codes for this serious gain of function that increases the potential for the virus to successfully infiltrate the host find its way into SARS-CoV-2?

That's the trillion dollar question; it demands a real and honest answer.

8. Cloth masks may increase the risk of contracting Covid-19 and other respiratory infections.

See MacIntyre CR, Seale H, Dung TC, et al., A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, BMJ Open 2015; 5: e006577, US National Library of Medicine, National Institutes of Health, doi: 10.1136/bmjopen-2014-006577, April 22, 2015.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/pdf/bmjopen-2014-006577.pdf

- "This study is the first [Randomly Controlled Trial] of cloth masks, and the results caution against the use of cloth masks.
- This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection."

9. Wearing a face mask may give a false sense of security

- People adopt a reduction in compliance with other infection control measures, including social distancing and hands washing.[R]

10. Masks compromise communications and reduce social distancing

- The quality and volume of speech between two people wearing masks is considerably compromised and they may unconsciously move closer to improve communications
- This increases the likelihood of becoming exposed to the infectious viral particles in the respiratory plumes of aerosolized droplet nuclei that escape the top, bottom, and sides of the masks.

11. Untrained and inappropriate management of face masks:

- The public is untrained and inadequately educated in the proper selection of masks (most are wrongly wearing cloth masks), proper wear, sterility management, and importance of not reusing single use masks.
- People must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose of them correctly and adopt other management measures, otherwise their risks and those of others may increase.[R][R]
- We can all observe the countless ways in which people in communities are mis-wearing, mishandling, and increasing their own and the communities risk of contracting infectious disease, including CoVID-19.

12. Masks Worn Imperfectly Are Dangerous

To fully appreciate the danger of improper wear and handling of face masks, all you have to do is observe how the public is managing them. Take a trip to Walmart or your local school and observe how mask wearers pull masks from their pocket or purse, drop the masks on the floor, cough and sneeze in them, move them below the nose, on their heads, or under their chin. I see it every day. I also see their soiled and stained surgical face masks and know that these people are dangerously reusing a mask that should never be reused.

You don't need a clinical trial to determine that even when mask-wearers manage to don a fresh, sterile mask properly, keep them on for more than a few minutes at a time, they very quickly contaminate the mask, their environment, and increase their risk of infection as the mask induces them to compulsively touch their faces and their masks.

- The World Health Organization, which has repeatedly changed its position on universal masking, is adamant that **if face masks are not worn carefully, correctly, and kept sanitary, they are worse than ineffective.**

- In other words, masks worn imperfectly are dangerous.

    - See Linda Lacina, WHO updates guidance on masks for health workers and the public - here's what you need to know, World Economic Forum (June 5, 2020). https://www.weforum.org/agenda/2020/06/who-updates-guidance-on-masks-heres-what-to-know-now/

    People can infect themselves if they use contaminated hands to adjust a mask or repeatedly take it on or off," explained WHO Director-General, Dr Tedros Adhanom Ghebreyesus. "I cannot say this clearly enough. Masks alone will not protect you from COVID-19."

Failing to follow strict medical standards for wearing protective equipment and specification of sterilizing and cleaning often leads to "skin and mucous membrane injury, which may cause acute and chronic dermatitis, secondary infection and aggravation of underlying skin diseases."

- Yan, et al., Consensus of Chinese Experts on Protection of Skin and Mucous Membrane Barrier for Health-Care Workers Fighting against Coronavirus Disease 2019. Dermatologic Therapy, March 2020, e13310. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7228211/pdf/DTH-9999-e13310.pd

13. Masks collect and colonize viruses, bacteria, and mold.

In Germany, where schools are open and masks are mostly optional, the association of "Kinder f.Weltfrieden eV" commissioned a laboratory analysis to investigate the level of microbial contamination that results after a fresh mask is worn by a child for 6-8 hours in school. What they found was alarming to all those recommending we mask our children for several hours every day. The masks were found to be contaminated with **82 bacterial colonies and 4 mold colonies**. Where do you think the bacteria, molds, and viruses progressively colonizing and growing on the warm moist mask-mouth interface end up?

Many of the microbes get transferred to surfaces the child (or adult) touches after they touch, fiddle, and mishandle their mask. This is one of the many reasons that masks are almost certainly INCREASING the transmission of infectious disease. More dangerously, these microbes are being inhaled and delivered deep into the lungs where respiratory disease far worse than CoVID-19 can result.

The oxygen lowering effects of masks forces the body to compensate by increasing heart rate and deepening inspirations (increasing tidal volumes). Increased tidal volumes drives the mask pathogens deep into the lungs where they can cause serious pneumonia, inflammation, and tissue damage.

Furthermore, these risks are compounded by the immune suppression (CD4+ T-cell suppression) that results from diminished arterial oxygenation. **Thus, the mask-wearing child is at imminent risk for harm caused by lung infections that are far more dangerous than a CoVID-19 infection.**

In fact, based on reports from my colleagues in emergency medicine, pulmonology, and infectious disease, an **alarming explosion in bacterial pneumonias** is being reported at ERs and urgent care centers across the country.

Evidence that supports the points above:

- Zhiqing, Liu, Chang Yongyun, Chu Wenxiang, Yan Mengning, Mao Yuanqing, Zhu Zhenan, Wu Haishan, et al. 2018. “Surgical Masks as Source of Bacterial Contamination during Operative Procedures.” Journal of Orthopaedic Translation 14 (July): 57-62.
    - This study investigated whether surgical masks (SMs) could be a potential source of bacterial shedding leading to an increased risk of surgical site infection.
    - Results: **The longer the operating time the more bacterial colonization occurred.** A significant increase [in bacterial counts] was noted in the 2-hour group.
- Colleen Huber, NMD, “Masks Are Neither Effective nor Safe,” PrimaryDoctor.Org, July 6, 2020. https://www.primarydoctor.org/masks-not-effect
    - “The foregoing data show that masks serve more as instruments of obstruction of normal breathing, rather than as effective barriers to pathogens. Therefore, masks should not be used by the general public, either by adults or children, and their limitations as prophylaxis against pathogens should also be considered in medical settings.”

- Dr. Huber's article cites 42 supporting scientific studies.

- "Dr. Jenny Harries, England's deputy chief medical officer, has warned that it was not a good idea for the public to wear face masks as **the virus can get trapped in the material and causes infection when the wearer breathes in."**

  - Angela Betsaida B. Laguipo, BSN, "Reusing Masks May Increase Your Risk of Coronavirus Infection, Expert Says," News, Medical, Life Sciences, March 15, 2020. https://www.news-medical.net/news/20200315/Reusing-masks-may-increase-your-risk-of-coronavirus-infection-expert-says.aspx
- See also, Melkorka Licea, "Mask Mouth" Is a Seriously Stinky Side Effect of Wearing Masks. New York Post, August 5, 2020. https://nypost.com/2020/08/05/mask-mouth-is-a-seriously-stinky-side-effect-of-wearing-masks/
- Consider this: Health department investigating after high number of strep throat cases reported at Shepherd schools.

  The Central Michigan District Health Department is investigating after more than **a dozen cases of strep throat** were reported within Shepherd Public Schools **despite COVID-19 protocols**.

14. Wearing a face mask makes the exhaled air (respiratory plumes) go into the eyes.

- Masks may capture respiratory jets and large respiratory droplets, but they cannot prevent the respiratory plumes composed of aerosolizable respiratory droplet nuclei to escape the top, bottom, and sides of the masks.
- The respiratory plume wafts into the eyes and generates an uncomfortable feeling and compulsion to touch and rub the eyes. If your hands are contaminated and you touch or rub your eyes, you are transmitting and infecting yourself through the ocular mucosa.[R]

15. Contact tracing studies show that asymptomatic carrier transmission is very rare.

- Asymptomatic carriers are not a major driver of the disease.[R]
- Therefore, one of the key reasons the public was told to wear masks, asymptomatic spreaders, should not be used as a reason for community wearing of masks.

16. Face masks and stay at home orders prevent the development of herd immunity.

- Only herd immunity can prevent pandemics; it is the only thing that ever has.
- Only herd immunity will protect the vulnerable members of society.
- Sweden's example continues to prove this point.

17. Face masks are dangerous and contraindicated for a large number of people with pre-existing medical conditions and disabilities.

- Large percentages of the population have medical conditions that make wearing a mask dangerous. Individuals should be examined by a medical professional to ensure that mask wear will not further compromise their medical condition.
    - Children with asthma (7.5% of American children) and other respiratory disabilities are being harmed by mask mandates, they are being discriminated against by businesses, schools, and public spaces that require masks.
    - Children with autism and other neurodevelopmental disorders are extremely prone to agitation and severe anxiety that results from the adverse effects, e.g., oxygen lowering effects, of masks.
    - An ever increasing number of children and young adults with autism are sensitive to touch and texture.[R] Covering the nose and mouth with fabric can cause sensory overload, feelings of panic, and extreme anxiety.
- If a person with a disability is not able to wear a face mask, state and local government agencies and private businesses must consider reasonable modifications to a face mask policy so that the person with the disability can participate in, or benefit from, the programs offered or goods and services that are provided. A reasonable modification means changing policies, practices, and procedures, if needed, to provide goods, services, facilities, privileges, advantages, or accommodations to an individual with a disability.
- Examples of a person with a disability who might not be able to wear a face mask include individuals with asthma, chronic obstructive pulmonary disease (COPD), or other respiratory disabilities may not be able to wear a face mask because of difficulty in or impaired breathing. People with respiratory disabilities should consult their own medical professional for advice about using face masks.
- **The CDC also states that anyone who has trouble breathing should not wear a face mask.[R]**
- People with post-traumatic stress disorder (PTSD), severe anxiety, or claustrophobia (an abnormal fear of being in enclosed or narrow places), may feel afraid or terrified when wearing a face mask. These individuals may not be able to stay calm or function when wearing a face mask.
- A person who has cerebral palsy may have difficulty moving the small muscles in the hands, wrists, or fingers. Due to their limited mobility, they may not be able to

tie the strings or put the elastic loops of a face mask over the ears. This means that the individual may not be able to put on or remove a face mask without assistance.

- A person who uses mouth control devices such as a sip and puff to operate a wheelchair or assistive technology, or uses their mouth or tongue to use assistive ventilators will be unable to wear a mask.

back to Pandemic Parallax View | rat haus | Index | Search | tree

More than 170 Comparative Studies and Articles on Mask Ineffectiveness and Harms

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December 20, 2021

It is not unreasonable to conclude that surgical and cloth masks, used as they currently are being used (without other forms of PPE protection), have no impact on controlling the transmission of Covid-19 virus. Current evidence implies that face masks can be actually harmful. The body of evidence indicates that face masks are largely ineffective.

My focus is on COVID face masks and the prevailing science that we have had for nearly 20 months. Yet I wish to address this mask topic at a 50,000-foot level on the lockdown restrictive policies in general. I build on the backs of the fine work done by Gupta, Kulldorff, and Bhattacharya on the Great Barrington Declaration (GBD) and similar impetus by Dr. Scott Atlas (advisor to POTUS Trump) who, like myself, was a strong proponent for a focused type of protection that was based on an age-risk stratified approach.

Because we saw very early on that the lockdowns were the single greatest mistake in public health history. We knew the history and knew they would not work. We also knew very early of COVID's risk stratification. Sadly, our children will bear the catastrophic consequences and not just educationally, of the deeply flawed school closure policy for decades to come (particularly our minority children who were least able to afford this). Many are still pressured to wear masks and punished for not doing so.

I present the masking 'body of evidence' below (n=167 studies and pieces of evidence), comprised of comparative effectiveness research as well as related evidence and high-level reporting. To date, the evidence has been stable and clear that masks do not work to control the virus and they can be harmful and especially to children.

Table 1: The evidence on COVID-19 face masks and mask mandates and harms

MASK-INEFFECTIVENESS

1) Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers, Bundgaard, 2021	"Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point (95% CI, −1.2 to 0.4 percentage point; P = 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P = 0.33). Multiple imputation accounting for loss to follow-up yielded similar results…the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use."
2) SARS-CoV-2 Transmission among Marine Recruits during Quarantine, Letizia, 2020	"Our study showed that in a group of predominantly young male military recruits, approximately 2% became positive for SARS-CoV-2, as determined by qPCR assay, during a 2-week, strictly enforced quarantine. Multiple, independent virus strain transmission clusters were identified…all recruits wore double-layered cloth masks at all times indoors and outdoors."
3) Physical interventions to interrupt or reduce the spread of respiratory viruses, Jefferson, 2020	"There is low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18. There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants)…the pooled results of randomised trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."
4) The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh, Abaluck, 2021 Heneghan et al.	A cluster-randomized trial of community-level mask promotion in rural Bangladesh from November 2020 to April 2021 (N=600 villages, N=342,126 adults. Heneghan writes: "In a Bangladesh study, surgical masks reduced symptomatic COVID infections by between 0 and 22 percent, while the efficacy of cloth masks led to somewhere between an 11 percent increase to a 21 percent decrease. Hence, based on these randomized studies, adult masks appear to have either no or limited efficacy."

5) Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review, Liu/CATO, 2021	“The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle.”
6) Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures, CDC/Xiao, 2020	“Evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza…none of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group…the overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies.”
7) CIDRAP: Masks-for-all for COVID-19 not based on sound data, Brosseau, 2020	“We agree that the data supporting the effectiveness of a cloth mask or face covering are very limited. We do, however, have data from laboratory studies that indicate cloth masks or face coverings offer very low filter collection efficiency for the smaller inhalable particles we believe are largely responsible for transmission, particularly from pre- or asymptomatic individuals who are not coughing or sneezing…though we support mask wearing by the general public, we continue to conclude that cloth masks and face coverings are likely to have limited impact on lowering COVID-19 transmission, because they have minimal ability to prevent the emission of small particles, offer limited personal protection with respect to small particle inhalation, and should not be recommended as a replacement for physical distancing or reducing time in enclosed spaces with many potentially infectious people.”

8) Universal Masking in Hospitals in the Covid-19 Era, Klompas/NEJM, 2020	"We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic…The calculus may be different, however, in health care settings. First and foremost, a mask is a core component of the personal protective equipment (PPE) clinicians need when caring for symptomatic patients with respiratory viral infections, in conjunction with gown, gloves, and eye protection… universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."
9) Masks for prevention of viral respiratory infections among health care workers and the public: PEER umbrella systematic review, Dugré, 2020	"This systematic review found limited evidence that the use of masks might reduce the risk of viral respiratory infections. In the community setting, a possible reduced risk of influenza-like illness was found among mask users. In health care workers, the results show no difference between N95 masks and surgical masks on the risk of confirmed influenza or other confirmed viral respiratory infections, although possible benefits from N95 masks were found for preventing influenza-like illness or other clinical respiratory infections. Surgical masks might be superior to cloth masks but data are limited to 1 trial."
10) Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis, Saunders-Hastings, 2017	"Facemask use provided a non-significant protective effect (OR = 0.53; 95% CI 0.16–1.71; I^2 = 48%) against 2009 pandemic influenza infection."
11) Experimental investigation of indoor aerosol dispersion and accumulation in the context of COVID-19: Effects of masks and ventilation, Shah, 2021	"Nevertheless, high-efficiency masks, such as the KN95, still offer substantially higher apparent filtration efficiencies (60% and 46% for R95 and KN95 masks, respectively) than the more commonly used cloth (10%) and surgical masks (12%), and therefore are still the recommended choice in mitigating airborne disease transmission indoors."

12) Exercise with facemask; Are we handling a devil's sword?- A physiological hypothesis, Chandrasekaran, 2020	"Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus."
13) Surgical face masks in modern operating rooms–a costly and unnecessary ritual?, Mitchell, 1991	"Following the commissioning of a new suite of operating rooms air movement studies showed a flow of air away from the operating table towards the periphery of the room. Oral microbial flora dispersed by unmasked male and female volunteers standing one metre from the table failed to contaminate exposed settle plates placed on the table. The wearing of face masks by non-scrubbed staff working in an operating room with forced ventilation seems to be unnecessary."
14) Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial, Alfelali, 2020	"By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections (odds ratio [OR], 1.4; 95% confidence interval [CI], 0.9 to 2.1, p = 0.18) nor against clinical respiratory infection (OR, 1.1; 95% CI, 0.9 to 1.4, p = 0.40)."
15) Simple respiratory protection–evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles, Rengasamy, 2010	"Results obtained in the study show that common fabric materials may provide marginal protection against nanoparticles including those in the size ranges of virus-containing particles in exhaled breath."
16) Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range, Lee, 2008	"The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses. An exhalation valve on the N95 respirator does not affect the respiratory protection; it appears to be an appropriate alternative to reduce the breathing resistance."
17) Aerosol penetration and leakage characteristics of masks used in the health care industry, Weber, 1993	"We conclude that the protection provided by surgical masks may be insufficient in environments containing potentially hazardous sub-micrometer-sized aerosols."
18) Disposable surgical face masks for preventing surgical wound infection in clean surgery, Vincent, 2016	"We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials…from the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery."
19) Disposable surgical face masks: a systematic review, Lipp, 2005	"From the limited results it is unclear whether wearing surgical face masks results in any harm or benefit to the patient undergoing clean surgery."

20) Comparison of the Filter Efficiency of Medical Nonwoven Fabrics against Three Different Microbe Aerosols, Shimasaki, 2018	“We conclude that the filter efficiency test using the phi-X174 phage aerosol may overestimate the protective performance of nonwoven fabrics with filter structure compared to that against real pathogens such as the influenza virus.”
21) The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence21) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2012	The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence“None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.”
22) Facial protection for healthcare workers during pandemics: a scoping review, Godoy, 2020	“Compared with surgical masks, N95 respirators perform better in laboratory testing, may provide superior protection in inpatient settings and perform equivalently in outpatient settings. Surgical mask and N95 respirator conservation strategies include extended use, reuse or decontamination, but these strategies may result in inferior protection. Limited evidence suggests that reused and improvised masks should be used when medical-grade protection is unavailable.”
23) Assessment of Proficiency of N95 Mask Donning Among the General Public in Singapore, Yeung, 2020	“These findings support ongoing recommendations against the use of N95 masks by the general public during the COVID-19 pandemic.[5] N95 mask use by the general public may not translate into effective protection but instead provide false reassurance. Beyond N95 masks, proficiency among the general public in donning surgical masks needs to be assessed.”
24) Evaluating the efficacy of cloth facemasks in reducing particulate matter exposure, Shakya, 2017	“Standard N95 mask performance was used as a control to compare the results with cloth masks, and our results suggest that cloth masks are only marginally beneficial in protecting individuals from particles<2.5 μm.”
25) Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial, Jacobs, 2009	“Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds.”
26) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	“Among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza.”
27) Does Universal Mask Wearing Decrease or Increase the Spread of COVID-19?, Watts up with that? 2020	“A survey of peer-reviewed studies shows that universal mask wearing (as opposed to wearing masks in specific settings) does not decrease the transmission of respiratory viruses from people wearing masks to people who are not wearing masks.”

28) Masking: A Careful Review of the Evidence, Alexander, 2021	“In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, have absolutely no impact on controlling the transmission of Covid-19 virus, and current evidence implies that face masks can be actually harmful.”
29) Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020, Fisher, 2020	Reported characteristics of symptomatic adults ≥18 years who were outpatients in 11 US academic health care facilities and who received positive and negative SARS-CoV-2 test results (N = 314)* — United States, July 1–29, 2020, revealed that 80% of infected persons wore face masks almost all or most of the time.
30) Impact of non-pharmaceutical interventions against COVID-19 in Europe: a quasi-experimental study, Hunter, 2020	Face masks in public was not associated with reduced incidence.
31) Masking lack of evidence with politics, CEBM, Heneghan, 2020	“It would appear that despite two decades of pandemic preparedness, there is considerable uncertainty as to the value of wearing masks. For instance, high rates of infection with cloth masks could be due to harms caused by cloth masks, or benefits of medical masks. The numerous systematic reviews that have been recently published all include the same evidence base so unsurprisingly broadly reach the same conclusions.”
32) Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study, Marks, 2021	“We observed no association of risk of transmission with reported mask usage by contacts, with the age or sex of the index case, or with the presence of respiratory symptoms in the index case at the initial study visit.”
33) Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza, WHO, 2020	“Ten RCTs were included in the meta-analysis, and there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza.”
34) The Strangely Unscientific Masking of America, Younes, 2020	“One report reached its conclusion based on observations of a “dummy head attached to a breathing simulator.” Another analyzed use of surgical masks on people experiencing at least two symptoms of acute respiratory illness. Incidentally, not one of these studies involved cloth masks or accounted for real-world mask usage (or misusage) among lay people, and none established efficacy of widespread mask-wearing by people not exhibiting symptoms. There was simply no evidence whatsoever that healthy people ought to wear masks when going about their lives, especially outdoors.”

35) Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review, Brainard, 2020	“31 eligible studies (including 12 RCTs). Narrative synthesis and random-effects meta-analysis of attack rates for primary and secondary prevention in 28 studies were performed. Based on the RCTs we would conclude that wearing facemasks can be very slightly protective against primary infection from casual community contact, and modestly protective against household infections when both infected and uninfected members wear facemasks. However, the RCTs often suffered from poor compliance and controls using facemasks.”
36) The Year of Disguises, Koops, 2020	“The healthy people in our society should not be punished for being healthy, which is exactly what lockdowns, distancing, mask mandates, etc. do…Children should not be wearing face coverings. We all need constant interaction with our environments and that is especially true for children. This is how their immune system develops. They are the lowest of the low-risk groups. Let them be kids and let them develop their immune systems… The “Mask Mandate” idea is a truly ridiculous, knee-jerk reaction and needs to be withdrawn and thrown in the waste bin of disastrous policy, along with lockdowns and school closures. You can vote for a person without blindly supporting all of their proposals!”
37) Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden, Ludvigsson, 2020	“1,951,905 children in Sweden (as of December 31, 2019) who were 1 to 16 years of age, were examined…social distancing was encouraged in Sweden, but wearing face masks was not…No child with Covid-19 died.”
38) Double-Masking Benefits Are Limited, Japan Supercomputer Finds, Reidy, 2021	“Wearing two masks offers limited benefits in preventing the spread of droplets that could carry the coronavirus compared to one well-fitted disposable mask, according to a Japanese study that modeled the dispersal of droplets on a supercomputer.”
39) Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 – Face masks, eye protection and person distancing: systematic review and meta-analysis, Jefferson, 2020	“There was insufficient evidence to provide a recommendation on the use of facial barriers without other measures. We found insufficient evidence for a difference between surgical masks and N95 respirators and limited evidence to support effectiveness of quarantine.”
40) Should individuals in the community without respiratory symptoms wear facemasks to reduce the spread of COVID-19?, NIPH, 2020	“Non-medical facemasks include a variety of products. There is no reliable evidence of the effectiveness of non-medical facemasks in community settings. There is likely to be substantial variation in effectiveness between products. However, there is only limited evidence from laboratory studies of potential differences in effectiveness when different products are used in the community.”
41) Is a mask necessary in the operating theatre?, Orr, 1981	“It would appear that minimum contamination can best be achieved by not wearing a mask at all but operating in silence. Whatever its relation to contamination, bacterial counts, or the dissemination of squames, there is no direct evidence that the wearing of masks reduces wound infection.”

42) The surgical mask is a bad fit for risk reduction, Neilson, 2016	“As recently as 2010, the US National Academy of Sciences declared that, in the community setting, “face masks are not designed or certified to protect the wearer from exposure to respiratory hazards.” A number of studies have shown the inefficacy of the surgical mask in household settings to prevent transmission of the influenza virus.”
43) Facemask versus No Facemask in Preventing Viral Respiratory Infections During Hajj: A Cluster Randomised Open Label Trial, Alfelali, 2019	“Facemask use does not prevent clinical or laboratory-confirmed viral respiratory infections among Hajj pilgrims.”
44) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	“The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression.”
45) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2011	“None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.”
46) Are Face Masks Effective? The Evidence., Swiss Policy Research, 2021	“Most studies found little to no evidence for the effectiveness of face masks in the general population, neither as personal protective equipment nor as a source control.”
47) Postoperative wound infections and surgical face masks: A controlled study, Tunevall, 1991	“These results indicate that the use of face masks might be reconsidered. Masks may be used to protect the operating team from drops of infected blood and from airborne infections, but have not been proven to protect the patient operated by a healthy operating team.”
48) Mask mandate and use efficacy in state-level COVID-19 containment, Guerra, 2021	“Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID-19 growth surges.”

49) Twenty Reasons Mandatory Face Masks are Unsafe, Ineffective and Immoral, Manley, 2021	"A CDC-funded review on masking in May 2020 came to the conclusion: "Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza… None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group." If masks can't stop the regular flu, how can they stop SAR-CoV-2?"
50) A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, MacIntyre, 2015	"First RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection…the rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%."
51) Horowitz: Data from India continues to blow up the 'Delta' fear narrative, Blazemedia, 2021	"Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the "Delta" variant — continues to refute every current premise of COVID fascism…Masks failed to stop the spread there."
52) An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021, Hetemäki, 2021	Reporting on a nosocomial hospital outbreak in Finland, Hetemäli et al. observed that "both symptomatic and asymptomatic infections were found among vaccinated health care workers, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment."
53) Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021, Shitrit, 2021	In a hospital outbreak investigation in Israel, Shitrit et al. observed "high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals." They added that "this suggests some waning of immunity, albeit still providing protection for individuals without comorbidities." Again, despite use of personal protective equipment.
54) 47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects, Lifesite news staff, 2021	"No studies were needed to justify this practice since most understood viruses were far too small to be stopped by the wearing of most masks, other than sophisticated ones designed for that task and which were too costly and complicated for the general public to properly wear and keep changing or cleaning. It was also understood that long mask wearing was unhealthy for wearers for common sense and basic science reasons."

55) Are EUA Face Masks Effective in Slowing the Spread of a Viral Infection?, Dopp, 2021	The vast evidence shows that masks are ineffective.
56) CDC Study finds overwhelming majority of people getting coronavirus wore masks, Boyd/Federalist, 2021	“A Centers for Disease Control report released in September shows that masks and face coverings are not effective in preventing the spread of COVID-19, even for those people who consistently wear them.”
57) Most Mask Studies Are Garbage, Eugyppius, 2021	“The other kind of study, the proper kind, would be a randomised controlled trial. You compare the rates of infection in a masked cohort against rates of infection in an unmasked cohort. Here things have gone much, much worse for mask brigade. They spent months trying to prevent the publication of the Danish randomised controlled trial, which found that masks do zero. When that paper finally squeaked into print, they spent more months trying desperately to poke holes in it. You could feel their boundless relief when the Bangladesh study finally appeared to save them in early September. Every last Twitter blue-check could now proclaim that Science Shows Masks Work. Such was their hunger for any scrap of evidence to prop up their prior convictions, that none of them noticed the sad nature of the Science in question. The study found a mere 10% reduction in seroprevalence among the masked cohort, an effect so small that it fell within the confidence interval. Even the study authors couldn’t exclude the possibility that masks in fact do zero.”
58) Using face masks in the community: first update, ECDC, 2021	“No high-quality evidence in favor of face masks and recommended their use only based on the ‘precautionary principle.”
59) Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?, Cochrane, 2020	“Seven studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask, wearing a mask may make little to no difference in how many people caught a flu-like illness (9 studies; 3507 people); and probably makes no difference in how many people have flu confirmed by a laboratory test (6 studies; 3005 people). Unwanted effects were rarely reported, but included discomfort.”

60) Mouth-nose protection in public: No evidence of effectiveness, Thieme/ Kappstein, 2020	“The use of masks in public spaces is questionable simply because of the lack of scientific data. If one also considers the necessary precautions, masks must even be considered a risk of infection in public spaces according to the rules known from hospitals… If masks are worn by the population, the risk of infection is potentially increased, regardless of whether they are medical masks or whether they are so-called community masks designed in any way. If one considers the precautionary measures that the RKI as well as the international health authorities have pronounced, all authorities would even have to inform the population that masks should not be worn in public spaces at all. Because no matter whether it is a duty for all citizens or voluntarily borne by the citizens who want it for whatever reason, it remains a fact that masks can do more harm than good in public.”
61) US mask guidance for kids is the strictest across the world, Skelding, 2021	“Kids need to see faces,” Jay Bhattacharya, a professor of medicine at Stanford University, told The Post. Youngsters watch people’s mouths to learn to speak, read and understand emotions, he said.“We have this idea that this disease is so bad that we must adopt any means necessary to stop it from spreading,” he said. “It’s not that masks in schools have no costs. They actually do have substantial costs.”
62) Masking young children in school harms language acquisition, Walsh, 2021	“This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development.”
63) The Case Against Masks for Children, Makary, 2021	“It’s abusive to force kids who struggle with them to sacrifice for the sake of unvaccinated adults… Do masks reduce Covid transmission in children? Believe it or not, we could find only a single retrospective study on the question, and its results were inconclusive. Yet two weeks ago the Centers for Disease Control and Prevention sternly decreed that 56 million U.S. children and adolescents, vaccinated or not, should cover their faces regardless of the prevalence of infection in their community. Authorities in many places took the cue to impose mandates in schools and elsewhere, on the theory that masks can’t do any harm. That isn’t true. Some children are fine wearing a mask, but others struggle. Those who have myopia can have difficulty seeing because the mask fogs their glasses. (This has long been a problem for medical students in the operating room.) Masks can cause severe acne and other skin problems. The discomfort of a mask distracts some children from learning. By increasing airway resistance during exhalation, masks can lead to increased levels of carbon dioxide in the blood. And masks can be vectors for pathogens if they become moist or are used for too long.”

64) Face Covering Mandates, Peavey, 2021	“Face Covering Mandates And Why They AREN’T Effective.”
65) Do masks work? A Review of the evidence, Anderson, 2021	“In truth, the CDC’s, U.K.’s, and WHO’s earlier guidance was much more consistent with the best medical research on masks’ effectiveness in preventing the spread of viruses. That research suggests that Americans’ many months of mask-wearing has likely provided little to no health benefit and might even have been counterproductive in preventing the spread of the novel coronavirus.”
66) Most face masks won’t stop COVID-19 indoors, study warns, Anderer, 2021	“New research reveals that cloth masks filter just 10% of exhaled aerosols, with many people not wearing coverings that fit their face properly.”
67) How face masks and lockdowns failed/the face mask folly in retrospect, Swiss Policy Research, 2021	“Mask mandates and lockdowns have had no discernible impact.”
68) CDC Releases School COVID Transmission Study But Buries One of the Most Damning Parts, Davis, 2021	“The 21% lower incidence in schools that required mask use among students was not statistically significant compared with schools where mask use was optional… With tens of millions of American kids headed back to school in the fall, their parents and political leaders owe it to them to have a clear-sighted, scientifically rigorous discussion about which anti-COVID measures actually work and which might put an extra burden on vulnerable young people without meaningfully or demonstrably slowing the spread of the virus…that a masking requirement of students failed to show independent benefit is a finding of consequence and great interest.”
69) World Health Organization internal meeting, COVID-19 – virtual press conference – 30 March 2020, 2020	“This is a question on Austria. The Austrian Government has a desire to make everyone wear a mask who’s going into the shops. I understood from our previous briefings with you that the general public should not wear masks because they are in short supply. What do you say about the new Austrian measures?… I’m not specifically aware of that measure in Austria. I would assume that it’s aimed at people who potentially have the disease not passing it to others. In general WHO recommends that the wearing of a mask by a member of the public is to prevent that individual giving the disease to somebody else. We don’t generally recommend the wearing to masks in public by otherwise well individuals because it has not been up to now associated with any particular benefit.”
70) Face masks to prevent transmission of influenza virus: a systematic review, Cowling, 2010	“Review highlights the limited evidence base supporting the efficacy or effectiveness of face masks to reduce influenza virus transmission.”“None of the studies reviewed showed a benefit from wearing a mask, in either HCW or community members in households (H).”

71) Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis, Smith, 2016	"Although N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings, our meta-analysis showed that there were insufficient data to determine definitively whether N95 respirators are superior to surgical masks in protecting health care workers against transmissible acute respiratory infections in clinical settings."
72) Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis, Offeddu, 2017	"We found evidence to support universal medical mask use in hospital settings as part of infection control measures to reduce the risk of CRI and ILI among HCWs. Overall, N95 respirators may convey greater protection, but universal use throughout a work shift is likely to be less acceptable due to greater discomfort…Our analysis confirms the effectiveness of medical masks and respirators against SARS. Disposable, cotton, or paper masks are not recommended. The confirmed effectiveness of medical masks is crucially important for lower-resource and emergency settings lacking access to N95 respirators. In such cases, single-use medical masks are preferable to cloth masks, for which there is no evidence of protection and which might facilitate transmission of pathogens when used repeatedly without adequate sterilization…We found no clear benefit of either medical masks or N95 respirators against pH1N1…Overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power."
73) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	"Use of N95 respirators, compared with medical masks, in the outpatient setting resulted in no significant difference in the rates of laboratory-confirmed influenza."
Effectiveness of N95 respirators versus surgical masks againstinfluenza: A systematic review and meta-analysis74) Masks Don't Work: A Review of Science Relevant to COVID-19 Social Policy, Rancourt, 2020	The use of N95 respirators compared with surgical masks is not associated with alower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be rec-ommended for general public and nonhigh-risk medical staff those are not in close contact withinfluenza patients or suspected patients. "No RCT study with verified outcome shows a benefit for HCW or community members in households to wearing a mask or respirator. There is no such study. There are no exceptions. Likewise, no study exists that shows a benefit from a broad policy to wear masks in public (more on this below). Furthermore, if there were any benefit to wearing a mask, because of the blocking power against droplets and aerosol particles, then there should be more benefit from wearing a respirator (N95) compared to a surgical mask, yet several large meta-analyses, and all the RCT, prove that there is no such relative benefit."

75) More Than a Dozen Credible Medical Studies Prove Face Masks Do Not Work Even In Hospitals!, Firstenberg, 2020	“Mandating masks has not kept death rates down anywhere. The 20 U.S. states that have never ordered people to wear face masks indoors and out have dramatically lower COVID-19 death rates than the 30 states that have mandated masks. Most of the no-mask states have COVID-19 death rates below 20 per 100,000 population, and none have a death rate higher than 55. All 13 states that have death rates higher 55 are states that have required the wearing of masks in all public places. It has not protected them.”
76) Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery?, Bahli, 2009	“From the limited randomized trials it is still not clear that whether wearing surgical face masks harms or benefit the patients undergoing elective surgery.”
77) Peritonitis prevention in CAPD: to mask or not?, Figueiredo, 2000	“The current study suggests that routine use of face masks during CAPD bag exchanges may be unnecessary and could be discontinued.”
78) The operating room environment as affected by people and the surgical face mask, Ritter, 1975	“The wearing of a surgical face mask had no effect upon the overall operating room environmental contamination and probably work only to redirect the projectile effect of talking and breathing. People are the major source of environmental contamination in the operating room.”
79) The efficacy of standard surgical face masks: an investigation using “tracer particles, Ha’eri, 1980	“Particle contamination of the wound was demonstrated in all experiments. Since the microspheres were not identified on the exterior of these face masks, they must have escaped around the mask edges and found their way into the wound.”
80) Wearing of caps and masks not necessary during cardiac catheterization, Laslett, 1989	“Prospectively evaluated the experience of 504 patients undergoing percutaneous left heart catheterization, seeking evidence of a relationship between whether caps and/or masks were worn by the operators and the incidence of infection. No infections were found in any patient, regardless of whether a cap or mask was used. Thus, we found no evidence that caps or masks need to be worn during percutaneous cardiac catheterization.”
81) Do anaesthetists need to wear surgical masks in the operating theatre? A literature review with evidence-based recommendations, Skinner, 2001	“A questionnaire-based survey, undertaken by Leyland’ in 1993 to assess attitudes to the use of masks, showed that 20% of surgeons discarded surgical masks for endoscopic work. Less than 50% did not wear the mask as recommended by the Medical Research Council. Equal numbers of surgeons wore the mask in the belief they were protecting themselves and the patient, with 20% of these admitting that tradition was the only reason for wearing them.”

82) Mask mandates for children are not backed by data, Faria, 2021	“Even if you want to use the 2018-19 flu season to avoid overlap with the start of the COVID-19 pandemic, the CDC paints a similar picture: It estimated 480 flu deaths among children during that period, with 46,000 hospitalizations. COVID-19, mercifully, is simply not as deadly for children. According to the American Academy of Pediatrics, preliminary data from 45 states show that between 0.00%-0.03% of child COVID-19 cases resulted in death. When you combine these numbers with the CDC study that found mask mandates for students — along with hybrid models, social distancing, and classroom barriers — did not have a statistically significant benefit in preventing the spread of COVID-19 in schools, the insistence that we force students to jump through these hoops for their own protection makes no sense.”
83) The Downsides of Masking Young Students Are Real, Prasad, 2021	“The benefits of mask requirements in schools might seem self-evident—they have to help contain the coronavirus, right?—but that may not be so. In Spain, masks are used in kids ages 6 and older. The authors of one study there examined the risk of viral spread at all ages. If masks provided a large benefit, then the transmission rate among 5-year-olds would be far higher than the rate among 6-year-olds. The results don’t show that. Instead, they show that transmission rates, which were low among the youngest kids, steadily increased with age—rather than dropping sharply for older children subject to the face-covering requirement. This suggests that masking kids in school does not provide a major benefit and might provide none at all. And yet many officials prefer to double down on masking mandates, as if the fundamental policy were sound and only the people have failed.”
84) Masks In Schools: Scientific American Fumbles Report On Childhood COVID Transmission, English/ACSH, 2021	“Masking is a low-risk, inexpensive intervention. If we want to recommend it as a precautionary measure, especially in situations where vaccination isn’t an option, great. But that’s not what the public has been told. “Florida governor Ron DeSantis and politicians in Texas say research does not support mask mandates,” SciAm’s sub-headline bellowed. “Many studies show they are wrong.”If that’s the case, demonstrate that the intervention works before you mandate its use in schools. If you can’t, acknowledged what UC San Francisco hematologist-oncologist and Associate Professor of Epidemiology Vinay Prasad wrote over at the Atlantic:”No scientific consensus exists about the wisdom of mandatory-masking rules for schoolchildren … In mid-March 2020, few could argue against erring on the side of caution. But nearly 18 months later, we owe it to children and their parents to answer the question properly: Do the benefits of masking kids in school outweigh the downsides? The honest answer in 2021 remains that we don’t know for sure.”

85) Masks ‘don’t work,’ are damaging health and are being used to control population: Doctors panel, Haynes, 2021	“The only randomized control studies that have ever been done on masks show that they don’t work,” began Dr. Nepute. He referred to Dr. Anthony Fauci’s “noble lie,” in which Fauci “changed his tune,” from his March 2020 comments, where he downplayed the need and efficacy of mask wearing, before urging Americans to use masks later in the year. “Well, he lied to us. So if he lied about that, what else has he lied to you about?” questioned Nepute.Masks have become commonplace in almost every setting, whether indoors or outdoors, but Dr. Popper mentioned how there have been “no studies” which actually examine the “effect of wearing a mask during all your waking hours.”“There’s no science to back any of this and particularly no science to back the fact that wearing a mask twenty four-seven or every waking minute, is health promoting,” added Popper.”
86) Aerosol penetration through surgical masks, Chen, 1992	“The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the sub-micrometer-sized aerosols containing pathogens to which these health care workers are potentially exposed.”
87) CDC: Schools With Mask Mandates Didn’t See Statistically Significant Different Rates of COVID Transmission From Schools With Optional Policies, Miltimore, 2021	“The CDC did not include its finding that “required mask use among students was not statistically significant compared with schools where mask use was optional” in the summary of its report.”
88) Horowitz: Data from India continues to blow up the ‘Delta’ fear narrative, Howorwitz, 2021	“Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the “Delta” variant — continues to refute every current premise of COVID fascism…Unless we do that, we must return to the very effective lockdowns and masks. In reality, India’s experience proves the opposite true; namely:1) Delta is largely an attenuated version, with a much lower fatality rate, that for most people is akin to a cold.2) Masks failed to stop the spread there.3) The country has come close to the herd immunity threshold with just 3% vaccinated.
89) Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam, Chau, 2021	While not definitive in the LANCET publication, it can be inferred that the nurses were all masked up and had PPE etc. as was the case in Finland and Israel nosocomial outbreaks, indicating the failure of PPE and masks to constrain Delta spread.

90) Aerosol penetration through surgical masks, Willeke, 1992	“The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the submicrometer-size aerosols containing pathogens to which these health care workers are potentially exposed.”
91) The efficacy of standard surgical face masks: an investigation using “tracer particles”, Wiley, 1980	“Particle contamination of the wound was demonstrated in all aexperiments. Since the microspheres were not identified on the exterior of these face masks, they must have escped around the mask edges and found their way into the wound. The wearing of the mask beneath the headgear curtails this route of contamination.”
92) An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful, Meehan, 2020	“Decades of the highest-level scientific evidence (meta-analyses of multiple randomized controlled trials) overwhelmingly conclude that medical masks are ineffective at preventing the transmission of respiratory viruses, including SAR-CoV-2…those arguing for masks are relying on low-level evidence (observational retrospective trials and mechanistic theories), none of which are powered to counter the evidence, arguments, and risks of mask mandates.”
93) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	“Oral masks in healthy individuals are ineffective against the spread of viral infections.”
94) Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis, Long, 2020	“The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and nonhigh-risk medical staff those are not in close contact with influenza patients or suspected patients.”
95) Advice on the use of masks in the context of COVID-19, WHO, 2020	“However, the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses.”
96) Farce mask: it’s safe for only 20 minutes, The Sydney Morning Herald, 2003	“Health authorities have warned that surgical masks may not be an effective protection against the virus.”Those masks are only effective so long as they are dry,” said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney.”As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets.”Professor Cossart said that could take as little as 15 or 20 minutes, after which the mask would need to be changed. But those warnings haven’t stopped people snapping up the masks, with retailers reporting they are having trouble keeping up with demand.”

97) Study: Wearing A Used Mask Is Potentially Riskier Than No Mask At All, Boyd, 2020 Effects of mask-wearing on the inhalability and deposition of airborne SARS-CoV-2 aerosols in human upper airway	"According to researchers from the University of Massachusetts Lowell and California Baptist University, a three-layer surgical mask is 65 percent efficient in filtering particles in the air. That effectiveness, however, falls to 25 percent once it is used."It is natural to think that wearing a mask, no matter new or old, should always be better than nothing," said author Jinxiang Xi."Our results show that this belief is only true for particles larger than 5 micrometers, but not for fine particles smaller than 2.5 micrometers," he continued."
98) Unravelling the Role of the Mandatory Use of Face Covering Masks for the Control of SARS-CoV-2 in Schools: A Quasi-Experimental Study Nested in a Population-Based Cohort in Catalonia (Spain), Coma, 2022	"A recent study (Catalonia, Spain) done on face masks and their effectiveness was a retrospective population-based study among near 600,000 children aged 3 to 11 years attending preschool (3-5 years, without facial covering mandate) and primary education (6-11 years, with facial covering mandate); to assess the incidence of SARS-CoV-2, secondary attack rates (SAR) and the effective reproductive number (R*) for each grade during the first trimester of the 2021-2022 academic year, including an analysis of the differences between 5-year-old, without facial covering mandate, and 6 year-old children, with mandate. Researchers found that "the SARS-CoV-2 incidence was significantly lower in preschool than in primary education, and an age-dependent trend was observed. Children aged 3 and 4 showed lower outcomes for all the analyzed epidemiological variables, while children aged 11 had the higher values. Six-year-old children showed higher incidence than 5 year-olds (3·54% vs 3·1%; OR: 1·15 [95%CI: 1·08-1·22]) and slightly lower but not statistically significant SAR and R*: SAR were 4·36% in 6 year-old children, and 4·59% in 5 year-old (IRR: 0·96 [95%CI: 0·82-1·11]); and R* was 0·9 and 0·93 (OR: 0·96 [95%CI: 0·87-1·09]), respectively." Overall, facial covering mandates (face masks) in examined schools were not linked to lower SARS-CoV-2 incidence or spread, implying that these masks were not effective."
99) Correlation Between Mask Compliance and COVID-19 Outcomes in Europe, Spira, 2022	"The aim of this short study was to analyse the correlation between mask usage against morbidity and mortality rates in the 2020-2021 winter in Europe. Data from 35 European countries on morbidity, mortality, and mask usage during a six-month period were analysed and crossed. Mask usage was more homogeneous in Eastern Europe than in Western European countries. Spearman's correlation coefficients between mask usage and COVID-19 outcomes were either null or positive, depending on the subgroup of countries and type of outcome (cases or deaths). Positive correlations were stronger in Western than in Eastern European countries. These findings indicate that countries with high levels of mask compliance did not perform better than those with low mask usage."

100) The Foegen effect A mechanism by which facemasks contribute to the COVID-19 case fatality rate, Fögen, 2022	“The most important finding from this study is that contrary to the accepted thought that fewer people are dying because infection rates are reduced by masks, this was not the case. Results from this study strongly suggest that mask mandates actually caused about 1.5 times the number of deaths or ∼50% more deaths compared to no mask mandates. This means that the risk for the individual wearing the mask should even be higher, because there is an unknown number of people in MMC who either do not obey mask mandates, are exempted for medical reasons or do not go to public places where mask mandates are in effect. These people do not have an increased risk and thus the risk on the other people under a mask mandate is actually higher.”
101) Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota, Sood &Høeg, 2022	Unique study “of two adjacent K-12 school districts in Fargo, North Dakota, one which had a mask mandate and one which did not in the fall of the 2021-2022 academic year. In the winter, both districts adopted a masks-optional policy allowing for a partial crossover study design. We observed no significant difference between student case rates while the districts had differing masking policies (IRR 0.99; 95% CI: 0.92 to 1.07) nor while they had the same mask policies (IRR 1.04; 95% CI: 0.92 to 1.16). The IRRs across the two periods were also not significantly different (p = 0.40).” Researchers concluded that school-based mask mandates have “limited to no impact on the case rates of COVID-19 among K-12 students.”
102) Medical Masks Versus N95 Respirators for Preventing COVID-19 Among Health Care Workers, Loeb, 2022	Researchers found that both the surgical masks and the N95 fitted COVID masks do not stop infection as in both trial arms (non-inferiority multi-center trial), participants got infected; moreover, there was no difference between the surgical masks and the N95 fitted masks in terms of stopping infection. “In the intention-to-treat analysis, RT-PCR–confirmed COVID-19 occurred in 52 of 497 (10.46%) participants in the medical mask group versus 47 of 507 (9.27%) in the N95 respirator group (hazard ratio [HR], 1.14 [95% CI, 0.77 to 1.69]). There were 47 (10.8%) adverse events related to the intervention reported in the medical mask group and 59 (13.6%) in the N95 respirator group.”
103) Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort, Chandra, 2022	“Successfully replicated the original result using 565 counties; non-masking counties had around 30 additional daily cases per 100,000 children after two weeks of schools reopening. However, after nine weeks, cases per 100,000 were 18.3 in counties with mandates compared to 15.8 in those without them (p = 0.12). In a larger sample of 1832 counties, between weeks 2 and 9, cases per 100,000 fell by 38.2 and 37.9 in counties with and without mask requirements, respectively (p = 0.93). The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are prone to multiple biases and provide insufficient evidence for recommending mask mandates.”

104) Physical interventions to interrupt or reduce the spread of respiratory viruses (Review), Jefferson, 2023	Ten studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask in the community studies only, wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (9 studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (6 studies; 13,919 people). Unwanted effects were rarely reported; discomfort was mentioned. **N95/P2 respirators** Four studies were in healthcare workers, and one small study was in the community. Compared with wearing medical or surgical masks, wearing N95/P2 respirators probably makes little to no difference in how many people have confirmed flu (5 studies; 8407 people); and may make little to no difference in how many people catch a flu-like illness (5 studies; 8407 people), or respiratory illness (3 studies; 7799 people). Unwanted effects were not well-reported; discomfort was mentioned.
MASK MANDATES	
1) Mask mandate and use efficacy for COVID-19 containment in US States, Guerra, 2021	“Calculated total COVID-19 case growth and mask use for the continental United States with data from the Centers for Disease Control and Prevention and Institute for Health Metrics and Evaluation. We estimated post-mask mandate case growth in non-mandate states using median issuance dates of neighboring states with mandates…did not observe association between mask mandates or use and reduced COVID-19 spread in US states.”
2) These 12 Graphs Show Mask Mandates Do Nothing To Stop COVID, Weiss, 2020	“Masks can work well when they’re fully sealed, properly fitted, changed often, and have a filter designed for virus-sized particles. This represents none of the common masks available on the consumer market, making universal masking much more of a confidence trick than a medical solution…Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated. The narrative says that if cases go down it’s because masks succeeded. It says that if cases go up it’s because masks succeeded in preventing more cases. The narrative simply assumes rather than proves that masks work, despite overwhelming scientific evidence to the contrary.”
3) Mask Mandates Seem to Make CCP Virus Infection Rates Climb, Study Says, Vadum, 2020	“Protective-mask mandates aimed at combating the spread of the CCP virus that causes the disease COVID-19 appear to promote its spread, according to a report from RationalGround.com, a clearinghouse of COVID-19 data trends that’s run by a grassroots group of data analysts, computer scientists, and actuaries.”

4) Horowitz: Comprehensive analysis of 50 states shows greater spread with mask mandates, Howorwitz, 2020 Justin Hart	"How long do our politicians get to ignore the results?… The results: When comparing states with mandates vs. those without, or periods of times within a state with a mandate vs. without, there is absolutely no evidence the mask mandate worked to slow the spread one iota. In total, in the states that had a mandate in effect, there were 9,605,256 confirmed COVID cases over 5,907 total days, an average of 27 cases per 100,000 per day. When states did not have a statewide order (which includes the states that never had them and the period of time masking states did not have the mandate in place) there were 5,781,716 cases over 5,772 total days, averaging 17 cases per 100,000 people per day."
5) The CDC's Mask Mandate Study: Debunked, Alexander, 2021	"Thus, it is not surprising that the CDC's own recent conclusion on the use of nonpharmaceutical measures such as face masks in pandemic influenza, warned that scientific "evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission…" Moreover, in the WHO's 2019 guidance document on nonpharmaceutical public health measures in a pandemic, they reported as to face masks that "there is no evidence that this is effective in reducing transmission…" Similarly, in the fine print to a recent double-blind, double-masking simulation the CDC stated that "The findings of these simulations [supporting mask usage] should neither be generalized to the effectiveness …nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings."
6) Phil Kerpin, tweet, 2021 The Spectator	"The first ecological study of state mask mandates and use to include winter data: "Case growth was independent of mandates at low and high rates of community spread, and mask use did not predict case growth during the Summer or Fall-Winter waves."
7) How face masks and lockdowns failed, SPR, 2021	"Infections have been driven primarily by seasonal and endemic factors, whereas mask mandates and lockdowns have had no discernible impact"
8) Analysis of the Effects of COVID-19 Mask Mandates on Hospital Resource Consumption and Mortality at the County Level, Schauer, 2021	"There was no reduction in per-population daily mortality, hospital bed, ICU bed, or ventilator occupancy of COVID-19-positive patients attributable to the implementation of a mask-wearing mandate."

9) Do we need mask mandates, Harris, 2021	"But masks proved far less useful in the subsequent 1918 Spanish flu, a viral disease spread by pathogens smaller than bacteria. California's Department of Health, for instance, reported that the cities of Stockton, which required masks, and Boston, which did not, had scarcely different death rates, and so advised against mask mandates except for a few high-risk professions such as barbers….Randomized controlled trials (RCTs) on mask use, generally more reliable than observational studies, though not infallible, typically show that cloth and surgical masks offer little protection. A few RCTs suggest that perfect adherence to an exacting mask protocol may guard against influenza, but meta-analyses find little on the whole to suggest that masks offer meaningful protection. WHO guidelines from 2019 on influenza say that despite "mechanistic plausibility for the potential effectiveness" of masks, studies showed a benefit too small to be established with any certainty. Another literature review by researchers from the University of Hong Kong agrees. Its best estimate for the protective effect of surgical masks against influenza, based on ten RCTs published through 2018, was just 22 percent, and it could not rule out zero effect."
MASK HARMS	
1) Corona children studies: Co-Ki: First results of a German-wide registry on mouth and nose covering (mask) in children, Schwarz, 2021	"The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%)."
2) Dangerous pathogens found on children's face masks, Cabrera, 2021	"Masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and pneumonia-causing bacteria."
3) Masks, false safety and real dangers, Part 2: Microbial challenges from masks, Borovoy, 2020/2021	"Laboratory testing of used masks from 20 train commuters revealed that 11 of the 20 masks tested contained over 100,000 bacterial colonies. Molds and yeasts were also found. Three of the masks contained more than one million bacterial colonies… The outside surfaces of surgical masks were found to have high levels of the following microbes, even in hospitals, more concentrated on the outside of masks than in the environment. Staphylococcus species (57%) and Pseudomonas spp (38%) were predominant among bacteria, and Penicillium spp (39%) and Aspergillus spp. (31%) were the predominant fungi."

4) Preliminary report on surgical mask induced deoxygenation during major surgery, Beder, 2008	“Considering our findings, pulse rates of the surgeon’s increase and SpO2 decrease after the first hour. This early change in SpO2 may be either due to the facial mask or the operational stress. Since a very small decrease in saturation at this level, reflects a large decrease in PaO2, our findings may have a clinical value for the health workers and the surgeons.”
5) Mask mandates may affect a child’s emotional, intellectual development, Gillis, 2020	“The thing is we really don’t know for sure what the effect may or may not be. But what we do know is that children, especially in early childhood, they use the mouth as part of the entire face to get a sense of what’s going on around them in terms of adults and other people in their environment as far as their emotions. It also has a role in language development as well… If you think about an infant, when you interact with them you use part of your mouth. They are interested in your facial expressions. And if you think about that part of the face being covered up, there is that possibility that it could have an effect. But we don’t know because this is really an unprecedented time. What we wonder about is if this could play a role and how can we stop it if it would affect child development.”
6) Headaches and the N95 face-mask amongst healthcare providers, Lim, 2006	“Healthcare providers may develop headaches following the use of the N95 face-mask.”
7) Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021, Brooks, 2021	“Although use of double masking or knotting and tucking are two of many options that can optimize fit and enhance mask performance for source control and for wearer protection, double masking might impede breathing or obstruct peripheral vision for some wearers, and knotting and tucking can change the shape of the mask such that it no longer covers fully both the nose and the mouth of persons with larger faces.”
8) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	“Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression.”
9) Wearing a mask can expose children to dangerous levels of carbon dioxide in just THREE MINUTES, study finds, Shaheen/Daily Mail, 2021	“European study found that children wearing masks for only minutes could be exposed to dangerous carbon dioxide levels…Forty-five children were exposed to carbon dioxide levels between three to twelve times healthy levels.”
10) How many children must die? Shilhavy, 2020	“How long are parents going to continue masking their children causing great harm to them, even to the point of risking their lives? Dr. Eric Nepute in St. Louis took time to record a video rant that he wants everyone to share, after the 4-year-old child of one of his patients almost died from a bacterial lung infection caused by prolonged mask use.”

11) Medical Doctor Warns that “Bacterial Pneumonias Are on the Rise” from Mask Wearing, Meehan, 2021	“I’m seeing patients that have facial rashes, fungal infections, bacterial infections. Reports coming from my colleagues, all over the world, are suggesting that the bacterial pneumonias are on the rise…Why might that be? Because untrained members of the public are wearing medical masks, repeatedly… in a non-sterile fashion… They’re becoming contaminated. They’re pulling them off of their car seat, off the rear-view mirror, out of their pocket, from their countertop, and they’re reapplying a mask that should be worn fresh and sterile every single time.”
12) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	“Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of an increased transmission of the virus in case of inappropriate use of the mask.”
13) Face coverings for covid-19: from medical intervention to social practice, Peters, 2020	“At present, there is no direct evidence (from studies on Covid19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including Covid19. Contamination of the upper respiratory tract by viruses and bacteria on the outside of medical face masks has been detected in several hospitals. Another research shows that a moist mask is a breeding ground for (antibiotic resistant) bacteria and fungi, which can undermine mucosal viral immunity. This research advocates the use of medical / surgical masks (instead of homemade cotton masks) that are used once and replaced after a few hours.”
14) Face masks for the public during the covid-19 crisis, Lazzarino, 2020	“The two potential side effects that have already been acknowledged are: (1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing. (2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and adopt other management measures, otherwise their risks and those of others may increase. Other potential side effects that we must consider are: (3) The quality and the volume of speech between two people wearing masks is considerably compromised and they may unconsciously come closer. While one may be trained to counteract side effect n.1, this side effect may be more difficult to tackle. (4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself.”

15) Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers, Chughtai, 2019	“Respiratory pathogens on the outer surface of the used medical masks may result in self-contamination. The risk is higher with longer duration of mask use (> 6 h) and with higher rates of clinical contact. Protocols on duration of mask use should specify a maximum time of continuous use, and should consider guidance in high contact settings.”
16) Reusability of Facemasks During an Influenza Pandemic, Bailar, 2006	“After considering all the testimony and other information we received, the committee concluded that there is currently no simple, reliable way to decontaminate these devices and enable people to use them safely more than once. There is relatively little data available about how effective these devices are against flu even the first time they are used. To the extent they can help at all, they must be used correctly, and the best respirator or mask will do little to protect a person who uses it incorrectly. Substantial research must be done to increase our understanding of how flu spreads, to develop better masks and respirators, and to make it easier to decontaminate them. Finally, the use of face coverings is only one of many strategies that will be needed to slow or halt a pandemic, and people should not engage in activities that would increase their risk of exposure to flu just because they have a mask or respirator.”
17) Exhalation of respiratory viruses by breathing, coughing, and talking, Stelzer-Braid, 2009	“The exhaled aerosols generated by coughing, talking, and breathing were sampled in 50 subjects using a novel mask, and analyzed using PCR for nine respiratory viruses. The exhaled samples from a subset of 10 subjects who were PCR positive for rhinovirus were also examined by cell culture for this virus. Of the 50 subjects, among the 33 with symptoms of upper respiratory tract infections, 21 had at least one virus detected by PCR, while amongst the 17 asymptomatic subjects, 4 had a virus detected by PCR. Overall, rhinovirus was detected in 19 subjects, influenza in 4 subjects, parainfluenza in 2 subjects, and human metapneumovirus in 1 subject. Two subjects were co-infected. Of the 25 subjects who had virus-positive nasal mucus, the same virus type was detected in 12 breathing samples, 8 talking samples, and in 2 coughing samples. In the subset of exhaled samples from 10 subjects examined by culture, infective rhinovirus was detected in 2.”
18) [Effect of a surgical mask on six minute walking distance], Person, 2018	“Wearing a surgical mask modifies significantly and clinically dyspnea without influencing walked distance.”

19) Protective masks reduce resilience, Science ORF, 2020	“The German researchers used two types of face masks for their study – surgical masks and so-called FFP2 masks, which are mainly used by medical personnel. The measurements were carried out with the help of spiroergometry, in which patients or in this case the test persons exert themselves physically on a stationary bicycle – a so-called ergometer – or a treadmill. The subjects were examined without a mask, with surgical masks and with FFP2 masks. The masks therefore impair breathing, especially the volume and the highest possible speed of the air when exhaling. The maximum possible force on the ergometer was significantly reduced.”
20) Wearing masks even more unhealthy than expected, Coronoa transition, 2020	“They contain microplastics – and they exacerbate the waste problem…”Many of them are made of polyester and so you have a microplastic problem.” Many of the face masks would contain polyester with chlorine compounds: “If I have the mask in front of my face, then of course I breathe in the microplastic directly and these substances are much more toxic than if you swallow them, as they get directly into the nervous system,” Braungart continues.”
21) Masking Children: Tragic, Unscientific, and Damaging, Alexander, 2021	“Children do not readily acquire SARS-CoV-2 (very low risk), spread it to other children or teachers, or endanger parents or others at home. This is the settled science. In the rare cases where a child contracts Covid virus it is very unusual for the child to get severely ill or die. Masking can do positive harm to children – as it can to some adults. But the cost benefit analysis is entirely different for adults and children – particularly younger children. Whatever arguments there may be for consenting adults – children should not be required to wear masks to prevent the spread of Covid-19. Of course, zero risk is not attainable – with or without masks, vaccines, therapeutics, distancing or anything else medicine may develop or government agencies may impose.”
22) The Dangers of Masks, Alexander, 2021	“With that clarion call, we pivot and refer here to another looming concern and this is the potential danger of the chlorine, polyester, and microplastic components of the face masks (surgical principally but any of the mass-produced masks) that have become part of our daily lives due to the Covid-19 pandemic. We hope those with persuasive power in the government will listen to this plea. We hope that the necessary decisions will be made to reduce the risk to our populations.”

23) 13-year-old mask wearer dies for inexplicable reasons, Corona Transition, 2020	“The case is not only causing speculation in Germany about possible poisoning with carbon dioxide. Because the student “was wearing a corona protective mask when she suddenly collapsed and died a little later in the hospital,” writes Wochenblick.Editor’s Review: The fact that no cause of death was communicated nearly three weeks after the girl’s death is indeed unusual. The carbon dioxide content of the air is usually about 0.04 percent. From a proportion of four percent, the first symptoms of hypercapnia, i.e. carbon dioxide poisoning, appear. If the proportion of the gas rises to more than 20 percent, there is a risk of deadly carbon dioxide poisoning. However, this does not come without alarm signals from the body. According to the medical portal netdoktor, these include “sweating, accelerated breathing, accelerated heartbeat, headaches, confusion, loss of consciousness”. The unconsciousness of the girl could therefore be an indication of such poisoning.”
24) Student Deaths Lead Chinese Schools to Change Mask Rules, that’s, 2020	“During the month of April, three cases of students suffering sudden cardiac death (SCD) while running during gym class have been reported in Zhejiang, Henan and Hunan provinces. Beijing Evening News noted that all three students were wearing masks at the time of their deaths, igniting a critical discussion over school rules on when students should wear masks.”
25) Blaylock: Face Masks Pose Serious Risks To The Healthy, 2020	“As for the scientific support for the use of face mask, a recent careful examination of the literature, in which 17 of the best studies were analyzed, concluded that, “ None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection.”[1] Keep in mind, no studies have been done to demonstrate that either a cloth mask or the N95 mask has any effect on transmission of the COVID-19 virus. Any recommendations, therefore, have to be based on studies of influenza virus transmission. And, as you have seen, there is no conclusive evidence of their efficiency in controlling flu virus transmission.”
26) The mask requirement is responsible for severe psychological damage and the weakening of the immune system, Coronoa Transition, 2020	“In fact, the mask has the potential to “trigger strong psychovegetative stress reactions via emerging aggression, which correlate significantly with the degree of stressful after-effects”. Prousa is not alone in her opinion. Several psychologists dealt with the mask problem — and most came to devastating results. Ignoring them would be fatal, according to Prousa.”
27) The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease, Kao, 2004	“Wearing an N95 mask for 4 hours during HD significantly reduced PaO2 and increased respiratory adverse effects in ESRD patients.”

28) Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?, Kisielinski, 2021	“We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.”“Here are the pathophysiological changes and subjective complaints: 1) Increase in blood carbon dioxide 2) Increase in breathing resistance 3) Decrease in blood oxygen saturation 4) Increase in heart rate 5) Decrease in cardiopulmonary capacity 6) Feeling of exhaustion 7) Increase in respiratory rate 8) Difficulty breathing and shortness of breath 9) Headache 10) Dizziness 11) Feeling of dampness and heat 12) Drowsiness (qualitative neurological deficits) 13) Decrease in empathy perception 14) Impaired skin barrier function with acne, itching and skin lesions”
29) Is N95 face mask linked to dizziness and headache?, Ipek, 2021	“Respiratory alkalosis and hypocarbia were detected after the use of N95. Acute respiratory alkalosis can cause headache, anxiety, tremor, muscle cramps. In this study, it was quantitatively shown that the participants’ symptoms were due to respiratory alkalosis and hypocarbia.”
30) COVID-19 prompts a team of engineers to rethink the humble face mask, Myers, 2020	“But in filtering those particles, the mask also makes it harder to breathe. N95 masks are estimated to reduce oxygen intake by anywhere from 5 to 20 percent. That’s significant, even for a healthy person. It can cause dizziness and lightheadedness. If you wear a mask long enough, it can damage the lungs. For a patient in respiratory distress, it can even be life threatening.”
31) 70 doctors in open letter to Ben Weyts: ‘Abolish mandatory mouth mask at school’ – Belgium, World Today News, 2020	“In an open letter to the Flemish Minister of Education Ben Weyts (N-VA), 70 doctors ask to abolish the mandatory mouth mask at school, both for the teachers and for the students. Weyts does not intend to change course. The doctors ask that Minister Ben Weyts immediately reverses his working method: no mouth mask obligation at school, only protect the risk group and only the advice that people with a possible risk profile should consult their doctor.”

32) Face masks pose dangers for babies, toddlers during COVID-19 pandemic, UC Davis Health, 2020	“Masks may present a choking hazard for young children. Also, depending on the mask and the fit, the child may have trouble breathing. If this happens, they need to be able to take it off,” said UC Davis pediatrician Lena van der List. “Children less than 2 years of age will not reliably be able to remove a face mask and could suffocate. Therefore, masks should not routinely be used for young children…“The younger the child, the more likely they will be to not wear the mask properly, reach under the mask and touch potentially contaminated masks,” said Dean Blumberg, chief of pediatric infectious diseases at UC Davis Children’s Hospital. “Of course, this depends on the developmental level of the individual child. But I think masks are not likely to provide much potential benefit over risk until the teen years.”
33) Covid-19: Important potential side effects of wearing face masks that we should bear in mind, Lazzarino, 2020	“Other potential side effects that we must consider, however, are 1) The quality and volume of speech between people wearing masks is considerably compromised and they may unconsciously come closer2) Wearing a mask makes the exhaled air go into the eyes. This generates an impulse to touch the eyes. 3) If your hands are contaminated, you are infecting yourself, 4) Face masks make breathing more difficult. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those phenomena increase breathing frequency and deepness, and they may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs, 5) The innate immunity’s efficacy is highly dependent on the viral load. If masks determine a humid habitat where SARS-CoV-2 can remain active because of the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load (by re-inhaling exhaled viruses) and therefore they can cause a defeat of the innate immunity and an increase in infections.”
34) Risks of N95 Face Mask Use in Subjects With COPD, Kyung, 2020	“Of the 97 subjects, 7 with COPD did not wear the N95 for the entire test duration. This mask-failure group showed higher British modified Medical Research Council dyspnea scale scores and lower FEV_1 percent of predicted values than did the successful mask use group. A modified Medical Research Council dyspnea scale score ≥ 3 (odds ratio 167, 95% CI 8.4 to >999.9; P = .008) or a FEV_1 < 30% predicted (odds ratio 163, 95% CI 7.4 to >999.9; P = .001) was associated with a risk of failure to wear the N95. Breathing frequency, blood oxygen saturation, and exhaled carbon dioxide levels also showed significant differences before and after N95 use.”

35) Masks too dangerous for children under 2, medical group warns, The Japan Times, 2020	"Children under the age of 2 shouldn't wear masks because they can make breathing difficult and increase the risk of choking, a medical group has said, launching an urgent appeal to parents as the nation reopens from the coronavirus crisis…Masks can make breathing difficult because infants have narrow air passages," which increases the burden on their hearts, the association said, adding that masks also raise the risk of heat stroke for them."
36) Face masks can be problematic, dangerous to health of some Canadians: advocates, Spenser, 2020	"Face masks are dangerous to the health of some Canadians and problematic for some others…Asthma Canada president and CEO Vanessa Foran said simply wearing a mask could create risk of an asthma attack."
37) COVID-19 Masks Are a Crime Against Humanity and Child Abuse, Griesz-Brisson, 2020	"The rebreathing of our exhaled air will without a doubt create oxygen deficiency and a flooding of carbon dioxide. We know that the human brain is very sensitive to oxygen depravation. There are nerve cells for example in the hippocampus, that can't be longer than 3 minutes without oxygen – they cannot survive. The acute warning symptoms are headaches, drowsiness, dizziness, issues in concentration, slowing down of the reaction time – reactions of the cognitive system. However, when you have chronic oxygen depravation, all of those symptoms disappear, because you get used to it. But your efficiency will remain impaired and the undersupply of oxygen in your brain continues to progress. We know that neurodegenerative diseases take years to decades to develop. If today you forget your phone number, the breakdown in your brain would have already started 20 or 30 years ago…The child needs the brain to learn, and the brain needs oxygen to function. We don't need a clinical study for that. This is simple, indisputable physiology. Conscious and purposely induced oxygen deficiency is an absolutely deliberate health hazard, and an absolute medical contraindication."
38) Study shows how masks are harming children, Mercola, 2021	"Data from the first registry to record children's experiences with masks show physical, psychological and behavioral issues including irritability, difficulty concentrating and impaired learning.Since school shutdowns in spring 2020, an increasing number of parents are seeking drug treatment for attention deficit hyperactivity disorder (ADHD) for their children.Evidence from the U.K. shows schools are not the super spreaders health officials said they were; measured rates of infection in schools were the same as the community, not higher.A large randomized controlled trial showed wearing masks does not reduce the spread of SARS-CoV-2."

39) New Study Finds Masks Hurt Schoolchildren Physically, Psychologically, and Behaviorally, Hall, 2021 https://www.researchsquare.com/article/rs-124394/v2	"A new study, involving over 25,000 school-aged children, shows that masks are harming schoolchildren physically, psychologically, and behaviorally, revealing 24 distinct health issues associated with wearing masks…Though these results are concerning, the study also found that 29.7% of children experienced shortness of breath, 26.4% experienced dizziness, and hundreds of the participants experiencing accelerated respiration, tightness in chest, weakness, and short-term impairment of consciousness."
40) Protective Face Masks: Effect on the Oxygenation and Heart Rate Status of Oral Surgeons during Surgery, Scarano, 2021	"In all 20 surgeons wearing FFP2 covered by surgical masks, a reduction in arterial O_2 saturation from around 97.5% before surgery to 94% after surgery was recorded with increase of heart rates. A shortness of breath and light-headedness/headaches were also noted."
41) Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity, Fikenzer, 2020	"Ventilation, cardiopulmonary exercise capacity and comfort are reduced by surgical masks and highly impaired by FFP2/N95 face masks in healthy individuals. These data are important for recommendations on wearing face masks at work or during physical exercise."
42) Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19, Ong, 2020	"Most healthcare workers develop de novo PPE-associated headaches or exacerbation of their pre-existing headache disorders."
43) Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media, The American Institute of Stress, 2020	"Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems, and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of increased transmission of the virus in case of inappropriate use of the mask."
44) Reusing masks may increase your risk of coronavirus infection, expert says, Laguipo, 2020	"For the public, they should not wear facemasks unless they are sick, and if a healthcare worker advised them."For the average member of the public walking down a street, it is not a good idea," Dr. Harries said."What tends to happen is people will have one mask. They won't wear it all the time, they will take it off when they get home, they will put it down on a surface they haven't cleaned," she added.Further, she added that behavioral issues could adversely put themselves at more risk of getting the infection. For instance, people go out and don't wash their hands, they touch parts of the mask or their face, and they get infected."
45) What's Going On Under the Masks?, Wright, 2021	"Americans today have pretty good chompers on average, at least relative to most other people, past and present. Nevertheless, we do not think enough about oral health as evidenced by the almost complete lack of discussion regarding the effect of lockdowns and mandatory masking on our mouths."

46) Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Healthy ChildrenA Randomized Clinical Trial, Walach, 2021	"A large-scale surveyin Germany of adverse effects in parents and children using data of 25 930 children has shown that 68% of the participating children had problems when wearing nose and mouth coverings."
47) NM Kids forced to wear masks while running in 100-degree heat; Parents are striking back, Smith, 2021	"Nationally, children have a 99.997% survival rate from COVID-19. In New Mexico, only 0.7% of child COVID-19 cases have resulted in hospitalization. It is clear that children have an extremely low risk of severe illness or death from COVID-19, and mask mandates are placing a burden upon kids which is detrimental to their own health and well-being."
48) Health Canada issues advisory for disposable masks with graphene, CBC, 2021	"Health Canada is advising Canadians not to use disposable face masks that contain graphene. Health Canada issued the notice on Friday and said wearers could inhale graphene, a single layer of carbon atoms. Masks containing the toxic particles may have been distributed in some health-care facilities."
49) COVID-19: Performance study of microplastic inhalation risk posed by wearing masks, Li, 2021 Is graphene safe?	"Wearing masks considerably reduces the inhalation risk of particles (e.g., granular microplastics and unknown particles) even when they are worn continuously for 720 h. Surgical, cotton, fashion, and activated carbon masks wearing pose higher fiber-like microplastic inhalation risk, while all masks generally reduced exposure when used under their supposed time (<4 h). N95 poses less fiber-like microplastic inhalation risk. Reusing masks after they underwent different disinfection pre-treatment processes can increase the risk of particle (e.g., granular microplastics) and fiber-like microplastic inhalation. Ultraviolet disinfection exerts a relatively weak effect on fiber-like microplastic inhalation, and thus, it can be recommended as a treatment process for reusing masks if proven effective from microbiological standpoint. Wearing an N95 mask reduces the inhalation risk of spherical-type microplastics by 25.5 times compared with not wearing a mask."
50) Manufacturers have been using nanotechnology-derived graphene in face masks — now there are safety concerns, Maynard, 2021	"Early concerns around graphene were sparked by previous research on another form of carbon — carbon nanotubes. It turns out that some forms of these fiber-like materials can cause serious harm if inhaled. And following on from research here, a natural next-question to ask is whether carbon nanotubes' close cousin graphene comes with similar concerns.Because graphene lacks many of the physical and chemical aspects of carbon nanotubes that make them harmful (such as being long, thin, and hard for the body to get rid of), the indications are that the material is safer than its nanotube cousins. But safer doesn't mean safe. And current research indicates that this is not a material that should be used where it could potentially be inhaled, without a good amount of safety testing first…As a general rule of thumb, engineered nanomaterials should not be used in products where they might inadvertently be inhaled and reach the sensitive lower regions of the lungs."

51) Masking young children in school harms language acquisition, Walsh, 2021	“This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development.“Studies show that by age four, kids from low-income households will hear 30 million less words than their more affluent counterparts, who get more quality face-time with caretakers.” (https://news.stanford.edu/news/2014/november/language-toddlers-fernald-110514.html).”
52) Dangerous pathogens found on children’s face masks, Rational Ground, 2021	“A group of parents in Gainesville, FL, sent 6 face masks to a lab at the University of Florida, requesting an analysis of contaminants found on the masks after they had been worn. The resulting report found that five masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and pneumonia-causing bacteria. Although the test is capable of detecting viruses, including SARS-CoV-2, only one virus was found on one mask (alcelaphine herpesvirus 1)…Half of the masks were contaminated with one or more strains of pneumonia-causing bacteria. One-third were contaminated with one or more strains of meningitis-causing bacteria. One-third were contaminated with dangerous, antibiotic-resistant bacterial pathogens. In addition, less dangerous pathogens were identified, including pathogens that can cause fever, ulcers, acne, yeast infections, strep throat, periodontal disease, Rocky Mountain Spotted Fever, and more.”
53) Face mask dermatitis” due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care and non-health care workers in Germany, Niesert, 2021	“The duration of wearing masks showed a significant impact on the prevalence of symptoms ($p < 0.001$). Type IV hypersensitivity was significantly more likely in participants with symptoms compared to those without symptoms ($p = 0.001$), whereas no increase in symptoms was observed in participants with atopic diathesis. HCWs used facial skin care products significantly more often than non-HCWs ($p = 0.001$).”
54) Effect of Wearing Face Masks on the Carbon Dioxide Concentration in the Breathing Zone, AAQR/Geiss, 2020	“Detected carbon dioxide concentrations ranged from 2150 ± 192 to 2875 ± 323 ppm. The concentrations of carbon dioxide while not wearing a face mask varied from 500–900 ppm. Doing office work and standing still on the treadmill each resulted in carbon dioxide concentrations of around 2200 ppm. A small increase could be observed when walking at a speed of 3 km h–1 (leisurely walking pace)…concentrations in the detected range can cause undesirable symptoms, such as fatigue, headache, and loss of concentration.”

55) Surgical masks as source of bacterial contamination during operative procedures, Zhiqing, 2018	“The source of bacterial contamination in SMs was the body surface of the surgeons rather than the OR environment. Moreover, we recommend that surgeons should change the mask after each operation, especially those beyond 2 hours.”
56) The Damage of Masking Children Could be Irreparable, Hussey, 2021	“When we surround children with mask-wearers for a year at a time, are we impairing their face barcode recognition during a period of hot neural development, thus putting full development of the FFA at risk? Does the demand for separation from others, reducing social interaction, add to the potential consequences as it might in autism? When can we be sure that we won’t interfere with visual input to the face recognition visual neurology so we don’t interfere with brain development? How much time with stimulus interference can we allow without consequences? Those are all questions currently without answers; we don’t know. Unfortunately, the science implies that if we mess up brain development for faces, we may not currently have therapies to undo everything we’ve done.”
57) Masks can be Murder, Grossman, 2021	“Wearing masks can create a sense of anonymity for an aggressor, while also dehumanizing the victim. This prevents empathy, empowering violence, and murder.” Masking helps remove empathy and compassion, allowing others to commit unspeakable acts on the masked person.”
58) London high school teacher calls face masks an ‘egregious and unforgivable form of child abuse, Butler, 2020	“In his email, Farquharson called the campaign to legislate mask wearing a “shameful farce, a charade, an act of political theatre” that’s more about enforcing “obedience and compliance” than it is about public health. He also likened children wearing masks to “involuntary self-torture,” calling it “an egregious and unforgivable form of child abuse and physical assault.”
59) UK Government Advisor Admits Masks Are Just “Comfort Blankets” That Do Virtually Nothing, ZeroHedge, 2021	“As the UK Government heralds “freedom day” today, which is anything but, a prominent government scientific advisor has admitted that face masks do very little to protect from coronavirus and are basically just “comfort blankets…the professor noted that “those aerosols escape masks and will render the mask ineffective,” adding “The public were demanding something must be done, they got masks, it is just a comfort blanket. But now it is entrenched, and we are entrenching bad behaviour…all around the world you can look at mask mandates and superimpose on infection rates, you cannot see that mask mandates made any effect whatsoever,” Axon further noted, adding that “The best thing you can say about any mask is that any positive effect they do have is too small to be measured.”

60) Masks, false safety and real dangers, Part 1: Friable mask particulate and lung vulnerability, Borovoy, 2020	“Surgical personnel are trained to never touch any part of a mask, except the loops and the nose bridge. Otherwise, the mask is considered useless and is to be replaced. Surgical personnel are strictly trained not to touch their masks otherwise. However, the general public may be seen touching various parts of their masks. Even the masks just removed from manufacturer packaging have been shown in the above photos to contain particulate and fiber that would not be optimal to inhale… Further concerns of macrophage response and other immune and inflammatory and fibroblast response to such inhaled particles specifically from facemasks should be the subject of more research. If widespread masking continues, then the potential for inhaling mask fibers and environmental and biological debris continues on a daily basis for hundreds of millions of people. This should be alarming for physicians and epidemiologists knowledgeable in occupational hazards.”
61) Medical Masks, Desai, 2020	“Face masks should be used only by individuals who have symptoms of respiratory infection such as coughing, sneezing, or, in some cases, fever. Face masks should also be worn by health care workers, by individuals who are taking care of or are in close contact with people who have respiratory infections, or otherwise as directed by a doctor. Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill.”

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EXCLUSIVE: Face masks may raise risk of stillbirths, testicular dysfunction and cognitive decline due to build-up of carbon dioxide, study warns

By Caitlin Tilley, Health Reporter For Dailymail.Com
Updated 20:58 EDT 22 Apr 2023



216-RICR-30-05-4

Mark I <marcus21980@gmail.com>

Fri 2/9/2024 6:09 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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RE: Proposed Masking Rule

I'm writing in opposition to proposed rule 216-RICR-30-05-4.

The RI Department of Health should not be allowed a blank check over our children who choose to attend public school. They should not be allowed to forcibly mask a child against their will or their parents will. This proposed rule also allows masking without any data to support said masking. This would be the only rule of its kind for the entire country. How can RI make up such a rule that rejects any and all medical treatises.

We already saw the damage done to our students due to missed school and making. Test scores are still behind and learning loss has been well documented. We cannot allow our children to be masked again over others perceived fear or thoughts about the efficacy of masks without actual scientific data.

In conclusion, I am in strong opposition of this proposed rule.

Regards,

Mark Iorfida
Cranston, RI

Proposed Mask Rule

meowmommy2@gmail.com <meowmommy2@gmail.com>
Sat 2/10/2024 9:23 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Mr. Garceau,
I am extremely against masking in school as a mandate. There have been more negative consequences of masking in school than positive. The mental health of our children has been severely impacted by masking. I understand why we did it then, but we know more now and it's not something I would ever put my child through again.

Thank you,
Elizabeth Ryder
69 Forestdale Dr.
Cumberland

Masking children

anthony miranda <tmiranda89@gmail.com>

Sun 2/11/2024 9:29 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I don't understand after the last few year how anyone can think that forcing anyone especially children to wear a mask is a good thing. It is not healthy to wear a mask and it does not stop or protect anything.

Anyone pushing this idea and enforcing it clearly does Not care about the safety or well being of our children. This only makes things worse and anyone who thinks that this is a good idea should be criminally charges with endangering the well being of children.

Masking in School

Kelli Lynn <kellilynn128@yahoo.com>

Sun 2/11/2024 12:29 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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My name is Kelli Desrosiersmiranda, a Rhode Island member, in cumberland. Just read about the proposed adoption for Masking in schools again? I'm pissed about this topic. Masking was horrible for the students. Horrible for their health, mentally and physically and not to mention socially. This is all about control and such bull. Covid is nothing more than the flu. We've been without mask for years now. They kids are still trying to get back to normalcy and RI wants to brings this back? Absolutely not okay. Masking doesn't work. After 15 mins with a mask on, the air drops go through it anyways. Whoever brought up with this idea again needs their head evaluated.

Sent from Yahoo Mail for iPhone [mail.onelink.me]

March 15 hearing for Masking in Schools

J <heyjay1971@verizon.net>

Sun 2/11/2024 8:25 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Hi,

I would like to be added to the list for public comments at the masking in school hearing. It seems this is the process for that? Thank you.

Jason Romblad

Mask regulations

Katie Miranda <katiemiranda8109@gmail.com>
Mon 2/12/2024 2:06 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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[city-journal.org]The Harm Caused by Masks
[city-journal.org]
city-journal.org [city-journal.org]

Sent from my iPhone

Jeffrey H. Anderson

The Harm Caused by Masks

A new study suggests that the excess carbon dioxide breathed in by mask-wearers can have major health consequences.

/ Eye on the News / Health Care May 09 2023

Evidence continues to mount that mask mandates were perhaps the worst public-health intervention in modern American history. While concluding that wearing masks "probably makes little or no difference" in preventing the spread of viruses, a recent Cochrane review also emphasized that "more attention should be paid to describing and quantifying the harms" that may come from wearing masks. A new study from Germany does just that, and it suggests that the excess carbon dioxide breathed in by mask-wearers may have substantial ill-effects on their health—and, in the case of pregnant women, their unborn children's.

Mask-wearers breathe in greater amounts of air that should have been expelled from their bodies and released out into the open. "[A] significant rise in carbon dioxide occurring while wearing a mask is scientifically proven in many studies," write the German authors. "Fresh air has around 0.04% CO2," they observe, while chronic exposure at CO2 levels of 0.3 percent is "toxic." How much CO2 do mask-wearers breathe in? The authors write that "masks bear a possible chronic exposure to low level carbon dioxide of 1.41–3.2% CO2 of the inhaled air in reliable human experiments."

In other words, while eight times the normal level of carbon dioxide is toxic, research suggests that mask-wearers (specifically those who wear masks for more than 5 minutes at a time) are breathing in 35 to 80 times normal levels.

The German study, a scoping review of existing research, aimed "to investigate the toxicological effects of face masks in terms of CO2 rebreathing on developing life, specifically for pregnant women, children, and adolescents." The latter two groups, of course, have been among those most frequently subjected to mask mandates in schools, despite Covid's low levels of risk for them and the evidence that masks don't work.

What can breathing too much carbon dioxide do to you? The authors write that "at levels between 0.05% and 0.5% CO2," one might experience an "increased heart rate, increased blood pressure and overall increased circulation with the symptoms of headache, fatigue, difficulty concentrating, dizziness, rhinitis, and dry cough." Rates above 0.5 percent can lead to "reduced cognitive performance, impaired decision-making and reduced speed of cognitive solutions." Beyond 1 percent, "the harmful effects include respiratory acidosis, metabolic stress, increased blood flow and decreased exercise tolerance." Again, mask-wearers are likely breathing in CO2 levels between 1.4 percent and 3.2 percent—well above any of these

thresholds. What's more, "Testes metabolism and cell respiration have been shown to be inhibited increasingly by rising levels of CO2."

So, high blood pressure, reduced thinking ability, respiratory problems, and reproductive concerns are among the many possible results of effectively poisoning oneself by breathing in too much carbon dioxide.

The authors write that "it is clear that carbon dioxide rebreathing, especially when using N95 masks, is above the 0.8% CO2 limit set by the US Navy to reduce the risk of stillbirths and birth defects on submarines with female personnel who may be pregnant." In other words, mandates have forced pregnant women to wear masks resulting in levels of CO2 inhalation that would be prohibited if they were serving on a Navy submarine.

Indeed, according to the authors, there exists "circumstantial evidence that popular mask use may be related to current observations of a significant rise of 28% to 33% in stillbirths worldwide and a reduced verbal, motor, and overall cognitive performance of two full standard deviations in scores in children born during the pandemic." They cite recent data from Australia, which "shows that lockdown restrictions and other measures (including masks that have been mandatory in Australia), in the absence of high rates of COVID-19 disease, were associated with a significant increase in stillborn births." Meantime, "no increased risk of stillbirths was observed in Sweden," which famously defied the public-health cabal and went its own way in setting Covid policies.

As for countries where mask-wearing has long been common, the authors write, "Even before the pandemic, in Asia the stillbirth rates have been significantly higher" than in Eurasia, Oceania, or North Africa.

"It has to be pointed out that this data on the toxicity of carbon dioxide on reproduction has been known for 60 years," the authors observe. For this reason, they write, the National Institute for Occupational Safety and Health (NIOSH), which is part of the Centers for Disease Control and Prevention (CDC), has CO2 threshold limits of 3 percent for 15 minutes and 0.5 percent for eight hours in workplace ambient air. Yet the CDC has been perhaps the primary pusher of masks in the United States.

Nor is increased CO2 intake the only health danger that results from wearing masks. The study focused only on CO2, but the authors note that "other noxious agents in the masks contribute to toxicological long-term effects like the inhalation of synthetic microfibers, carcinogenic compounds and volatile organic compounds." They add that "the increased carbon dioxide content of the breathing air behind the mask may also lead to a displacement of oxygen." Masks are also uncomfortable and unhygienic, and they profoundly compromise human social interaction.

In light of all this, it seems indefensible to mandate—or even to advise—the wearing of masks, especially among the young. The authors write, "Keeping in mind the weak antiviral mask efficacy, the general trend

of forcing mask mandates even for the vulnerable subgroups is not based on sound scientific evidence and not in line with the obligation in particular to protect born or unborn children from potential harmful influences."

Public-health officials—and the executive-branch leaders who credulously listened to them—ignored centuries of Western norms, the best medical evidence, and common sense, deciding that their own novel and evidence-free course was the one that all of society should be forced to follow. We should never again indulge such an obvious and destructive misstep.

Jeffrey H. Anderson is president of the American Main Street Initiative, a think tank for everyday Americans. He served as director of the Bureau of Justice Statistics at the U.S. Department of Justice from 2017 to 2021.

Photo by ANTHONY WALLACE/AFP via Getty Images

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Mask Mandate Regulation

Marianthy Barakos <marianthybarakos@gmail.com>

Mon 2/12/2024 1:26 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To whom this may concern,
In reference to the upcoming March 15, 2024 hearing, I strongly oppose any Mask Mandate Regulation.

Marianthy Barakos
5 Northwest Passage
Barrington, RI 02806

Proposed 216-RICR-30-05-4

Erika Twohig <erika.twohig@gmail.com>

Mon 2/12/2024 7:40 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:ttwohig260@gmail.com <ttwohig260@gmail.com>

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Good evening Mr. Garceau,

As a RI resident and parent of school age children, I would like to officially document my opposition to proposed 216-RICR-30-05-4 for mask mandates for school age children.

I will be at the hearing on March 15th to speak about my opposition.

Thank you,

Erika Twohig
Sent from my iPhone

Masking in School (216-RICR-30-05-4)

Peter Saakov <thespacerace89@gmail.com>

Mon 2/12/2024 9:47 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hi Zachary,

I am writing to you to submit a written comment concerning the proposed adoption of Masking in School (216-RICR-30-05-4) by the Rhode Island Department of Health.

I oppose this. Please do not adopt this.

Thanks, Peter

Testimony Against 216-RICR-30-05-4 Masking in School

Wendy Fachon <wendyf13@cox.net>
Tue 2/13/2024 10:14 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4ri@hotmail.com <consent4ri@hotmail.com>

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Report Suspicious

To the Rhode Island Department of Health,

I am a childhood educator, and me and my colleagues, have been witness to the damaging social and emotional effects of masking. It is clear to us that the current mental health crisis among our youth, brought about by cellphones and social media, was exacerbated by masking. One study in the National Library of Medicine, *Mask wearing effects emotion perception*, states:

"Recent studies have demonstrated that face masks negatively affect hearing, understanding, speaker engagement, and connection (Calbi et al., 2021 [ncbi.nlm.nih.gov]; Kastendieck et al., 2021 [ncbi.nlm.nih.gov]; Saunders et al., 2021 [ncbi.nlm.nih.gov]). Interpersonal connection is particularly challenging, partly because face masks dampen one's ability to express the appropriate emotion and partly because they restrict another individual's ability to detect the expressed emotion."

How can one teach or learn effectively with masks on everybody's faces? I pivoted to teaching students virtually on Zoom, so that I could read their expressions, they could read one anther's expressions, and they could read my face and those of my teaching team. This is critical to running a successful class. I taught via Zoom so we could all share our infectious smiles, because the science of psychology tells us smiles makes people happier and healthier.

I also wanted my students to be able to breathe. In fact, we make a point of beginning each Zoom class with mindful breathing.

More than 160 comparative scientific studies and articles show what should have been obvious: masks are ineffective in preventing spread of disease and, in fact, masking can be harmful to health. Thinking intuitively, masks prevent the breathing of fresh air and intake of appropriate levels of oxygen for a heart, brain and body to function. Furthermore, bacteria get trapped inside the mask and get inhaled repeatedly. After ten minutes of wearing a mask, I was breathing in an unpleasant

odor. It's gross!

If I'm sick, I stay home and away from people. Masking should be a choice. Mandating would be an unfortunate decision. If people feel safer wearing a mask, let them. Personally, I feel safer without a mask.

Thank you for considering my testimony,

Wendy Fachon
East Greenwich, RI 02818

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Mask wearing affects emotion perception

Carmel A. Levitan, Isabelle Rusk, Danielle Jonas-Delson, Hanyun Lou, Lennon Kuzniar, Gray Davidson, and Aleksandra Sherman

Abstract

To reduce the spread of COVID-19, mask wearing has become ubiquitous in much of the world. We studied the extent to which masks impair emotion recognition and dampen the perceived intensity of facial expressions by naturalistically inducing positive, neutral, and negative emotions in individuals while they were masked and unmasked. Two groups of online participants rated the emotional intensity of each presented image. One group rated full faces (N=104); the other (N=102) rated cropped images where only the upper face was visible. We found that masks impaired the recognition of and rated intensity of positive emotions. This happened even when the faces were cropped and the lower part of the face was not visible. Masks may thus reduce positive emotion and/or expressivity of positive emotion. However, perception of negativity was unaffected by masking, perhaps because unlike positive emotions like happiness which are signaled more in the mouth, negative emotions like anger rely more on the upper face.

Keywords: emotion perception, mask wearing

Introduction

Understanding others' facial expressions is an important part of our daily interpersonal communication. Effective social communication relies on recognizing others' emotions during a conversation or interaction (e.g., recognizing that someone is happy), and is a means of revealing one's own internal emotional states to the listener (e.g., by smiling at another individual). Since the onset of the global COVID-19 pandemic in January 2020, mask wearing has become ubiquitous internationally. Mask wearing has not only been crucial for curbing the spread of the virus, but it has also in-

Feedback

creased our capacity to safely interact with one another. However, because masks cover 60%–70% of the face, obscuring the nose, mouth, cheeks, and portions of the face under the eyes, emotion expression and recognition during social interaction may be compromised.

Indeed, recent studies have demonstrated that face masks negatively affect hearing, understanding, speaker engagement, and connection (Calbi et al., 2021; Kastendieck et al., 2021; Saunders et al., 2021). Interpersonal connection is particularly challenging, partly because face masks dampen one's ability to express the appropriate emotion and partly because they restrict another individual's ability to detect the expressed emotion. When someone's face is occluded by a mask, people are significantly less accurate at detecting the depicted emotion, are more likely to confuse the depicted emotion with other emotions, and tend to perceive the depicted emotion as less intense than its unmasked counterpart (e.g., happy faces look less happy) (Bani et al., 2021; Carbon, 2020; Freud et al., 2020; Grundmann et al., 2021; Kret et al., 2021; Langbehn et al., 2020; Noyes et al., 2021; Tsantani et al., 2022). As a result, processes such as facial mimicry, which are crucial for social interaction, are impaired when one is interacting with a masked individual (Kastendieck et al. 2021).

Masking affects the perception of some expressions more than others, as certain parts of the face are more important for different emotions. For example, when expressing happiness, the mouth and lips are crucial. In contrast, the eye region exhibits the most prominent changes when expressing fear or anger, with the eyelid raising or tightening to express fear or anger, respectively (Eisenbarth & Alpers, 2011; Gagnon et al., 2014; Wegrzyn et al., 2017). Thus, emotions that rely heavily on the lower part of the face, such as happiness, disgust, and sadness, are more difficult to discriminate when masks are worn than emotions that rely more on the upper portion of the face, such as anger and surprise (Bani et al., 2021; Langbehn et al., 2020; Noyes et al., 2021; Tsantani et al., 2022). The idea that our ability to discriminate between emotions is enhanced when we have visual access to the entire face, is consistent with theories about holistic processing of faces. Specifically, evidence shows that participants are slower and less accurate at detecting emotional states when presented with only the top or bottom half of the face (e.g., Calder et al., 2000). Meanwhile, neutral expressions tend to be recognized accurately in both masked and unmasked conditions (Noyes et al., 2021).

Although masking may impair the expression and perception of emotions, it is possible that people's exposure to mask wearing over the past 2 years has resulted in changes in communication, emotion expressivity while masked, and perception of emotions. In a recent study conducted in the UK, 60% of individuals reported communicating differently when wearing face coverings (Saunders et al., 2021). In order to be better understood, people may overcompensate by increasing the volume and expressivity of their speech, using body language such as gestures, and attempting to communicate through their eyes (Saunders et al. 2021). Increasing emotional signals in the eyes would decrease the negative effects of masking on emotion perception. It is also possible that increased mask exposure has led to a more nuanced perception of emotions, meaning that people with more mask exposure may be able to better discriminate emotions from the eyes, even when the signal remains relatively unchanged. Barrick et al., 2021 support this, finding that when completing an emotion recognition and similarity task, participants with increased mask exposure used cues from the eyes to a greater extent than those with less mask exposure. These

findings suggest that mask wearing is shifting the way that emotions are recognized from more holistic processing of the entire face to extracting signals from a more localized area such as the eyes and forehead.

The present study aims to replicate and extend the recent work on emotion expression and perception while masking. We were interested in whether mask wearing causes people to exaggerate their emotions and increase the emotion-related information in their eyes. We were particularly interested in the differential effects that mask wearing may have on the expression of happiness, which relies primarily on the mouth, and on the expression of anger, which relies primarily on the eyes. Whereas many previous studies use emotional face stimuli that are produced by actors, we induced negative and positive emotions in a more naturalistic setting via Zoom interviews with non-actors. Moreover, several previous studies investigating the effects of masking on emotion perception digitally overlay a mask onto a face stimulus. However, because we hypothesized that an individual might exaggerate their emotions when masked, we induced emotions both when participants were masked and unmasked. Second, we were interested in the extent to which mask exposure and social interaction might affect emotion expression perception. We predicted that people with greater mask exposure would be more accurate at recognizing both positive and negative emotions from the eyes alone.

Method

Overview

We conducted a mixed 3 × 2 × 2 experiment with within-participants variables of emotion (positive, negative, and neutral) and masking (masked and unmasked face stimuli), and a between-participants variable of cropping (whether the full face was visible or just a cropped image of the upper face). Participants rated the valence of the faces, and we conducted two sets of analyses of this data. In the first analysis, we used the raw valence as a dependent variable. In the second set of analyses, we used the valence ratings to calculate accuracy for the ratings of the positive and negative faces. All data and stimuli are available on OSF (https://osf.io/bjuqm/).

Participants

We recruited 206 participants via Prolific Academic (98 women, 79 men, and 29 no gender reported due to an error in presenting the questions; the most common countries represented in our sample were Mexico, South Africa, United States, United Kingdom, and Portugal). They were compensated $5. The Human Subjects Research Review Committee at Occidental College (HSRRC-IRB) approved the study.

Stimuli

We created the stimuli by inducing negative and positive emotions in a group (N=93) of undergraduate students via Zoom while they were both masked and unmasked. Each participant was interviewed by an experimenter and asked to respond to prompts designed to elicit positive, neu-

tral, or negative emotions (e.g., positive: “Talk about a time when you did something kind for another person or when someone did something nice for you. How did they react? How did you feel?”, neutral: “What are you currently reading for class?”, and negative: “Describe a negative situation, caused by someone else, in which you experienced an extremely intense emotional response. For example, a time you have been cheated, lied to, labeled, or blamed unfairly. How did or does that make you feel?”). They answered one set of questions while masked, and a different set of questions while unmasked; order was randomized across participants for both the variables of masking and emotional valence. Interviews were conducted in a consistent way by three of the undergraduate coauthors. The interviews were then assessed frame-by-frame by multiple members of the research team to identify moments of most intense expression for each participant in each of the six conditions. For all expression types (positive/negative/neutral), at least two frames were selected per individual. The selected frames were edited to focus on the face. These images were used in the uncropped condition. For the cropped condition, the images were further edited so that the regions of the face that normally would be covered by a mask were cropped out. To ensure that participants would not be able to determine whether the depicted individual was masked or unmasked, all images were cropped in the same way. To select the final stimulus set, five members of the research team rated images by categorizing them as positive, negative, or neutral, as well as to rate how intense the emotion was. Only stimuli that were correctly classified by at least three team members for all three expression types were included in the final stimulus set. The final stimulus set included 19 unique individuals (gender: 3 males, 13 females, 3 nonbinary; race/ethnicity: 6 Asian, 6 Latinx, 2 Black, 2 White) expressing positive, neutral, and negative emotions while masked and unmasked, with a total of 228 images (114 cropped and 114 uncropped). Figure 1 shows sample stimuli. The final stimulus set is available on OSF (https://osf.io/74jbu/).



Figure 1.

Sample masked and cropped images displaying positive, neutral, and negative conditions, respectively.

Procedure

Participants (N=102 for cropped condition; N=104 for uncropped condition) gave informed consent, and then were instructed to rate the valence of each emotional face using a scale that ranged from −10 to 10, with −10 labeled as negative, 0 labeled as neutral, and + 10 labeled as positive. They then answered a survey about their own mask exposure and wearing, and finally answered demographic questions. For a small number of participants, the mask exposure questions were not initially displayed, but the majority of those participants answered the additional questions the same day for an extra $1.25 in compensation. Most participants completed the study in less than 20 min.

Results

We assessed how masking affected expression perception of positive, negative, and neutral faces. Our primary dependent measures were valence ratings, measured on a scale from −10 (most negative) to + 10 (most positive), and accuracy (measured as the percentage of correct responses; this metric was not applied to neutral faces). A response was marked as correct when participants' valence ratings aligned with the intended expression valence. For example, if participants were shown an image of a face expressing a positive emotion, any rating above 0 would be marked as correct, whereas a rating below 0 would be marked as incorrect. Average valence ratings and accuracy scores across all stimuli in each category were computed for each participant. Statistics were conducted using JASP (https://jasp-stats.org/).

For valence ratings, we ran a mixed 3 × 2 × 2 ANOVA with emotion (positive, neutral, and negative) and masking (mask, no mask) as within-subjects variables and cropping (full face, upper face only) as a between-subjects variable (Figure 2). Where sphericity assumptions were not met, we report Greenhouse–Geisser corrections. First, there was a main effect of emotion ($F(1.191, 203) = 694.444$, $p < .001$, $\eta_p^2 = 0.773$) such that positive faces were rated as significantly more positive than both neutral and negative faces ($t(204) > 30.95$, $p_{holm} < 0.001$, Cohen's $d > 2.16$). Although negative faces were rated as significantly more negative than neutral faces ($t(204)=2.53$, $p_{holm} = 0.012$, Cohen's $d = 0.18$), the effect was quite small. This could be because negative emotions like anger were harder to induce or that naturalistic negative emotions like anger are a more subtle expression than naturalistic happiness. There was also a significant three-way interaction ($F(1.809, 368.958) = 41.78$, $p < .001$, $\eta_p^2 = 0.170$). Of particular interest is that positive faces were the most affected by masking. As predicted, participants rated the valence of positive masked faces similarly whether or not they were shown the full face which included the mask, or the upper face only where they were unaware that a mask was being worn ($t(204) = 1.812$, $p_{holm}=0.602$, $M_{diff} = −0.434$, 95% CI [−1.245, 0.377]). However, unmasked positive faces were rated as significantly less positive when only the upper face was shown relative to when the full face was shown ($t(204) = 8.320$, $p_{holm} < 0.001$, $M_{diff} = −1.993$, 95% CI [−2.804, −1.183]); this is consistent with the notion that the mouth conveys a portion of the positive signal. Crucially, masking dampened expression perception of positive faces both when full faces were shown ($t(204) = 20.967$, $p_{holm} < .001$, $M_{diff} = −2.686$, 95% CI [−3.120, −2.252] and when only the upper face was shown ($t(204) = 8.709$, $p_{holm} < .001$, $M_{diff} = −1.216$, 95% CI [−1.565, −.688]). Since participants in the upper face only condition were unaware of whether the person was masked or not, the fact that there is a significant difference between the two masking conditions suggests that the amount of positive signal within the eyes varies depending on if the depicted person was masked. In contrast to our hypothesis that

masking may increase expressivity, these data suggest that masking actually makes people less expressive (or potentially less happy). Neutral and negative faces were not impacted by masking or cropping in the same way. This is consistent with past results that suggest much of the perception of happy faces is contained within the lower half of the face in the smile, whereas anger is more in the eyes, forehead, and eyebrows.

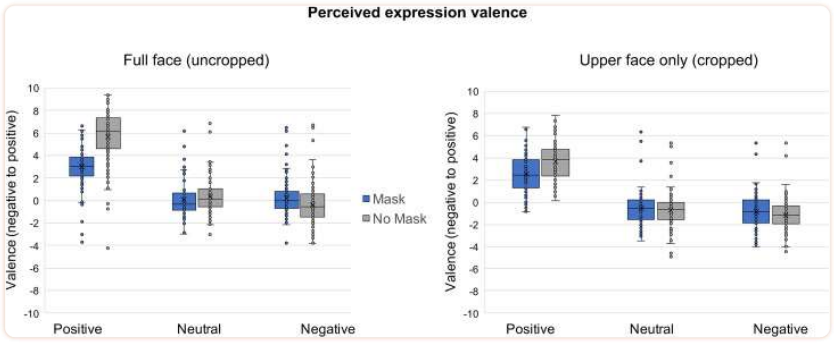


Figure 2.

Perceived valence for uncropped (left panel) and cropped (right panel) positive, neutral, and negative faces. Blue bars (left bars) are masked faces and gray bars (right bars) are unmasked faces.

For average accuracy scores, we ran a mixed 2 × 2 × 2 ANOVA with emotion (positive, negative) and masking (mask, no mask) as within-subjects variables and cropping (full face, upper face only) as a between-subjects variable (Figure 3). Again, there was a significant main effect of emotion such that positive faces were correctly identified more often than negative faces ($F(1, 204) = 333.28$, $p < .001$, $\eta_p^2 = 0.620$). This is consistent with the valence ratings, showing that there was more confusion in rating and identifying negative emotions than positive emotions. There was also the main effect of masking such that masked faces were more difficult to identify than unmasked faces, regardless of emotion ($F(1, 204) = 164.697$, $p < .001$, $\eta_p^2 = 0.447$). Similarly to the valence ratings, we observed a significant interaction between emotions and masking ($F(1, 204) = 13.556$, $p < .001$, $\eta_p^2 = 0.462$) indicating that masking affected accuracy more for positive faces than for negative faces. Moreover, an interaction between masking and cropping ($F(1, 204) = 14.127$, $p < .001$, $\eta_p^2 = 0.065$) demonstrates that masking led to accuracy differences moreso when full faces were shown. There was no significant three-way interaction ($F(1, 204) = 0.022$, p=.882).

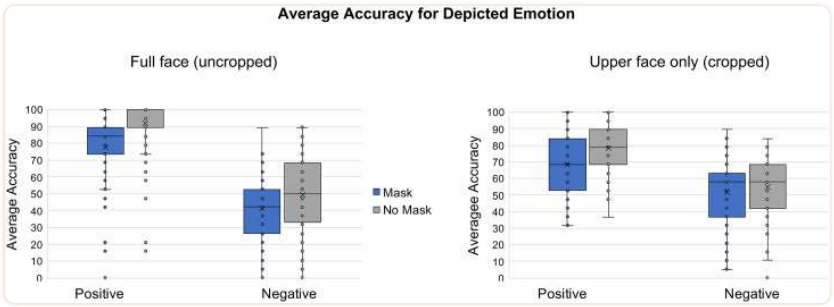


Figure 3.

Mean accuracy for uncropped (left panel) and cropped (right panel) positive and negative faces. Blue bars (left bars) are masked faces and gray bars (right bars) are unmasked faces.

We had originally hypothesized that participants who are exposed to more mask wearing might be better at extracting emotional information from cropped and masked faces than participants with less exposure to masked faces. Interestingly, the participants in the full face (cropped) compared to the upper-face only (uncropped) experiments had very different reports of their own mask use and that of others. Specifically, those in the full face experiment reported more mask wearing than those in the upper face only experiment, though other demographics of the samples were similar (age, country, gender, and ethnicity). This may suggest that exposure within the experiment to people wearing masks influences people's retrospective memories, such that seeing others in masks leads you to overestimate your own mask wearing habits. We thus did not further investigate the relationship between reports of mask-wearing and emotional perception.

Discussion

The present study investigated the extent to which masks impair emotion recognition and the intensity of perceived expressions. Because of the increased prevalence of masks, we hypothesized that people would compensate for the emotion-dampening nature of masks by exaggerating their expressions in their upper face. To test this, we asked participants to rate the emotional intensity of naturalistic images depicting masked and unmasked individuals expressing positive, negative, and neutral emotions. Whereas previous research exclusively used images or videos of masks superimposed on individuals expressing specific emotions, we created our stimuli by inducing emotions in individuals over Zoom while they were masked and unmasked. This approach has the advantage of better characterizing people's natural emotional expressions while masked, especially as face coverings may on their own inhibit expression production. Moreover, we validated that participants' emotion ratings were not biased by the knowledge of whether the individual was masked by comparing ratings of full-face images to cropped images depicting only the upper face.

We found that masks impaired the recognition of and intensity of positive, but not negative emotions. This effect was evident both when the full face was shown and when participants only saw the upper face and could not determine whether the individual was masked or unmasked. Contrary to our hypothesis, people wearing masks did not compensate by exaggerating their emo-

tional expressions; instead, masked positive faces were actually rated as less positive than unmasked positive faces even when the lower part of the face was not visible. This could be due to masks dampening positive emotion (e.g., people feel less happy when wearing a mask), and/or to masks reducing expressivity of positive emotion (e.g., facial expressions might be diminished while wearing a mask). Thus, mask wearing might lead to both reduced expression of positive emotion as well as underestimation of positive emotion. The fact that masks did not affect perception of negative faces is also consistent with prior research. In particular, prior work suggests masks affect emotions like happiness because it relies on the mouth more than anger and disgust which rely on the eyes and eyebrows. Another possibility is that we didn't see an effect of masking because of the specific stimuli we employed. Notably, the negative emotion ratings were less intense than the positive ratings, and participants were significantly less accurate in categorizing negative emotions relative to positive ones, irrespective of masking. This could mean that our method for inducing negative emotions was less powerful than our method for inducing positive emotions. Alternatively, it could be that naturalistic, everyday negative emotions like anger are more subtle than naturalistic happiness. It is possible that with a more robust induction of negative emotions, we would see a more robust effect of masking.

There are also additional interesting avenues worth expanding on that were outside of the scope of the present study. First, it is possible that people do exaggerate their emotional expressions, but this effect is modulated by social factors such as increased exposure to masks, increased likelihood of wearing masks while engaged in social interactions, and increased empathy and compassion for others. Recent research suggests that increased exposure to masks improves people's ability to perceive emotional expressions in others (Barrick et al., 2021) and this might similarly extend to emotion production. Second, dynamic displays rather than static images may show the effects of masking on both production and perception more robustly. Computational techniques using dynamic displays might be especially useful in discriminating small signal differences between masked and unmasked expressions (e.g., Murugappan & Mutawa, 2021).

Footnotes

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Oppose 216-RICR-30-05-4

Denise Champney <dchampney996@gmail.com>
Tue 2/13/2024 11:05 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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This message came from outside your organization.
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Hello,
I am writing in strong opposition to 216-RICR-30-05-4. I am a speech language pathologist with over 25 years experience and a focus on social skill and language development. As an SLP, I have specific knowledge and expertise in the area of language and communication. I have witnessed first hand the harms that pandemic policies such as masking have had on children's social, emotional and educational development. Kids suffer when required to wear masks as well as when adults wear masks communicating with them.

The Cochrane Review, a gold-standard of review of medical data, indicated in their meta analysis of numerous research: "Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence." Simply stated - masks do nothing. Not only is there no scientific evidence to support masking, there is significant harm caused to children by masking.

A study, *Effect of face mask and noise on word recognition by children and adults* [academia.edu] by Anna Sfakianaki and George Kafaentzis reveal "Preliminary results indicate that word identification is significantly compromised when produced with a surgical face mask, with more pronounced negative effects for children listening in noise." Also, the article, Effect of face masks on speech understanding: A clinical perspective during speech audiometry [pubmed.ncbi.nlm.nih.gov] found "However, as the signal-to-noise ratio decreased, even the surgical, cloth, and N95 masks significantly impacted the word recognition score even in normal-hearing individuals." Another article: COVID-19 Face Masks, and Social Interaction: How a GlobImpact of COVID-19al Pandemic Is Shining a Light on the Importance of Face-to-Face Communication [researchgate.net], discusses the negative impacts that restrictions and mandates have had on children due to disruptions of face to face communication.

Also, there is decades worth of literature that highlights the importance of social interaction, especially for young children. Research conducted in 2012 [webmail.chariho.k12.ri.us]Neural Synchronization during Face-to-Face Communication [jneurosci.org] reported that "findings suggest that face-to-face communication has important neural features that other types of communication lack, and also that people should take more time to communicate face-to-face".

Please oppose 216-RICR-30-05-4 and do not allow our children to be masked again. Children suffered significantly during the pandemic, we need to recognize errors made in the past and never allow them to happen again.

Sincerely,

Denise Champney MS CCC/SLP

Effect of face mask and noise on word recognition by children and adults

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Abstract

Previous studies have shown that noise has a detrimental effect on speech intelligibility and language comprehension, more so for children than adults. Furthermore, the mandatory use of face masks due to the COVID-19 pandemic presents an additional communication and learning barrier. The current study investigates the effect of face mask on low frequency word recognition in quiet and noise by adults and, more importantly, by young children who just completed the first grade of primary school. Preliminary results indicate that word identification is significantly compromised when produced with a surgical face mask, with more pronounced negative effects for children listening in noise. Implications on new word recognition and learning by first graders in noisy classrooms with compulsory mask usage are considered.

Keywords: face masks, noise, word recognition, children, adults

Introduction

A lot of research has been conducted on the speech perception abilities of children vs adults in adverse listening conditions (for a review, see Leibold & Buss, 2019), as understanding speech in noise is an everyday challenge for children in school settings and has a negative impact on learning (Erickson & Newman, 2017). There is consensus that children face greater difficulty recognising and understanding speech in background noise relative to adults, with competing speech posing a greater obstacle than white or speech-shaped noise (Corbin et al., 2016). Apart from noise, the use of face masks that has been mandated in educational institutions and other indoor spaces, presents an added barrier to speech recognition and communication (Toscano & Toscano, 2021).

Although the effect of noise and face mask on speech perception has been investigated for adults, to the best of our knowledge, there are no studies regarding children. Thus, the current paper investigates the influence of mask and noise on word recognition in adults and typically developing primary school children with normal hearing. Low frequency words were selected, as later acquired words have been shown to provide greater insight between linguistic knowledge and masked speech recognition (Leibold & Buss, 2019).

Methodology

Twenty six listeners, fourteen adults and twelve children were recruited for the study. Adults were aged 19 to 51 years old and children were aged 6;8 to 7;6 (years;months) and had just completed the first grade of primary school. All participants underwent formal audiological testing to ensure normal hearing, and two adults were excluded due to moderate hearing loss at high frequencies. All subjects had no reported speech, language and learning difficulties. Two adults and two children took part in a pilot experiment so as to choose a suitable SNR (signal-to-noise ratio) level for each type of noise and age group. Ten adults and ten children participated in the main experiment. All testing took place in the sound proof booth of the Speech Signal Processing Laboratory of the Computer Science Department of the University of Crete and was approved by the University Research Ethics Committee.

Listener performance reported in the present paper was based on linguistic material that included 250 low frequency words selected from the lexical database Greeklex 2 (Kyparissiadis et al., 2017) which were expected to be unfamiliar to first graders. The words were embedded in the carrier phrase «Πες τη λέξη …» ("Say the word …"). The material was recorded twice in quiet by a female primary school teacher, once wearing a surgical face mask and once with no mask. Two types of noise were selected, real classroom noise and two-talker noise. Classroom noise (CN) was recorded inside a real classroom of a local primary school. Two-talker noise (TTN) was a mixture of two female speakers, each recorded separately reading a different children's literature excerpt. According to the pilot experiment, children required higher SNR levels to reach adult performance (Leibold & Buss, 2019) and TTN posed a greater obstacle as documented in other studies (Corbin et al., 2016). Based on the pilot results, a single SNR level for each noise condition and age group was selected: 0 dB for adults and 2.5 dB for children for CN, and 5 dB for adults and 7.5 dB for children for TTN. A MATLAB algorithm was created in order to mix clean stimuli with the chosen SNR levels and randomise them for every listener.

For the main experiment, ten adults and ten children, five male and five female in each group, listened to 40 stimuli in each noise type, half produced with mask and half without mask, and afterwards the same words were presented in quiet, in the same mask condition as presented in noise. Thus each listener was tested on 160 words in total in three different sessions: one session in CN, one in TTN and one in quiet. A single loudspeaker was placed in front of the listener, at a radial distance of 0.9 m. Each mixture was presented at approximately 65 dB SPL. Listeners' responses were recorded using Audacity and were rated by the first author. Any response that did not exactly match the original word was marked as incorrect.

Results

Mixed Analysis of Variance (ANOVA) was used for the statistical treatment of the data. Participant score was analysed vs age group, gender, noise type and mask. All factors except gender were found statistically significant (age group: df=1, F=7.059, p=0.009; gender: df=1, F=0.163, p=0.687; noise type: df=2, F=325.8, p<0.001; mask: df=1, F=4.077, p=0.0463).

Both children and adults showed significantly better performance in the no mask (children: mean: 57.67%, SD: 24.89%, adults: mean: 60.67%, SD: 28.00%) than in the mask condition (children: mean: 51.50%, SD: 29.02%, adults: mean: 58.92%, SD: 27.65%). Also, children performed significantly worse than adults. Although the mask seems to impede children's performance more than that of adults (score reduction: 6.17% for children vs 1.75% for adults), the mask*age group interaction did not reach stat. significance (df=1, F=1.269, p=0.2628).

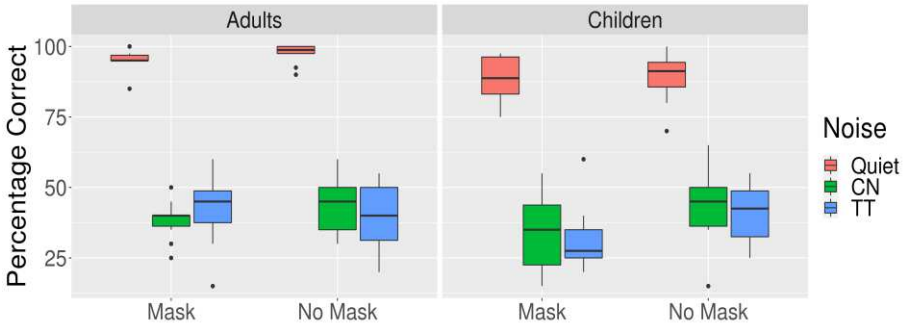


Figure 1. Percentage of correct responses for adults (left) and children (right) in the mask vs no mask condition and in quiet vs two noise types.

Among the three conditions, according to Tukey post-hoc tests, performance in quiet was significantly higher than in the two noise types (quiet vs. CN, p<0.001, quiet vs. TTN, p<0.001). No sig. differences were located between the two noise types (CN vs TTN, p = 0.862) which was expected due to the +5 SNR advantage in the TTN condition. A trend for worse performance by children than adults in the mask condition, and especially in TTN noise (children: mean: 31.50%, SD: 12.03%, adults: mean: 43.00%, SD: 13.58%), was manifested, although the interaction age group*mask*noise did not reach statistical significance (df=2, F=1.161, p=0.318).

Discussion

The pilot study confirms that children require higher SNR levels to reach adult performance (Leibold & Buss, 2019). Even with a +2.5 dB advantage, children still perform significantly worse than adults in the main experiment. TTN has been documented as a greater obstacle in relation to steady-state noise maskers

(Corbin et al., 2016); the pilot study exhibits that the same applies to TTN vs classroom noise (CN). The results of the main experiment demonstrate that recognition of low frequency words produced with a surgical mask is significantly lower for both children and adults in quiet and noise. This is an interesting finding as surgical masks have been reported to cause the least acoustic attenuation in comparison with other types of masks (Bottalico et al., 2020; Toscano & Toscano, 2021). The investigation of this matter, especially for children, is of great importance as auditory word recognition has an impact on language processing, the acquisition of new vocabulary and the development of the reading skill (Snowling et al., 1986). The choice of linguistic material (e.g. frequency of selected words or use of sentences vs individual words), as well as type of face mask are two significant factors in masked speech recognition (Vos et al., 2021). Thus, the trend for children's lower performance in the mask condition manifested in the present study should be investigated further, taking into account the aforementioned factors and including more child participants as well as participants with hearing or language impairments.

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J Otol. 2022 Jul;17(3):140-145. doi: 10.1016/j.joto.2022.04.004. Epub 2022 Apr 29.

Effect of face masks on speech understanding: A clinical perspective during speech audiometry

Rawish Kumar [1], Sanjay Kumar Munjal [1], Anuradha Sharma [1], Md Noorain Alam [1], Naresh K Panda [1]

Affiliations

PMID: 35847571 PMCID: PMC9270560 DOI: 10.1016/j.joto.2022.04.004

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Abstract

The objective was to measure the effect of various face masks on speech recognition threshold and the word recognition score in the presence of varying background noise levels. 20 normal-hearing adult subjects (a total of 40 ears) participated. Pure tone audiometry followed by speech recognition threshold and word recognition score at the most comfortable level in varying signal-to-noise ratios (SNR0, SNR10, and SNR15) using surgical, pleated cloth, and N95 masks. Using surgical, cloth, and N95 masks, speech recognition thresholds increased by 1.8 dB, 4.4 dB, and 5.05 dB, respectively. Word recognition scores decreased by 32% without a mask, 43.7% in a surgical mask, 46.3% in a cloth mask, and 46.7% in N95 mask conditions, between SNR15 and SNR0. The speech recognition threshold was negatively affected with cloth and N95 masks. Surgical masks do not affect the word recognition scores at lower background noise levels. However, as the signal-to-noise ratio decreased, even the surgical, cloth, and N95 masks significantly impacted the word recognition score even in normal-hearing individuals.

Keywords: Communication; Face masks; Signal-to-noise ratio; Speech recognition threshold; Word recognition score.

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Figures

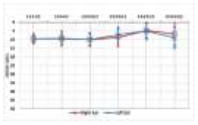


Fig. 1 Audiogram, Average Hearing Threshold at...

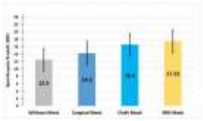


Fig. 2 Mean SRT (in dBHL) of...

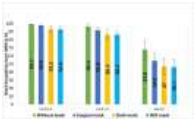


Fig. 3 Measures of WRS (in %)...

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Neural Synchronization during Face-to-Face Communication

Jing Jiang, Bohan Dai, Danling Peng, Chaozhe Zhu, Li Liu, and Chunming Lu
State Key Laboratory of Cognitive Neuroscience and Learning, Beijing Normal University, Beijing 100875, P.R. China

Although the human brain may have evolutionarily adapted to face-to-face communication, other modes of communication, e.g., telephone and e-mail, increasingly dominate our modern daily life. This study examined the neural difference between face-to-face communication and other types of communication by simultaneously measuring two brains using a hyperscanning approach. The results showed a significant increase in the neural synchronization in the left inferior frontal cortex during a face-to-face dialog between partners but none during a back-to-back dialog, a face-to-face monologue, or a back-to-back monologue. Moreover, the neural synchronization between partners during the face-to-face dialog resulted primarily from the direct interactions between the partners, including multimodal sensory information integration and turn-taking behavior. The communicating behavior during the face-to-face dialog could be predicted accurately based on the neural synchronization level. These results suggest that face-to-face communication, particularly dialog, has special neural features that other types of communication do not have and that the neural synchronization between partners may underlie successful face-to-face communication.

Introduction

Theories of human evolution converge on the view that our brain is designed to cope with problems that occurred intermittently in our evolutionary past (Kock, 2002). Evidence further indicates that during evolution, our ancestors communicated in a face-to-face manner characterized by a behavioral synchrony via facial expressions, gestures, and oral speech (Boaz and Almquist, 1997). Plausibly, many of the evolutionary adaptations of the brain for communication involve improvements in the efficiency of face-to-face communication. Today, however, other communication modes, such as telephone and e-mail, increasingly dominate the daily lives of many people (RoAne, 2008). Modern technologies have increased the speed and volume of communication, whereas opportunities for face-to-face communication have decreased significantly (Bordia, 1997; Flaherty et al., 1998). Thus, it would be interesting to determine the unique neural mechanistic features of face-to-face communication relative to other types of communication.

Two major features distinguish face-to-face communication from other types of communication. First, the former involves the integration of multimodal sensory information. The partner's nonverbal cues such as orofacial movements, facial expressions, and gestures can be used to actively modify one's own actions and speech during communication (Belin et al., 2004; Corina and Knapp, 2006). Moreover, infants show an early specialization of the cortical network involved in the perception of facial communication cues (Grossmann et al., 2008). Alteration of this integration can result in interference in speech perception (McGurk and MacDonald, 1976).

Another major difference is that face-to-face communication involves more continuous turn-taking behaviors between partners (Wilson and Wilson, 2005), a feature that has been shown to play a pivotal role in social interactions (Dumas et al., 2010). Indeed, turn-taking may reflect the level of involvement of a person in the communication. Research on nonverbal communication has shown that the synchronization of the brain activity between a gesturer and a guesser was affected by the level of involvement of the individuals involved in the communication (Schippers et al., 2010).

Despite decades of laboratory research on a single brain, the neural difference between face-to-face communication and other types of communication remains unclear, as it is difficult for single-brain measurement in a strictly controlled laboratory setting to reveal the neural features of communication involving two brains (Hari and Kujala, 2009; Hasson et al., 2012). Recently, Stephens et al. (2010) showed that brain activity was synchronized between the listener and speaker when the speaker's voice was aurally presented to the listener. Furthermore, Cui et al. (2012) established that functional near-infrared spectroscopy (fNIRS) can be used to measure brain activity simultaneously in two people engaging in nonverbal tasks, i.e., fNIRS-based hyperscanning. Thus, the current study used fNIRS-based hyperscanning to examine the neural features of face-to-face verbal communication within a naturalistic context.

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Author contributions: J.J., D.P., and C.L. designed research; J.J. and B.D. performed research; J.J., B.D., C.Z., and C.L. analyzed data; J.J., L.L., and C.L. wrote the paper.

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The authors declare no financial conflicts of interest.

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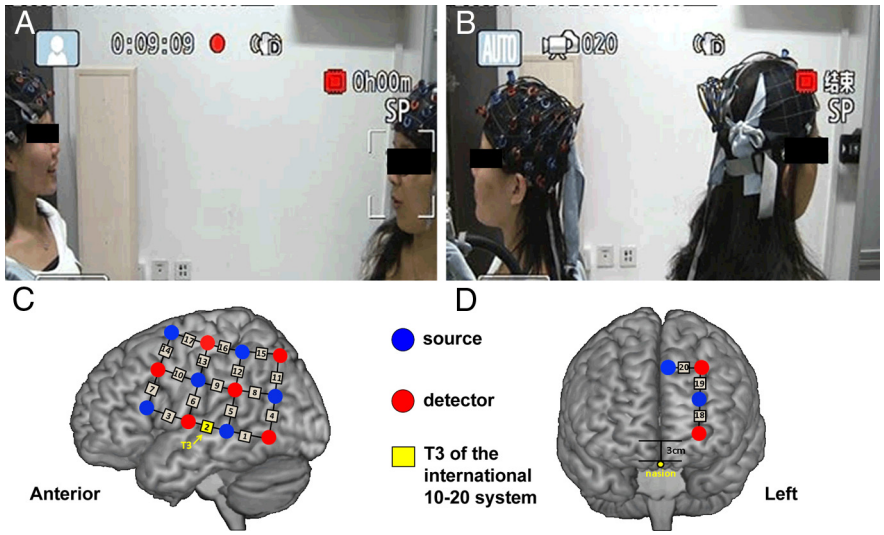


Figure 1. Experimental procedures. ***A***, Face-to-face communication. ***B***, Back-to-back communication. ***C***, The first optode probe set placed on the frontal, temporal, and parietal cortices. ***D***, The second optode probe set placed on the dorsal lateral prefrontal cortex.

Materials and Methods

Participants

Twenty adults (10 pairs, mean age: 23 ± 2) participated in this study. There were four male–male pairs and six female–female pairs, and all pairs were acquainted before the experiment. The self-rated acquaintance level did not show significant differences between the partners ($t_{(18)} = -0.429$, $p = 0.673$). Written informed consent was obtained from all of the participants. The study protocol was approved by the ethics committee of the State Key Laboratory of Cognitive Neuroscience and Learning, Beijing Normal University.

Tasks and procedures

For each pair, an initial resting-state session of 3 min served as a baseline. During this session, the participants were required to keep still with their eyes closed, relax their mind, and remain as motionless as possible (Lu et al., 2010).

Four task sessions immediately followed the resting state session. The four tasks were as follows: (1) face-to-face dialog (f2f_d), (2) face-to-face monologue (f2f_m), (3) back-to-back dialog (b2b_d), and (4) back-to-back monologue (b2b_m). It was assumed that the comparison between f2f_d and b2b_d would reveal the neural features specific to multimodal sensory information integration, and that the comparison between f2f_d and f2f_m would reveal the neural features specific to continuous turn-taking during communication. b2b_m served as a control. The sequence of the four task sessions was counterbalanced across the pairs. For each task session, there were two 30 s resting-state periods located at the beginning and ending phases to allow the instrument to reach a steady state. The overall procedures were video recorded.

The pairs of participants sat face-to-face during f2f_d and f2f_m (Fig. 1*A*); during b2b_d and b2b_m, they sat back-to-back and could not see each other (Fig. 1*B*). Two hot news topics were used during f2f_d and b2b_d and the participants were asked to talk with each other about the topic for 10 min. The sequence of the two topics was counterbalanced across the pairs. An assessment of the familiarity level of the topics was performed using a five-point scale (1 representing the lowest level, and 5 representing the highest level). No significant differences were found between f2f_d and b2b_d ($t_{(19)} = -0.818$, $p = 0.434$) or between partners, either during f2f_d ($t_{(18)} = -0.722$, $p = 0.48$) or b2b_d ($t_{(18)} = -0.21$, $p = 0.836$). Additionally, the participants were allowed to use gestures and/or expressions if they so chose during the dialogs.

Immediately after f2f_d and b2b_d, the participants were required to assess the quality of their communication using the five-point scale described above. A significant difference in the assessment scores between f2f_d and b2b_d ($t_{(9)} = 2.449$, $p = 0.037$) was found for the quality of the communication, but no significant difference in the assessment scores was found between the two partners for either f2f_d ($t_{(18)} = 1.342$, $p = 0.196$) or b2b_d ($t_{(18)} = 1.089$, $p = 0.291$). These results suggested that f2f_d represented a higher quality of communication than b2b_d and that the two participants of the pair had comparable opinions about the quality of their communication.

During f2f_m and b2b_m, one of the participants was required to narrate his/her life experiences to his/her partner for 10 min, while the partner was required to keep silent during the entire task and not to perform any nonverbal communication. The sequence of narrators was balanced across the pairs. To ensure the listeners attended to the speakers' speech during these tasks, the participants were required to repeat the key points of the speaker's monologue immediately after the task. All of the participants were able to repeat the key points adequately.

fNIRS data acquisition

The participants sat in a chair in a silent room during the fNIRS measurements, which were conducted using an ETG-4000 optical topography system (Hitachi Medical Company). A group of customized optode probe sets was used. The probe was placed only on the left hemisphere because it is well established that the left hemisphere is dominant for the language function and that the left inferior frontal cortex (IFC) and inferior parietal cortex (IPC) form the most thoroughly studied nodes of the putative mirror neuron system for joint actions, including verbal communication (Rizzolatti and Craighero, 2004; Stephens et al., 2010).

Two optode probe sets were used on each participant in each pair. Specifically, one 3 × 4 optode probe set (six emitters and six detector probes, 20 measurement channels, and 30 mm optode separation) was used to cover the left frontal, temporal, and parietal cortices. Channel 2 (CH2) was placed just at T3, in accordance with the international 10-20 system (Fig. 1*C*). Another probe set (two emitters and two detectors, 3 measurement channels) was placed on the dorsal lateral prefrontal cortex (Fig. 1*D*). The probe sets were examined and adjusted to ensure the consistency of the positions between the partners of each pair and across the participants.

The absorption of near-infrared light at two wavelengths (695 and 830 nm) was measured at a sampling rate of 10 Hz. Based on the modified Beer–Lambert law, the changes in the oxyhemoglobin (HBO) and deoxyhemoglobin concentrations were obtained for each channel. Because previous studies showed that HBO was the most sensitive indicator of changes in the regional cerebral blood flow in fNIRS measurements, this study only focused on the changes in the HBO concentration (Cui et al., 2012).

Imaging data analysis

Synchronization. During preprocessing, the initial and final periods of the data were removed, leaving 500 s of task data. Wavelet transform coherence (WTC) was used to assess the relationships between the fNIRS signals generated by a pair of participants (Torrence and Compo, 1998). As previously indicated (Cui et al., 2012), WTC can be used to measure the cross-correlation between two time series as a function of both frequency and time (for more details about WTC, see Grinsted et al., 2004). We used the wavelet coherence MatLab package (Grinsted et al., 2004). Specifically, for each CH from each pair of participants during f2f_d, two HBO time series were obtained simultaneously. WTC was applied to the two time series to generate a 2-D coherence map. According to Cui et al. (2012), the coherence value increases when there are cooperative tasks between partners, but decreases when there are no tasks, i.e., resting-state condition. Based on the same rationale, the average coherence value between 0.01 and 0.1 Hz was then calculated to remove the high- and low-frequency noise. Finally, the coherence value was time-averaged.

The same procedure was applied to the other conditions (f2f_m, b2b_d, b2b_m, and resting state).

The averaged coherence value in the resting-state condition was subtracted from that of the communication conditions, and the difference was used as an index of the neural synchronization increase between the partners. For each channel, after converting the synchronization increase into a z value, we performed a one-sample t test on the z value across the participant pairs and generated a t-map of the neural synchronization [$p < 0.05$, corrected by false discovery rate (FDR)]. The t-map was smoothed using the spline method.

Validation of the synchronization. To verify that the neural synchronization increase was specific for the pairs involved in the communication, the data for the 20 participants were randomly paired so that each participant was paired to a new partner who had not communicated with him/her during the task. The analytic procedures described above were applied to these new pairs. It was assumed that no significant synchronization increase would be found for any of the four communication conditions.

Contribution to the synchronization. The CHs that showed significant synchronization increases during f2f_d compared with the other types of communication were selected for further analysis to examine whether face-to-face interactions between the partners contributed to the neural synchronization. First, to identify the video frames corresponding to the coherence time points, the time course of the coherence values was downsampled to 1 Hz. Second, for each pair of participants, the videos for f2f_d and b2b_d were analyzed as follows: the time points of the video showing the interactions between partners, i.e., turn-taking behavior, body language (including orofacial movements, facial expressions, and gestures), were marked; and the coherence values that corresponded and those that did not correspond to these time points were separately averaged to obtain two indexes, one for synchronization that occurred during the interaction (SI) and another for synchronization that did not occur during the interaction (SDI). Finally, SI and SDI were compared across the pairs using a two-sample t test for each of the two tasks.

Prediction of communicating behavior. The predictability of communicating behavior on the basis of neural synchronization during f2f_d was examined. Equal numbers of SI and SDI data points were randomly selected from the identified CHs. The coherence value was used as the classification feature, whereas the SI and SDI marks were used as the classification labels. Fisher linear discrimination analysis was used and validated with the leave-one-out cross-validation method. Specifically, for a total of N samples, the leave-one-out cross-validation method trains the classifier N times; each time, a different sample is omitted from the training but is then used to test the model and compute the prediction accuracy (Zhu et al., 2008). For the outputs, the sensitivity and specificity indicated the proportions of SI and SDI that were correctly predicted, whereas the generalization rate indicated the overall proportions of SI and SDI that were correctly predicted.

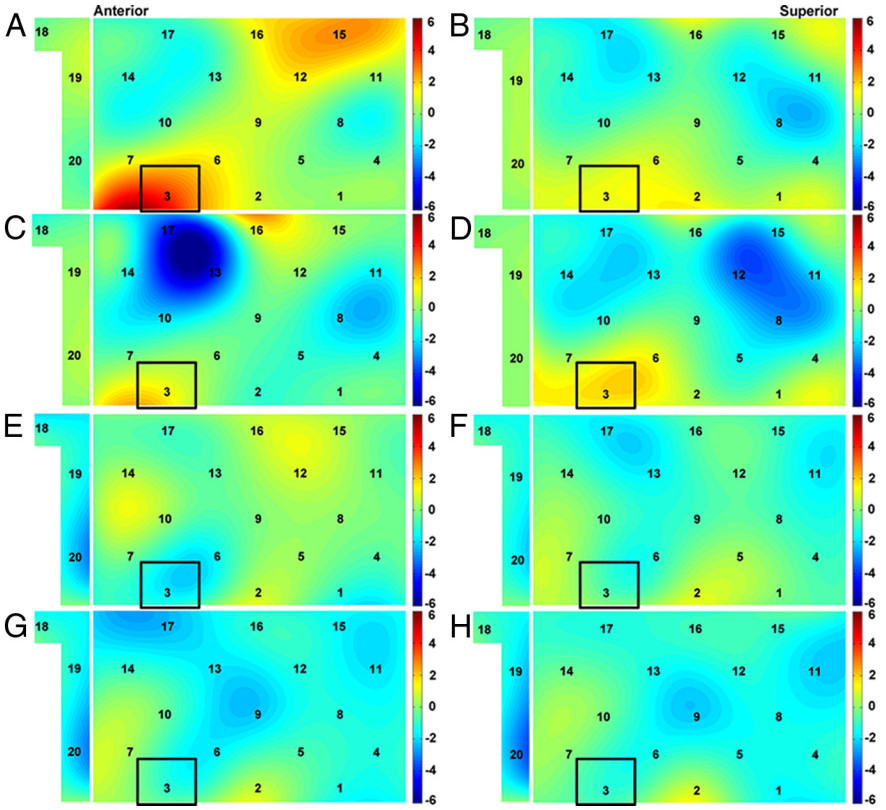


Figure 2. Neural synchronization increase. t-maps are for the original pairs (***A–D***), random pairs (***E–H***), face-to-face dialog (***A***, ***E***), face-to-face monologue (***B***, ***F***), back-to-back dialog (***C***, ***G***), and back-to-back monologue (***D***, ***H***). The warm and cold colors indicate increases and decreases in neural synchronization, respectively. The black rectangle highlights CH3, showing a significant increase in neural synchronization during the face-to-face dialog.

Results

Synchronization during communication

During f2f_d, a higher synchronization was found in CH3 than during the resting-state condition, suggesting a neural synchronization increase in CH3 during f2f_d (Fig. 2*A*). As shown in Figure 1*C*, CH3 covered the left IFC.

No significant neural synchronization increase was found during b2b_d, f2f_m, or b2b_m (Fig. 2*B–D*). Thus, the increase of neural synchronization in the left IFC (i.e., CH3) was specific for the face-to-face communication.

A further analysis of CH3, which showed a significant neural synchronization increase during f2f_d, showed that the synchronization increase during f2f_d differed significantly from that during b2b_d ($t_{(9)} = 4.475$, $p = 0.002$), but did not differ from that during f2f_m ($t_{(9)} = 1.547$, $p = 0.156$) or b2b_m ($t_{(9)} = 1.85$, $p = 0.097$) after an FDR correction at the $p < 0.05$ level.

In addition, during b2b_d, a lower synchronization was found in CH13 than during the resting-state condition (Fig. 2*C*). However, the synchronization of CH13 during b2b_d did not differ significantly from any other condition after an FDR correction at the $p < 0.05$ level (f2f_d: $t_{(9)} = 2.877$, $p = 0.018$; f2f_m: $t_{(9)} = 1.198$, $p = 0.262$; b2b_m: $t_{(9)} = -0.474$, $p = 0.647$).

Validation of the synchronization

No CHs showed a significant increase in neural synchronization between the randomly paired participants under any of the four communication conditions (Fig. 2*E–H*).

Contribution to the synchronization

To specify which characteristics of f2f_d contributed to the neural synchronization in the left IFC (i.e., CH3), we further examined the time course of the coherence value for each pair of participants. Two raters independently coded the SI and SDI for the video of each pair. The intraclass reliability was 0.905 for f2f_d

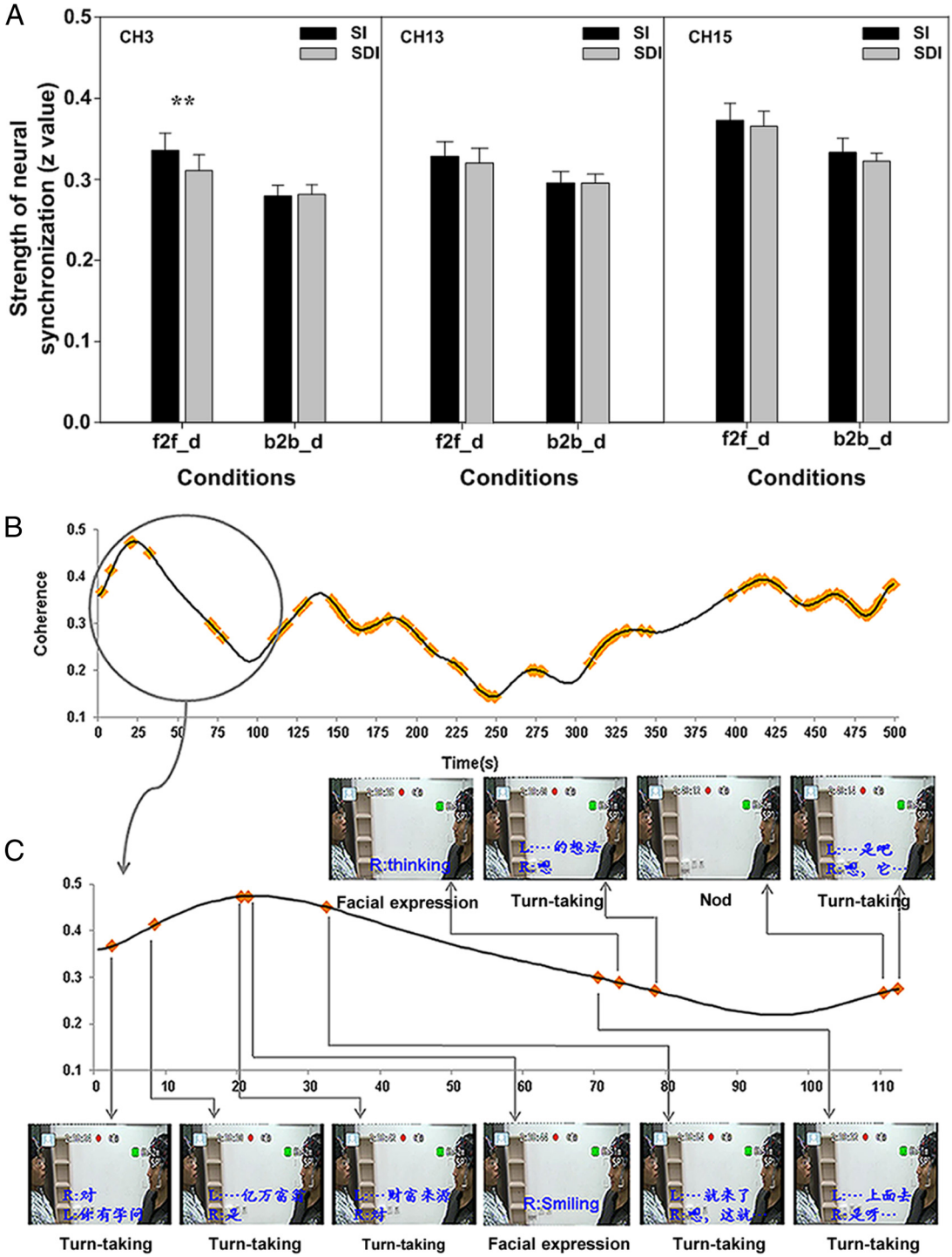


Figure 3. Contributions of nonverbal cues and turn-taking to the neural synchronization during the face-to-face and back-to-back dialogs. ***A***, Statistical comparisons between SI and SDI. Error bars indicate SE. $^{**}p < 0.01$. ***B***, Distribution of SI (yellow points) across the entire time course of coherence values in a randomly selected pair of participants. ***C***, A portion of the time course and the corresponding video images recorded during the experiment. The dialog content at that point is transcribed in blue. R and L, Right and left persons, respectively. The type of communication behavior is indicated in black below the image.

and 0.932 for b2b_d. Further statistical tests of the coherence value showed a significant difference between SI and SDI during f2f_d ($t_{(9)} = 3.491$, $p = 0.007$) but not during b2b_d ($t_{(9)} = -0.363$, $p = 0.725$), indicating that the synchronization in the left IFC was primarily contributed to by the face-to-face interaction rather than simply the verbal signal transmission (Fig. 3*A*). Figure 3*B* illustrates the distribution of SI across the time course for a randomly selected pair of participants. Figure 3*C* focuses on a portion of the time course and presents the recorded video images corresponding to SI, with most of the SI events being distributed around the peak or along the increasing portion of the time course of the coherence value.

Two validation analyses were conducted. First, the coherence value in CH3 was randomly split into two parts for each participant pair. A paired two-sample *t* test was then conducted to evaluate the difference between the two parts; no significant

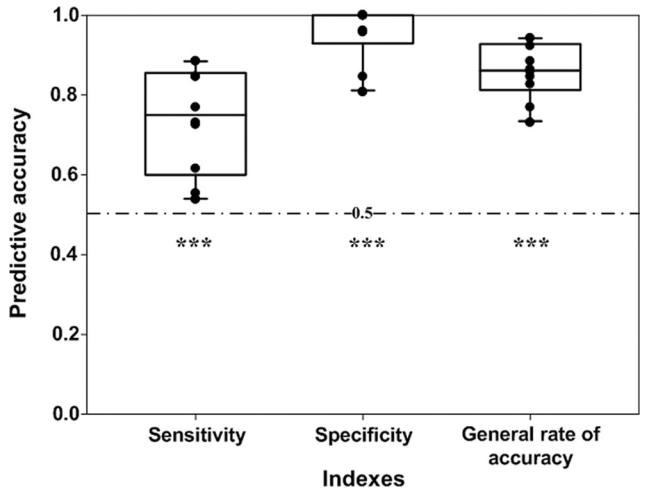


Figure 4. Prediction accuracy for communication behavior based on the neural synchronization of CH3 during face-to-face dialog. Each black point denotes one pair of participants. The dashed line indicates the chance level (0.5). Error bars are SE. ***$p < 0.001$.

difference was found ($t_{(9)} = -0.513$, $p = 0.62$). Second, two additional CHs, i.e., CH13, which covered the premotor area, and CH15, which covered the left IPC, were also examined using the above procedure, and no significant difference between SI and SDI was found during either f2f_d (CH13: $t_{(9)} = 1.004$, $p = 0.342$; CH15: $t_{(9)} = 1.252$, $p = 0.242$) or b2b_d (CH13: $t_{(9)} = 0.067$, $p = 0.948$; CH15: $t_{(9)} = 1.104$, $p = 0.298$). These results suggested that the synchronization increase in this region was primarily contributed to by the face-to-face interaction rather than simply the verbal signal transmission.

Prediction of communicating behavior

The leave-one-out cross-validation showed that the average accuracy of the prediction of communicating behavior during f2f_d was 0.74 ± 0.13 for the sensitivity, 0.96 ± 0.07 for the specificity, and 0.86 ± 0.07 for the generalization rate. The statistical tests showed that all three indexes exceeded the chance level (0.5) (sensitivity: $t = 5.745$, $p < 0.0001$; specificity: $t = 20.294$, $p < 0.0001$; generalization rate: $t = 16.162$, $p < 0.0001$; Fig. 4). These results suggested that the neural synchronization could accurately predict the communicating behavior.

Discussion

The current study examined the unique neural mechanistic features of face-to-face communication compared with other types of communication. The results showed a significant increase in the neural synchronization between the brains of the two partners during f2f_d but not during the other types of communication. Behavioral coupling between partners during communication, such as the structural priming effect, has been well documented: the two partners involved in a communication will align their representations by imitating each other's choice of grammatical forms (Pickering and Garrod, 2004). Recent studies suggest that behavioral synchronization between partners may rely on the neural synchronization between their brains (Hasson et al., 2012). It was found that successful communication between speakers and listeners resulted in a temporally coupled neural response pattern that decreased if the speakers spoke a language unknown to the listeners (Stephens et al., 2010). Moreover, neural synchronization between brains was confirmed in nonverbal communication protocols (Dumas et al., 2010; De Vico Fallani et al., 2010; Schippers et al., 2010; Cui et al., 2012). Thus, it can be concluded that the level of neural synchronization between brains is associated with behavioral synchronization and underlies successful communication.

The present findings extend previous evidence by showing significant neural synchronization in the left IFC during f2f_d but not the other types of communication. Compared with b2b_d, f2f_d involved verbal signal transmission and also nonverbal signal transmission, including orofacial movements, facial expressions, and/or gestures. This multimodal information would facilitate the alignment of behavior between partners at various levels of communication, resulting in higher-level neural synchronization during f2f_d (Belin et al., 2004; Corina and Knapp, 2006).

One possible explanation for this facilitation effect is the function of the action–perception system (Garrod and Pickering, 2004; Rizzolatti and Craighero, 2004; Hari and Kujala, 2009). Previous evidence has shown that the left IFC, in addition to several other brain regions, is the site where mirror neurons are located (Rizzolatti and Arbib, 1998). The mirror neurons respond to observations of an action, to a sound associated with that action, or even to observations of mouth-communicative gestures (Kohler et al., 2002; Ferrari et al., 2003). In the current study, no CHs that covered the left IPC showed a significant synchronization increase during f2f_d. This result indicated that the left IFC might be involved in such an action–perception system (Nishitani et al., 2005) and also that it might specifically provide a necessary bridge for human face-to-face communication (Fogassi and Ferrari, 2007).

Further analysis revealed that the difference between f2f_d and b2b_d was primarily based on the direct interactions between partners, i.e., turn-taking and body language, rather than simply on verbal signal transmission. This finding is consistent with previous evidence regarding the acquisition of communication. Research on infant language development has found that the native language is acquired through interactions with caregivers (Goldstein and Schwade, 2008). Interactions between caregivers and infants can help maintain proximity between the caregivers and the infants and reinforce the infants' earliest prelinguistic vocalizations. Thus, f2f_d offers important features for the acquisition of communication that b2b_d does not (Goldstein et al., 2003; Goldstein and Schwade, 2008).

The importance of turn-taking behavior during communication was further confirmed by the comparison between f2f_d and f2f_m, i.e., the left IFC showed a significant neural synchronization increase during f2f_d but not during f2f_m. This finding extended the previous evidence of neural synchronization in unidirectional emitter/receiver communication to dynamic bidirectional transmission communication and suggested that turn-taking, in addition to other types of interactions during f2f_d, contributes significantly to the neural synchronization between partners during real-time dynamic communication.

Based on the features of neural synchronization, two communication behaviors that included or that did not include interactive communication, such as turn-taking and body language, could be successfully predicted. This finding further validates that during face-to-face communication, multimodal sensory information integration and turn-taking behavior contribute to the neural synchronization between partners, and that communicating behavior can be predicted above chance level based on the neural synchronization. These results can also provide a potential approach for helping children with com-

munication disorders through neurofeedback techniques (i.e., a brain–computer interface).

It has been suggested that the human brain is evolutionarily adapted to face-to-face communication (Boaz and Almquist, 1997; Kock, 2002). However, such technologies as telephone and e-mail have changed the role of traditional face-to-face communication. The current study showed that, compared with other types of communication, face-to-face communication is characterized by a significant neural synchronization between partners based primarily on multimodal sensory information integration and turn-taking behavior during dynamic communication. These findings suggest that face-to-face communication has important neural features that other types of communication lack, and also that people should take more time to communicate face-to-face.

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Fwd: mask mandate

The Savvy Dachshunds <miarose.iannotti@gmail.com>

Wed 2/14/2024 9:42 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

Mask mandates are not backed by science, and science has proven that they do more harm than good in terms of mental illness and respiratory problems.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4868614/ [ncbi.nlm.nih.gov]

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The surgical mask is a bad fit for risk reduction

Shane Neilson, MD, PhD candidate in English and cultural studies

When I walk past my waiting room, I see people wearing surgical masks. This scene becomes surreal when my patients are watching pandemic disaster movies on the wall-mounted television screen, movies that feature frightened crowds who wear similar masks in the vain hope of protection. As my eyes move from mask-wearing patients to screaming on-screen characters and back, I wonder: What is happening here?

As represented by our cinema and other media, Western society expects too much of masks. In the public's mind, the still-legitimate use of masks for source control has gone off-label; masks are thought to prevent infection. From here, another problem arises: because surgical masks are thought to protect against infection in the community setting, people wearing masks for legitimate purposes (those who have a cough in a hospital, say) form part of the larger misperception and act to reinforce it. Even this proper use of surgical masks is incorporated into a larger improper use in the era of pandemic fear, especially in Asia, where such fear is high.[1] The widespread misconception about the use of surgical masks — that wearing a mask protects against the transmission of virus — is a problem of the kind theorized by German sociologist Ulrich Beck.

The surgical mask communicates *risk*. For most, risk is perceived as the potential loss of something of value, but there is another side to risk, memorably formulated by Beck in his *Risk Society*.[2] Beck states that risk society is "a systematic way of dealing with hazards and insecurities induced and introduced by modernisation itself."[2] For Beck, risk occurs not only in the form of threat and possible loss, but also in society's organized management and response to these risks, which create a forwarding of present risk into the future. Furthermore, Beck writes of the "symptoms symbols of risks" that combine in populations to create a "cosmetics of risk." He suggests th ple living in the present moment conceive of risk in terms of the physical tools used to mitig risk while still "maintaining the source of the filth." Beck critiques the cosmetics of risk as m

Feedback
Back to Top

sures that are not preventive but rather act as a "symbolic industry and policy of eliminating the increase in risks." I propose that the surgical mask is a symbol that protects from the perception of risk by offering nonprotection to the public while causing behaviours that project risk into the future.



Image courtesy of atbaei/iStock

Histories of the surgical mask offer some clues about our contemporary risk profile, a profile that is, according to the nature of risk, future-oriented. The birth of the mask came from the realization that surgical wounds need protection from the droplets released in the breath of surgeons.[3,4] The technology was applied outside the operating room in an effort to control the spread of infectious epidemics. In the 1919 influenza pandemic, masks *were* available and *were* dispensed to populations, but they had no impact on the epidemic curve.[3] At the time, it was unknown that the influenza organism is nanoscopic and can theoretically penetrate the surgical mask barrier. As recently as 2010, the US National Academy of Sciences declared that, in the community setting, "face masks are not designed or certified to protect the wearer from exposure to respiratory hazards."[5] A number of studies have shown the inefficacy of the surgical mask in household settings to prevent transmission of the influenza virus,[6,7] but Smith and colleagues,[8] in a recently published meta-analysis, concluded that the surgical mask was noninferior to the N95 mask in terms of influenza transmission rates among health care workers. So … health care workers *should* wear masks to prevent transmission for reasons other than source control, but the public *shouldn't?* This conflict creates an optics problem. When risk is perceived, readiness and protection for all those at risk becomes a goal, which thereby creates a constant state of preparedness in the universally vulnerable. Remember the sinister-looking beaked plague mask from the Middle Ages that instilled fear in onlookers? Wearing a mask reinforces fear. The cosmesis provided by the mask creates more risk of an affective kind.

An affective problem occurs in the present through anticipation of an unknowable, but somehow threatening, future. Beck suggests that the cosmetic symbols are themselves manifestations of risk that bear their own risks. The same mask donned in the present for the common cold at a local clinic forms part of the cosmetic framework of future pandemic risk management. The future pandemic is perceived in the present, but its materiality is not just in our minds, it is literally substantiated by the mask. Thus we have the means for a self-perpetuating system: the mask symbolically protects against infection just as it represents fear of that infection.

This fear surfaces in public policy. In an annex to the Canadian pandemic influenza preparedness plan covering public health measures,[9] the Public Health Agency of Canada (PHAC) does not recommend the use of masks by well individuals in pandemic situations, acknowledging that the mask has not been shown to be effective in such circumstances. However, this stance is complicated by the PHAC's supporting reasons, which relate to problems of supply, cost, distribution and feasibility: panic might occur if the availability of masks were limited; public purchase of masks might limit the availability of masks in health care settings where they are required; and not all members of the public can afford to purchase masks — if masks are recommended by public health authorities, there could be an expectation that they will be publicly funded and made available by public health programs.

The dimension of supply constitutes tacit acknowledgement that people expect masks to be available in pandemic situations. And they do, if the evidence of popular cinema can be believed. Western society has already emerged into a present reality in which citizens are conditioned to want masks on the basis of media representations of pandemics. The same annex on public health measures refers to the "false sense of security" that a mask can psychologically provide,[9] but the converse is the real risk posed to a government unable to mollify its population.

The PHAC has warned that "Just as we do not know when the next pandemic will strike, we cannot predict how severe it will be."[10] The pandemic preparedness plan operates in the present, however, with much evidence of the Canadian government's ongoing preparation, including the release of an updated version of the pandemic influenza preparedness plan in December 2015. Such a future-oriented plan mines anxiety in the present.

We act out our collective anxiety about pandemics by wearing masks even when there isn't a pandemic,[1] but wearing masks reinforces the idea of a possible future of pandemic. The problem of affect in political terms is a contagious one: fear spreads among the public, leading to intensification of risk management — the classic example being 9/11 and the war on terrorism. Fear of infective risk spreading communicably becomes an ironic pun. Pandemics occurred in 1918, 1957, 1968, 2003 and 2009. Thus, the conversation changes from *if* the next pandemic will occur to *when* the next pandemic will occur. Because we are currently "between pandemics," our existence is book-ended by the realized threats of the past and the reasonable threats of the future — to our detriment, with this detriment masked by the surgical mask itself.

Footnotes

This article has been peer reviewed.

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Re: Mask Mandate?

Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Wed 2/14/2024 1:28 PM

To:Chris <skylineboz@yahoo.com>
Bcc:Leclair, Cheryl (RIDOH) <Cheryl.Leclair@health.ri.gov>

Good Afternoon,

Thank you for submitting your comments. They have been received and will be added to the rulemaking record.

Best,

Zachary J. Garceau (he/him/his)
Chief Program Development
Office: 401-222-7884
Cell: 401-408-2747
Zachary.Garceau@health.ri.gov

From: Chris <skylineboz@yahoo.com>
Sent: Wednesday, February 14, 2024 12:34 PM
To: Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>; consent4RI@hotmail.com <consent4RI@hotmail.com>
Subject: Mask Mandate?

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We are writing to you to inform you that this will not happen, my daughter will absolutely NOT be wearing a mask. Zero proven results, and the harm is not living up to the hype the government tried to make it. My family does not live with the covid fear and its because i lead them! Fearlessly.
The town of Coventry will NOT allow this to stand.
Masks are for sheep, we are wolves.
How is this even being brought up? Why the agenda? What gives? Yeah right, no true answer.
Have fun trying, we will NOT bend.

Sent from my iPhone

Masking in RI Schools

Cara Rooney <clowe2933@hotmail.com>
Thu 2/15/2024 12:45 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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To whom it may concern,

I simply cannot believe I am writing this email. Let the record show that I am VEHEMENTLY OPPOSED to the mask mandate regulation that RIDOH is attempting to impose on our CHILDREN. The fact is that studies now show that masks are proven to be highly damaging to mental and emotional development, especially in children who have additional needs requiring IEPs and 504s. Doctors and most notably, epidemiologists have referred to both surgical and cloth masks as "false security blankets" in the way they had been used throughout the COVID-19 pandemic. The data backs this up. There has proven to be no more of a community spread in schools with mask mandates in place and those without. Who are any of you to pretend that you know what is best for MY child?

A mask mandate can NEVER happen again. We now know that – lockdowns don't work, cloth masks don't work and vaccines don't stop the spread. We cannot allow any entity to have the ability to put us in a situation where our children will be forced to wear masks EVER again.

The studies pointing to the harm and the damage mask mandates have done are published and available to all. I simply cannot believe that RIDOH is pushing to have the power to do this. After the way the pandemic was handled, most parents, like myself, are fed up and will no longer sit by quietly. I assure you that myself and many other parents in this state will not forget when we show up to the voting booth. I can also assure you that my son and other children is this state will not be held in the political crossfire. This is why as parents, it is time for us to speak and be heard.

If a policy takes away a parent's right to make decisions for their own children, creates an unbalanced learning environment for vulnerable learners, and data shows that a masking policy has the potential to negatively affect the health and wellbeing of our children, why are we even considering it???

I will no longer sit by in silence. In the future, I will not look both of my sons or my nieces and nephew for that matter, in the eye one day and tell them I did nothing to stand up for them. Our jobs as PARENTS is to put what is best for ALL of our children first, ahead of any other (personal or political) agenda. I am sorry that the state does not want to do the same.

I understand that the voices on both sides of this argument may be deafening but the SCIENCE has supported an end to the mandates and a move to parental choice. States across the country have responded accordingly with an end to the mandates, I would EXPECT the State of Rhode Island to do the same.

I can assure you that if this does get passed, I will retain legal counsel and seek retribution for not only my child but ever other child in the state that has been harmed by masks. This will not be the last you

will hear from me.

Please use this as my formal testimony and please confirm receipt of this email. Thank you!

Cara Rooney, East Greenwich, RI

Mask Mandate

Brandi Lynn <brandiii@outlook.com>

Fri 2/16/2024 9:39 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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We will not comply!

Brandi Lynne, Warwick RI

Comment for RIDOH Rule Hearing on Masking in School

Nicole Solas <nicolesolas@gmail.com>

Fri 2/16/2024 11:04 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Hey Zach,

I oppose any rule for masking in school that does NOT state the following:

"There will be no regulation requiring masking in schools for the alleged prevention of respiratory viral infections until evidence of their effectiveness has been demonstrated convincingly by multiple, rigorous, randomized controlled trials (RTCs) in school children."

That's how you "follow the science." If you don't have that rule, then you're not scientists - you're politicians.

The confidence and trust in public health has plummeted tremendously since your RIDOH covid policies debacle. Creating a rule that requires anything less than multiple, rigorous, randomized RTCs in school children demonstrating mask effectiveness will only harm the health of the public further. People already don't trust their everyday doctors after the curtain was pulled back on the imbeciles at RIDOH.

This is RIDOH's opportunity to STOP harming the public with unscientific mask policies that already resulted in a judicial finding of irreparable harm to children.

Nicole

NO MASKS ON OUR CHILDREN!

Missy Lemoine <susannahgallaghe@hotmail.com>

Fri 2/16/2024 11:26 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good morning,

Absolutely end this proposition about RIDOH trying to implement mask regulations on our children! This is beyond ridiculous and unacceptable. Studies have shown these mask mandates have done little to nothing in the spread of infection. The state DOES NOT HAVE THE POWER TO MAKE THESE CHOICES FOR OUR CHILDREN!

DONT even think about it.

Missy Lemoine
Sent from my iPhone

OPPOSITION to Reg. 216-RICR 30-05-4

Jessica Martin <jessicabmartin401@gmail.com>
Fri 2/16/2024 11:40 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Dear Zachary,
As an Educator and mother of Elementary School aged children in Rhode Island
I am strongly against a mandate that would allow Masking of children in any environment!
The damage Done to these children is incalculable and will be felt for decades.
NO MASKING/ HECK NO/ NEVER AGAIN

Jessica Martin

No for mask mandates

Sheena Mccarthy <shmccarthy1988@gmail.com>

Fri 2/16/2024 8:53 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Hello,
I am against mask mandates. This should not be a rule. Children should not have to be masked in schools.

The children need to be able to live fear free lives.

There should be freedom of choice. No mandates.

Kids should not have to worry about having their mouths and noses covered. They should only be expected to go to school and do the best they can with learning and to socialize and understand the emotions and body language of their adults and peers.

This should not be up to DOH. No to this proposal.

Germs are apart of life and can be taught basic expectation like washing hands and the difference between types of germs and just overall healthy habits.

Do the right thing and do not put masks back on our children.

S. McCarthy

Mask mandate regulation

patricia Hincks <phincks@icloud.com>

Sat 2/17/2024 1:12 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Never again should children be made to wear masks. As a grandparent I witnessed the literal abuse imposed on the poor kids. Nasty unhealthy masks that were mandated to be worn, caused more harm than good - health wise and mentally. It was outright abuse!
Never again!!!!!!
Patricia Hincks
Sent from my iPhone

RIDOH Oppose Mask Mandates

Deb Constantine <deb.constantine@gmail.com>

Sat 2/17/2024 7:20 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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I vehemently oppose giving the RIDOH the authority to impose mask mandates, especially for children in schools or other social settings.

As a parent of elementary and middle school children during the time when masks were enforced, I witnessed a decline in my childrens' social interactions, their ability to communicate and learn and even a decline in their ability to overcome even small cough/cold symptoms. In addition, mask wearing should be a personal choice that those who choose to protect themselves would make. There are countless examples where mask wearing negatively effects the individual; ie asthma, COPD, anxiety, claustrophobia, children with autism or sensory issues etc.

Additionally, should a mask mandate ever be reinstated in the State of RI, I will immediately remove my children from school and opt to home school them (which I did in 2021) or more likely move out of the State altogether.

Deborah Constantine
23 Beechwood Hollow Rd
Bradford RI

Opposition to 216-RICR-30-05-4

Sheila Clarkin <sheila.nsrtc@proton.me>

Sun 2/18/2024 4:54 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Greetings Zachary,

Please note that I vehemently oppose this attempt of a recycled mandate. We know it comes on the heels of the Parents United lawsuit against McKee and DOH which was won for the people's constitutional rights. The forcing of masks is a violation of the Constitution of the United States, violation of the Nuremberg Code and also violation of basic human rights.

It has been proven time and time again that masks of any kind do not work. The pore size of most average masks range from 20-100 microns, yet using covid as an example, the microns for that were 200-1000x smaller than the mask. This was proven in 2020, 2021, and so on. You cannot keep trying to push this Communist agenda on our children. We will not stand for this.

~ Sheila Clarkin
North Smithfield

Sent with Proton Mail [proton.me] secure email.

Proposed mask policy

Heather Murphy <hmurphy1230@gmail.com>

Mon 2/19/2024 11:29 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good Afternoon
I am following up on a proposed bill for mandate masks in school. I would like to prepare for comment on March 15th and wondering if you could you provide me with the evidence used to support this change/policy.

Thank you
Heather Murphy

Comment for mask policy under consideration -216-RICR-30-30-4

Heather Murphy <hmurphy1230@gmail.com>
Mon 2/19/2024 2:00 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I am writing to provide a comment on the mask policy that is being proposed.
1. Regulation: Our teachers have so much on their plates and have you considered who is going to be in charge of assuring this mandate is followed. I am sure you are aware that our school staff have so much responsibility. This would also put them in the middle of arguments with parents/guardians and will create a culture of agitation in the schools.

2. Trust: Sadly the Department of Health is a **group of public health officials who clearly do not understand the public**. The role of the department of health should be to inform and allow citizens to make decisions for their own health, allowing them to do their own risk assessments.

The Dept of Health has also lost trust in its community. We do not trust you are making decisions based on logic and science, but for optics. For example in May 2021, my son was playing in a State Championship at Rhode Island College. Those who attended the event were not required to wear masks, but the athletes were. This was for optics and not true protection of anyone. Did you not know that these students rode the bus without masks to the event, but were required to put them on when they arrived. In what universe did this make sense? It was also a volleyball match, so they did not have close contact with the other team. At the time I brought this to the attention of Danielle Quilliam who agreed with me but could do nothing to sway those of you in leadership. I also brought to the attention of the RIIL, who also agreed with me but had to follow what you all said. You lost my trust that day, you chose optics over logic and science, you also lost the trust of every RI citizen at that event.

3. Speaking of science and logic: There is no science nor evidence to support this decision. I have read the Cochrane review for masking in all populations and they have concluded that there is not enough evidence to recommend moving forward with masking. So I ask for specific evidence that you are using to move forward with this policy? **Any lawmaker reading this bill should require medical evidence to be summarized and explained.**

4. EBP: What best practices have you evaluated to come to the decision this policy would be necessary?

In summary, your proposal lacks merit and evidence and should not be passed
Regards,
Heather Murphy
North Kingstown

There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different

from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes. Harms associated with physical interventions were under-investigated.

There is a need for large, well-designed RCTs addressing the effectiveness of many of these interventions in multiple settings and populations, as well as the impact of adherence on effectiveness, especially in those most at risk of ARIs.

Masks

Gina <ginamc04@yahoo.com>
Mon 2/19/2024 11:12 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Dear Zachary…

Masks have been proven not to help with viruses. There are many published studies and even a book written explaining why. I have attacked a link for you to get a copy so you can see for yourself. The actual science is explained that masks are unnecessary and do NOT work. In fact, they are harmful, especially to children. I've read this book and understand the science so I believe it's only politicians pushing the masks at this point and it's ridiculous.

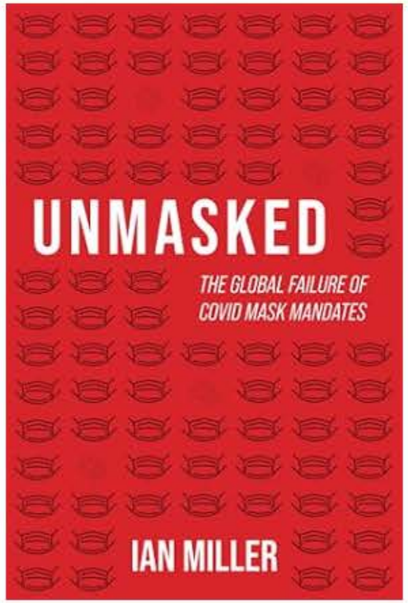
We will not be complying with any mask mandates.

https://www.amazon.com/Unmasked-Global-Failure-COVID-Mandates/dp/1637583761 [amazon.com]

Sincerely,
Fed up with the RIDOH & all the politicians supporting non scientific mandates

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Read sample

Unmasked: The Global Failure of COVID Mask Mandates

Paperback – January 20, 2022

by Ian Miller (Author)

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Since early 2020, masks have been promoted by experts and implemented as mandates by politicians in an attempt to slow the spread of COVID-19…but a thorough examination of the data shows they've failed.

Masks have been a ubiquitous and oft-politicized aspect of the COVID-19 pandemic. Years of painstakingly organized pre-pandemic planning documents led public health experts to initially discourage the use of masks, or even insinuate that they could lead to increased rates of spread.

Yet seemingly in a matter of days in spring 2020, leading infectious disease scientists and organizations reversed their previous positions and recommended masking as the key tool to slow the spread of COVID and dramatically reduce infections.

Unmasked tells the story of how effective or ineffective masks and mask mandate policies were in impacting the trajectory of the pandemic throughout the world.

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Oppose Masking in School/Mask Mandate

Amy <moms4libertywashington@gmail.com>

Thu 2/22/2024 5:53 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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To Zachary Garceau,

My name is Amy Rodrigues and I am writing to inform you that I strongly oppose any form of mask mandate, especially when it concerns masking children. Masking children has historically proven to be detrimental to their development and present other health risks. Masks not only dehumanize us as a society, they also serve as a constant reminder to “be afraid” which is harmful to children’s mental wellbeing. Mask requirements are not necessary to stop the spread of, nor are they scientifically proven to stop the spread of disease.

Thank you,

Amy Rodrigues
Chapter Chairwoman
Moms For Liberty - Washington County, RI

Proposed Mask Regulation 216-RICR-30-05-4

Sofia Sinclair <sofia.a.sinclair@gmail.com>

Sat 2/24/2024 8:55 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good morning,

I am writing to express my strong opposition to the regulation proposed by RIDOH for any future mask regulation for covid or any other virus.

The mask mandate had a negative impact on my three children. My son, who had been in speech therapy since he was three, was forced to mask during his 1st and 2nd grade years. This had a negative impact on his progress in regards to speech which was a setback for him emotionally and socially as well. My daughter was in 3rd and 4th grade and was bullied in school because she did not like wearing a mask and other students found it was their responsibility to police her, which was highly inappropriate. My youngest was in preschool, but I kept her in private kindergarten until the mask mandate was over because I was not going to subject a 5 year old who was learning how to read to all-day masking.

As a whole, student test scores suffered, reading scores suffered, children's emotional and social health suffered, and I'm not sure what ill-informed party came up with this proposed regulation and what they hope to accomplish. This is a power grab, plain and simple. RIDOH has no right to force MANDATES on parents, students or the general public. They are an advising body, and that's all. They can provide recommendations; mandates have no place in their toolbox, they've abused those in the past and they will abuse them again.

I might add, all three of my children are top performers, scoring in the 99% on their statewide assessments, and are high achievers on the RICAS tests. If any mask regulation were to go into effect again, I will promptly pull my high performers out of RI public schools. We will not comply with any future mask mandates. There are numerous studies and meta analysis available now showing mask mandates had no impact on covid spread, or outcomes, and anyone entertaining the idea of any future mask mandates should take a statistics class.

Thank you,

Sofia A. Sinclair

216-RICR-30-05-4 public comment

Comcast <c2lage@comcast.net>

Sat 2/24/2024 4:45 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Dear Mr. Garceau,
As a parent of a Junior in high school that will be looking to Rhode Island colleges as a possibility after graduation, I implore you to oppose any mask mandates in RI, especially one as broad and sweeping as the one that is being proposed. Masking has negative health effects, including mental health, which should be a top priority for children. Masking or not masking, should be a personal family choice, not a government mandate. Although this bill may be directed at grades K-12, we know that many colleges will likely follow this as guidance if they feel the situation warrants. If this bill passes, my daughter will remove RI colleges from her list of options. Please, for the sake of the children and young adults of Rhode Island, oppose this bill.
Cheryl Lage
Resident of Connecticut

Sent from my iPad

Written Testimony re: school masking regulations

Chris Schuler <cschuler1984@gmail.com>

Mon 2/26/2024 10:05 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Zachary,

Please see my testimony below:

As a Rhode Island resident, naturalized US citizen, immigrant, and parent, I've seen first-hand the hardships kids face in their youth. It's essential that adults, those in power create atmospheres that will positively influence the next generation. That starts first with their health and safety.

After looking back on how we responded during the pandemic, it is overwhelmingly clear that the forced medical intervention of masking on our most vulnerable population, our kids, was wrong, and harmful.

We saw no less disease transmission through masking. That has been proved in studies, and through the courts across the country.

If masks work, why did the FL grand jury conclude that, "*We have never had sound evidence of their effectiveness against SARS-CoV-2 transmission in the form of reliable RCTs that demonstrated statistically significant benefits* [flvoicenews.com]."? The jury addressed the, "*flawed observational and laboratory data the CDC has published to justify its Guidance.*" They concluded that, *"This is a "quality" problem, not a "quantity" problem. The number of published studies available cannot serve as a substitute for the quality of the underlying science upon which they are based*" (2/2/24)

I ask you to consider:

- Where's the quality data to support the efficacy of masks? **We're no longer in a state of emergency.**
- Why has RIDOH still not demonstrated mask efficacy?

I saw first-hand the irreparable harm done to my kids. They cried, they struggled, for no proven reason.

This should never happen to our kids again.

Please strike down this regulation that allows masking. Please use language as follows:

"RIDOH will implement a mask mandate on children when it can demonstrate with numerous randomized control trials that masks prevent infection and transmission." **Or**, " "There will be no

regulation requiring masking in schools for the alleged prevention of respiratory viral infections until evidence of their effectiveness has been demonstrated convincingly by multiple, rigorous randomized, controlled clinical trials." **Or**, “RIDOH will not implement a mask mandate because RIDOH cannot support its regulation with quality science.”

Thank you for your consideration.

Chris Schuler
12 Jack Pine Road
Coventry, RI 02816

Chris Schuler

516.650.7794 | cschuler1984@gmail.com

[linkedin.com]

#143

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- **INTRODUCTION** 2
  - Our Investigation 3
  - "Safety" and "Efficacy" 4
- **THE RISK OF SARS-COV-2** 7
  - Infection Risk 7
  - Symptomatic Infection Risk 9
  - Hospitalization Risk 9
  - Death Risk 10
- **PANDEMIC MODELING AND NONPHARMACEUTICAL INTERVENTIONS** 12
  - "Lockdowns" and Stay-at-Home Orders 14
  - Collateral Consequences 16
  - The Use of Masks and Social Distancing 20
- **CONCLUSION** 29

INTRODUCTION

On December 13, 2022, the Governor of the State of Florida issued a Petition for Order to Impanel the Twenty-Second Statewide Grand Jury. In its 19 pages, the Petition described a litany of statements by pharmaceutical executives, state and federal government officials, doctors, scientists, reporters and other individuals regarding the safety and efficacy of COVID-19 vaccines, ultimately deeming it "to be in the public interest to impanel a statewide grand jury to investigate criminal or wrongful activity in Florida relating to the development, promotion and distribution" of these vaccines. On December 22, 2022, the Florida Supreme Court responded to the Petition by issuing an Order Directing Impanelment of a Statewide Grand Jury and tasking what would eventually become this body to determine whether "pharmaceutical manufacturers (and their executive officers) and other medical associations or organizations" engaged in "criminal activity or wrongdoing" with respect to their involvement in the development, approval or marketing of COVID-19 vaccines. Over the ensuing months, hundreds of summonses were subsequently issued for prospective jurors from the Fifth, Sixth, Tenth, Twelfth and Thirteenth Judicial Circuits. This body was selected and ultimately sworn in on June 26, 2023. Since that date, we have been working diligently to address the issues raised in the Petition and Impanelment Order.

Given that this is our first Interim Presentment, we wish to make several things clear. First and foremost, as an institution, the Statewide Grand Jury is apolitical. The members of this Grand Jury are not public officials and we have no specific agenda with respect to these issues. We were selected at random, based solely on our commitment to impartiality and on our willingness to devote significant amounts of our own personal time, month after month, to this process. Through the operation of chance alone, this body is racially and ethnically diverse, diverse in age, diverse in gender, diverse in politics and even diverse in lifestyle. Our main uniting feature is that each of us believes the citizens of the State of Florida deserve unbiased answers to the important questions raised by the Petition and the Impanelment Order. Moreover, we concur that if violations of Florida criminal law occurred with respect to COVID-19 vaccines, they must be addressed by the appropriate authorities.

We also believe it is important for those who read this Interim Presentment to understand that by design, the Statewide Grand Jury is insulated from the influence of the political actors that caused us to be impaneled. Once the Governor of the State of Florida issues a Petition, his involvement in the Statewide Grand Jury is at an end. Once the Florida Supreme Court issues an

Impanelment Order, its involvement is essentially at an end. The Statewide Grand Jury's power, however, is limited to two outputs: Indictments, which subject individuals or organizations to criminal prosecution based on multi-circuit violations of Florida criminal law, and Presentments, which address issues of great public importance for which the law does not always provide a sufficient remedy. Grand Jury Presentments frequently involve allegations of corruption, neglect of duty or malfeasance by governmental agencies, private entities or individuals, and are often accompanied by legislative proposals to curb further misconduct. Occasionally, however, ***the entire purpose of a Presentment may be to raise public awareness*** about circumstances that should be addressed in some way, but for which our current laws are unequal to the task. All these situations share the same inherent limitation: The Statewide Grand Jury only has the power to ***recommend*** solutions; we cannot ***enact*** them. It will be up to state legislators, federal lawmakers or even the people themselves to ensure that our efforts are not wasted.

Our Investigation

Since last June, this Grand Jury has cast a wide net, eliciting sworn testimony from a range of both expert and lay witnesses on issues both central and adjacent to the questions we have been charged with resolving. We have learned a great deal—some of which we will discuss in detail below—and we would like to thank those witnesses who have appeared before us so far. Admittedly, however, we are not physicians. Some of us are involved in the medical field, but most of us work in other professions and vocations. We have, however, spoken to numerous doctors, professors and scientists with a broad range of viewpoints on the topics we will discuss below and other topics we intend to discuss in the future. In a way, this Grand Jury has allowed us to do something that most Americans simply do not have the time, access, or wherewithal to do: ***Follow the science.***

As of today, our investigation is nowhere near complete. We remain in regular session and our Legal Advisor is actively scheduling future witness appearances. There are still many months and much more testimony and evidence to come before our work will be finished. The issue we have been asked to examine is different from prior statewide grand juries in that it obviously affects people all over the United States—and perhaps the world—in much the same way as it affects citizens of the State of Florida. Most of the actions we have been asked to investigate and the people who took those actions are elsewhere. On the one hand, this complicates our efforts to compel testimony and slows down the statewide grand jury process. On the other hand, a surprising amount of scientific and other information about the COVID-19 pandemic is readily available in

the public sphere. Medical and scientific experts have been solicitous with both their perspectives and their time.

Unfortunately, not all our investigative efforts have been met with fulsome cooperation. Some prospective witnesses have elected not to testify, often citing potential professional or personal consequences arising from their involvement with the Statewide Grand Jury process. Occasionally, prospective witnesses have raised concerns about the underlying fairness of this body, which—for the reasons described above—we believe to be unfounded. Similarly, our Legal Advisor has sought the assistance of several agencies of the United States Government which have thus far declined to participate. The Center for Disease Control (CDC), the Food & Drug Administration (FDA) and the U.S. Army, among others, all had a substantial hand in the contracting, approval and distribution process for the COVID-19 vaccines at the center of our inquiry. These agencies have elected not to provide representatives to testify before this body, and federal law prohibits us from compelling their cooperation.

This is not as much an impediment as one might imagine, however. There is a wealth of information in the public sphere that explains the deliberative process and opinions of these federal agencies. We are not unfamiliar with their decisions or the claimed justifications for those decisions. Furthermore, we do not intend to penalize them for refusing to participate in the Grand Jury process. Rather, it is our goal to gather as much relevant information as we can regarding a given topic, interpret it, and, where appropriate, credit sound and reasonable decisions, even good-faith mistakes resulting from incorrect or incomplete information.

To the extent that any government entity or other witness who has thus far refused to participate in the Grand Jury process disagrees with any of our conclusions, they are welcome to come to Tampa and offer sworn testimony. So long as we are still in session, we will make the time to hear them out.

"Safety" and "Efficacy"

The Petition for Order to Impanel the Twenty-Second Statewide Grand Jury contains a wide variety of alleged misrepresentations by public and private officials involving qualities attributed to COVID-19 vaccines. These include assertions that side effects from the vaccines either were "not established," or, later on, "were 'extremely' or 'very' rare"; that "'the benefit risk profile of our vaccine remains positive'"; that the vaccines will "stop," "slow" or "limit" the "spread" of COVID-19; that the vaccines "prevent COVID-19 disease" with an efficacy of over 90%; that getting vaccinated "isn't just about protecting you, but also your community"; that

vaccination was the key to eventually developing "herd immunity"; and, perhaps most importantly, that "the vaccines were 'safe and effective as determined by data from the manufacturers.'" All of the alleged misrepresentations described above—and, for that matter, the broader category of attributed statements from the Petition—share two primary commonalities: (1) Every statement involving the "risk" of a vaccine or the "rarity" of a vaccine's side effects is essentially a statement about the vaccine's "safety"; and (2) every statement about a vaccine's ability to prevent COVID-19 disease is essentially a statement about its "effectiveness." Because these two concepts, "safety" and "effectiveness," form the axes around which the alleged misrepresentations orbit, we believe it appropriate that they form the primary focus of our inquiry.

Significantly, the concepts of "safety" and "effectiveness" are long-established principles in the world of federal drug, device and biological product approval. In fact, they form the primary goalposts of the FDA's approval process, meaning that every pharmaceutical manufacturer who submits applications to the FDA for new biological products—including vaccines—sets out to establish through clinical trials and other means that their products are "safe" and "effective" as the FDA defines those terms. However, both "safety" and "effectiveness" are considered terms of art, meaning that in this specific milieu, they have definitions that are similar, but not identical to their conventional, plain-language meaning.

The legal definition of the word "safety," with respect to biological products, can be found in the Code of Federal Regulations:

> The word safety means the ***relative*** freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, ***taking into consideration the character of the product in relation to the condition of the recipient at the time.***

(emphasis added). Right away, it should be apparent that when the FDA describes one of these products as "safe," it is semantically different from the way people describe things as "safe" in everyday language. The definition incorporates a degree of relativity, meaning that a biological product can be fully approved for market and described as "safe" by the federal government with the knowledge that it will harm at least some of the people who take it.

We do not mean for the above to be taken as criticism; the world is full of dangerous diseases and often, on balance, it makes sense to judge the safety of a given treatment in the context of the disease it is designed to manage. The flexibility of this definition allows the FDA to approve treatments with significant safety risks for dangerous diseases like late-stage cancer because, on

balance, they are relatively "safe." However, it should also be apparent that establishing the "safety" of a biological product ***necessitates a comprehensive, meaningful and accurate evaluation of the risk presented by the disease that product is designed to address.*** This is especially true in the case of vaccines because they are being administered to healthy people—not the afflicted—in the hopes of preventing or mitigating a disease they do not have.

We have drawn working definitions of both "efficacy" and "effectiveness" from a document entitled "Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," published by the FDA in May of 1998. This document defines the relevant terms as follows:

> [T]he term ***efficacy refers to the findings in an adequate and well-controlled clinical trial*** or the intent of conducting such a trial and the term ***effectiveness refers to the regulatory determination*** that is made on the basis of ***clinical efficacy and other data.***

(emphasis added). There are two aspects of this definition that are significant here. First, "efficacy" and "effectiveness" are distinct terms that have distinct meanings. The former refers solely to the outcomes of clinical trials, while the latter refers to the FDA's regulatory determination regarding a drug or biological product. Second, while clinical efficacy is a named component in the FDA's determination of "effectiveness," it appears that determination may also be based on "other data."

Once again, there is wisdom in allowing the FDA to be flexible. A popular hypothetical example illustrating the need for the flexibility to consider "other data" involves reducing the risk of death from jumping out of airplanes using parachutes. A well-designed randomized clinical trial would require the proponent of that intervention to assign some portion of study participants to jump out of planes ***without*** parachutes—as a "control" group—to establish the "efficacy" of the intervention. Obviously, such a study would be neither ethical nor informative; the "effectiveness" of using parachutes as an intervention is so obvious it can be well-established by observational data alone. In this way, considering "other data," especially when potential ethical concerns arise, is entirely necessary and appropriate.

The definitional relativity incorporated into these critical terms presents a conundrum to this Grand Jury: As a practical matter, one cannot determine the truth of any statement touting the "safety" or "effectiveness" of COVID-19 vaccines without first making some judgment about the risks posed by the SARS-CoV-2 virus. Not only has our understanding of those risks evolved substantially over the last four years, the danger posed by this novel virus has been arguably

diminished—to a greater or lesser extent—by: (1) The development of effective treatments for those stricken with symptomatic COVID-19 infection; (2) the imposition of nonpharmaceutical interventions (NPIs) designed to slow or stop the spread of the virus; and (3) our evolving, population-level immunity.

For that reason, as we embarked on this investigation, it became apparent that this body could not answer the questions posed by the Petition in a vacuum. Rather, the COVID-19 vaccines—their approval, their rollout, and their administration—were a significant part of a broad societal response to a true national emergency: A novel disease that is estimated to have killed almost a hundred thousand Floridians and millions worldwide. Examining the degree to which these other modalities were employed to combat COVID-19 and their relative success or failure is necessary to contextualize the questions presented by the Petition and the Impanelment Order.

THE RISK OF SARS-COV-2

As a word, "risk" is easy to use in conversation, lectures, and discussions, but as a concept, it can refer to one of several different ideas. Some of those ideas are themselves moving targets, in that the actual probability of their occurrence changes either with time or is dependent on one or more other factors, sometimes referred to as "confounders." When a person discusses the "risk" of the SARS-CoV-2, he or she could be referring to any of the following:

1. Infection Risk
2. Symptomatic Infection Risk
3. Hospitalization Risk
4. Long-Term Risk
5. Death Risk

For the purpose of discussing NPIs, we need not go into exhaustive detail regarding all of the "risks" described above. We will spend time in future presentments describing and explaining the details of each of these risks in a manner appropriate to the issue at hand.

Infection Risk

The risk of infection is the likelihood that anyone going about his or her ordinary life is going to be infected by SARS-CoV-2. This risk starts as a straightforward expression of viral contagiousness. However, it can vary substantially based on how many vectors exist through which a person may come into contact with the virus. The existence and number of viral vectors are heavily dependent on social and environmental factors like individual living arrangements, the size of crowds in cities, the density of people in residential communities or business districts,

seasonality, the proportion of time a given person spends indoors versus outdoors, air circulation, filtration quality in indoor spaces and a multitude of other factors. Infection risk is highly useful for discussing NPIs, which aim to reduce viral transmission by limiting the number of susceptible people who are exposed to a given pathogen.

The risk of infection is often referred to with an expression, written as R0 (pronounced R-Naught), which describes the number of people to whom a single person can transmit a given communicable disease. Influenza, for example, has an R0 that varies seasonally between 0.9 to 2.1. This means that averaging for all social and environmental factors, each person who gets seasonal influenza is expected to spread the virus to between 0.9 to 2.1 people. Significantly, however, an R0 of less than one means that the infected population will shrink, while an R0 of more than one means that the infected population will grow. Moreover, R0 affects the curve of infection exponentially: The higher the R0, the more quickly people will become infected. The higher the number of infected, the faster the number will grow.

It can be challenging to accurately estimate R0, especially when a given virus produces only minor symptoms or infects some portion of the population asymptomatically. Early estimates, which tend to be based primarily on those who appear for medical treatment or positive test results from those who are already symptomatic, tend to understate R0. On January 30, 2020, for example, the World Health Organization (WHO) estimated the mean (average) and median (midpoint) R0 for COVID-19 to be 3.28 and 2.79, respectively. In February 2020, a study of passengers on the Diamond Princess cruise ship found SARS-CoV-2's R0 to be 2.28. Later papers have given wider estimates of 1.9 to 6.5. The number is also likely to change based on viral variant. For example, a journal article published in March 2022 estimated the average R0 for SARS-CoV-2's Omicron variant to be as high as 9.5.

The infection risk of SARS-CoV-2 can also be better understood by studying viral presence in wastewater, which also can be used week over week to determine whether cases are rising or falling, or through seroprevalence studies, which evaluate the number of antibodies for a virus found in a random set of blood samples. These samples can then be extrapolated to estimate the distribution of a given infection at a population level. This number does not provide a rate of change, like R0 or wastewater surveillance, but it can shed light on the undercurrent of asymptomatic cases which tend not to be captured by other metrics like PCR testing, hospitalization, or death. As of April 2022, the CDC estimated that 58% percent of Americans, including 75% of children, had already been infected with SARS-CoV-2 based on seroprevalence.

That was almost two years ago. We expect, given the R0 of subsequent variants, that the number is significantly higher today and will continue to climb in the future. At this point, many Americans, like some of us here on the Grand Jury, have even been infected with SARS-CoV-2 more than once, confounding the efforts of even wastewater and seroprevalence studies to determine infection risk.

Symptomatic Infection Risk

The risk of symptomatic infection—more often referred to as "cases" or "confirmed cases"—is the most basic idea that most people consider when discussing "risk." According to the WHO, as of the writing of this Presentment, there have been roughly 110 million "confirmed cases" of COVID-19 in the United States and roughly 773 million worldwide. As we mentioned above, however, "confirmed cases" are only taken from PCR testing after symptoms emerge, from treatment data at medical facilities, or from health department figures at the state level—all of which usually derive from the same sources and thus run some risk of double-counting. Regardless of its shortcomings, however, comparing the population level to the "confirmed case" count is most representative of symptomatic infection risk.

The problem with using symptomatic infection risk as a metric—and the reason we mention it in this Presentment at all—is that when it is used as a denominator, it fails to account for asymptomatic cases, and thus tends to overstate downstream risks like hospitalization and death. Cases can be undercounted because persons do not have access to tests or choose not to report test results. As the pandemic took its toll, there was evidence that some people were hesitant to test or report for fear of being hospitalized, stigmatized or forced to quarantine. Early in the pandemic, for example, researchers estimated that the spread between "confirmed cases" and positive seroprevalence results was 8,430 to 367,000, resulting in only 2% of infections being confirmed. After PCR testing became more widespread, however, the ratio began to change significantly. Conservatively, later estimates put the percentage of symptomatic SARS-CoV-2 infections at anywhere from 45% to 65%, a rate which will likely fall as testing decreases and humans develop further immunological familiarity with the virus.

Hospitalization Risk

The risk of hospitalization from COVID-19 is the first level of risk that raises the question of intervention by public health in the way people live their day-to-day lives. Hospitalizations are often traumatic and difficult experiences that can stress families, disrupt careers, impose heavy

financial burdens and tax the medical system as a whole. As of the writing of this Presentment, the CDC reports roughly 6.75 million total hospitalizations in the United States for COVID-19 disease.

This number, however, is not free from controversy. In the CARES Act, the federal government created financial subsidies for Medicare and Medicaid patients with COVID-19 that were treated at hospitals and other medical facilities. The subsidy itself is not unjustified. During the pandemic, some medical facilities operated at a deficit, expanding hours for staff, dramatically and unexpectedly increasing costs for protective equipment and taking in far less revenue than usual from elective procedures that had been delayed. These CARES Act subsidy payments helped relieve the financial risk of their closure or collapse.

Nevertheless, putting that money on offer creates incentives to report more than just hospitalizations for COVID-19 disease. We know for a fact that this happened because numerous federal and state health officials have publicly stated that they did not ask or require hospitals to distinguish cases where someone was admitted with incidental SARS-CoV-2 infection versus cases where someone was so sick with symptoms of COVID-19 disease that he or she required hospitalization. Thus, it is highly likely that the CDC's number of total hospitalizations is inflated to some degree with asymptomatic or minor SARS-CoV-2 infections that were classified as "hospitalizations" in order to financially benefit the hospital.

Death Risk

The risk of death is the most salient and obvious risk presented by the SARS-CoV-2 virus. From an epidemiological perspective, it can also be one of the easier risks to compute, provided one starts with the proper inputs. In its simplest form, this can be expressed as a numerator (the number of people who died from a disease) and a denominator (the number of people who had the disease). We will deal with each of these categories and their distinct complications in turn.

First, the numerator. When people die, other people tend to notice. This means that unlike symptomatic or especially asymptomatic infections, the number of people who died from COVID-19 should be relatively easy to determine because deaths are recorded by hospitals, coroners and state agencies. For example, the CDC reports that as of the writing of this Presentment, roughly 1.17 million Americans have died from COVID-19 disease. Like the number of total hospitalizations, however, this figure is very likely inflated to some extent with people who died "with" rather than "of" COVID-19 disease in order to financially benefit whatever hospital the person died in. The CARES Act also provides for a "death benefit" of up to $9,000 to the families of those who died from COVID-19 disease.

Second, the denominator. The results of the equation can be dramatically different based primarily on whether one plugs in the number of "confirmed cases," or an estimate of total infections. "Confirmed cases" can be used to provide a "case fatality rate," but that rate is very likely to dramatically overstate the risk of death by ignoring unreported infections. The Director-General of the WHO did exactly this when he caused widespread panic by stating in a March 2020 press briefing that "[g]lobally, about 3.4% of reported COVID-19 cases have died." The statement itself was not inaccurate, it was just an incitive choice of denominator. The media reporting the story at the time did not catch the nuance, reporting breathlessly that the "coronavirus death rate is 3.4%, higher than previously thought."

Using an "infection fatality rate" (IFR), however, provides a much more accurate answer to the primary question people care about: "If I get infected by SARS-CoV-2, how likely am I to die?" The best way to do this is to use seroprevalence to estimate a total number of infections and use that as the denominator. This is still a moving target, however. Infection numbers can vary geographically based on the factors we described in the section above. Fatality numbers, too, can vary from place to place based on differences in the population, the availability of treatment and any number of other factors. With that in mind, some of the best combined estimates of IFR from 2020 published in scientific journals ranged from 0.00% to 1.63% with a median of 0.27%, or around 2.7 people per 1000. Those numbers have likely lowered over time, but because the NPIs we discuss in this Presentment occurred primarily in 2020-21, we will use those estimates here.

Significantly, the IFR estimate is itself highly stratified by age, which turns out to be by far the most important factor when it comes to the risk of death from SARS-CoV-2 infection:

Years of Age	Deaths per 100,000	Percentage
5	2	0.002%
15	6	0.006%
25	29	0.029%
35	105	0.105%
45	286	0.286%
55	624	0.624%
65	1,706	1.706%
75	4,840	4.840%
85	12,972	12.972%

These numbers make it clear that, depending heavily on age, a person's IFR could be dramatically under or dramatically over the median of 0.27%. Through the lens of these numbers, COVID-19 is statistically almost harmless to children and most adults, with catastrophic IFRs in populations above the age of 65.

How much difference do comorbidities make? Not as much as one might think. The CDC lumps all comorbid conditions together, stating that the "Risk Ratio" of COVID-19 death (the number by which one would multiply his or her baseline IFR based on other factors like the existence of comorbidities) increases with the number of comorbid conditions a person has. The risk ratio could be anywhere from 1.5 with a single condition to 3.8 with greater than 10 conditions. This explanation is not unfounded (multiple comorbidities do have an additive effect on risk) but it has the advantage of simplicity at the cost of accuracy. Data published in July of 2020 describe with specificity the degree to which various comorbid conditions can positively affect the "Hazard Ratio" of SARS-CoV-2 infections, raising risk by specific amounts in individuals with specific conditions. Importantly, however, all the individual condition-related Hazard Ratios are dwarfed by the massive, exponential impact of age, which is by far the most important comorbidity.

PANDEMIC MODELING AND NONPHARMACEUTICAL INTERVENTIONS

To better understand and predict how viruses flow within a host population, epidemiologists employ a mathematical model known as "SEIR," an acronym for four population states of humans with respect to a given pathogen:

- "S" - "Susceptible"
- "E" - "Exposed"
- "I" - "Infected"
- "R" - "Recovered."

These models can vary widely in complexity depending on the circumstances surrounding a particular pathogen (e.g., its lethality, its rate of mutation) or the characteristics of a particular population (e.g., the immunosuppressed, aged cohorts). For our purposes, each of these four descriptive states provides a vector by which one can affect the course of a pandemic. Providing those in the "Infected" category with medical treatment, for example, is designed to move "Infected" people into the "Recovered" category. Most vaccines act to remove individuals from the "Susceptible" category altogether, effectively preventing that population from entering the

SEIR model at all with respect to a particular virus. COVID-19 vaccines appear to have a dual effect, reducing the "Susceptible" population in a limited way and for a limited time, and providing the "Infected" with some protection from the more serious consequences of COVID-19 disease for a longer (but still apparently limited) period.

NPIs, however, are designed to reduce (or eliminate) people from the "Exposed" category. In the last four years, all manner of NPIs have been employed around the world in response to the SARS-CoV-2 virus at the government, corporate and individual levels. To be clear, NPIs do not have to be mandated to be effective. An individual who stays home from work because he or she comes down with a cold is essentially self-employing an NPI, removing himself or herself from a mixed environment and thus reducing the "Exposed" population in the SEIR model. A corporation that urges employees who feel sick to stay home, similarly, is effectively employing an NPI in the same manner as the individual, just on a potentially larger scale.

Those kinds of small-scale NPIs, however, are not the focus of our inquiry. We are interested in large-scale NPIs enforced by mandate at the government level and the question of whether these interventions had a significant impact on the overall risk of the SARS-CoV-2 virus. For purposes of this Presentment, we have divided NPIs into the following broad categories:

(1) "Lockdowns," Stay-at-Home Orders, School Closures and other similar acts that impeded the movement of individuals regardless of disease status; and

(2) Mask Mandates & Social Distancing Guidelines.

We recognize there may be other NPI measures that arguably had some impact on SARS-CoV-2 risk, but we believe the chosen categories are broad enough to address many of the more specific kinds of NPIs that were put in place during the pandemic.

Before we begin examining these categories, we would like to highlight a common refrain that has developed as our society struggles to canonize (and, perhaps, "memory-hole") the experiences of the past four years. It has become very popular in 2023 (and now 2024) for many erstwhile advocates of NPIs to point to a lack of available scientific data when confronted with some of the more unfair or egregious consequences of the NPIs they imposed. To be clear, scientific research into NPIs and their consequences did not begin with the outbreak of COVID-19. A wealth of contemporaneous scientific information already existed in major publications that could have informed a much more robust and meaningful response with respect to NPIs, but much of it was ignored or even attacked by mainstream public health and media entities in the early

months of the pandemic, for reasons that are not always clear. In short, this was not an "information" problem, it was a "judgment" problem.

"Lockdowns" and Stay-at-Home Orders

On August 5, 1969, astronaut Neil Armstrong celebrated his 39th birthday in an Airstream trailer—modified by NASA scientists to function as a mobile quarantine facility—after he and two other Americans returned from the world's first successful moon landing. This 21-day mandatory quarantine for the three astronauts, conceived by NASA, was a nod to the many unknowns faced by humanity in the wake of the Apollo 11 mission. Humans had never landed on the moon and certainly had never walked on it. No one had any concrete knowledge as to what could be hiding in the lunar dust the three astronauts had tracked back to Earth in their capsule and on their persons. Seen through the lens of an SEIR model, the quarantine was a reasonable way to avoid exposing the ground crew to any harmful pathogens picked up from the moon and brought back to Earth.

Fortunately for the astronauts, there were no dangerous pathogens brought back from the moon, but their story allows us to illustrate a meaningful difference between the popular notion of a small-scale quarantine, where one can use a targeted NPI to avoid altogether a population's exposure to a pathogen, and a large-scale quarantine—often referred to as a "lockdown"—where community spread has already taken place and the purpose is merely to blunt the impact of an epidemic disease. Terms like "lockdown" and "stay-at-home order" were popularized during the COVID-19 pandemic, but the NPIs themselves were previously theorized, modeled and studied. Often, those prior studies refer to both large and small-scale segregation measures alike as "quarantines," but it is the large-scale actions taken during the COVID-19 pandemic, commonly referred to as "lockdowns," that we address here, and we do not want to conflate the two. ***The logic behind small-scale quarantines should not be used to justify large-scale, sweeping lockdowns; likewise, the failings of large-scale lockdowns should not be used to undermine small-scale quarantines.***

Of course, between these large- and small-scale extremes, there is a spectrum of intensities. Some governments essentially put their population on an "honor system," trusting the sick to self-isolate and protect their fellow citizens. Other countries physically secured their own citizens inside their homes and kept them there for extended periods. Most people in the United States found themselves somewhere between these two extremes, largely due to one of the most profound problems with lockdowns: ***Our society is simply not organized in a way that could support long-term isolation.*** People must leave home for essential goods, and there is a population of "essential

workers" who must leave home to provide those goods. Even in a society that nails shut the doors of people's homes, someone must do the nailing. In short: ***Lockdowns leak.***

The scientific literature on lockdowns prior to 2020 understood this all too well. In 2006, a prominent epidemiological journal stated that "the number of infections averted through the use of quarantine is expected to be very low provided that isolation is effective." That same year, the WHO noted that "[i]ll persons . . . should remain home when they first become symptomatic, but forced isolation and quarantine are ineffective and impractical." In 2019, the WHO reiterated this position, stating that "home quarantine of exposed individuals to reduce transmission is not recommended because there is no obvious rationale for this measure, and there would be considerable difficulties in implementing it." As recently as January 2020, even the Director of the National Institute of Allergy and Infectious Diseases, responding to the Chinese government's apparent "success" with lockdowns, made the following statement:

> That's something that I don't think we could possibly do in the United States, I can't imagine shutting down New York or Los Angeles, but the judgement on the part of the Chinese health authorities is that given the fact that it's spreading throughout the provinces... it's their judgement that this is something that in fact is going to help in containing it. Whether or not it does or does not is really open to question because ***historically when you shut things down it doesn't have a major effect.***

(emphasis added). Astoundingly, however, within weeks and at the urging of these same officials, nearly every state in the United States was adopting some form of mandatory, government-enforced stay-at-home measure, closing schools and shuttering businesses.

This Grand Jury carefully examined contemporaneous scientific and popular media to find evidence of what shifted the opinions of these officials so dramatically in such a short period of time. What we found were a series of media articles and studies based on observational data touting the "success" of early lockdowns in China. One study was based entirely on claims by the Chinese government that it had "completely reversed the occurrence of COVID-19 cases reported daily." Similarly, WHO representatives returned from a February 2020 press junket in China claiming the country was "setting a new standard" for response to the virus. Prominent authors jumped on board, hyperbolizing that acting strongly in the short term could save millions of lives, but failing to act would cause millions to be infected and put our healthcare system at risk of collapse, pushing the Overton Window bit by bit into what had previously been anathema.

Of course, those authors were strictly correct. Millions of people were infected with SARS-CoV-2 and our healthcare system was, briefly and in a few particular areas, at risk of collapse. But it is obvious to this Grand Jury that no lockdown, regardless of its stringency, would have been able to prevent those events for one very important reason: By the time these measures were implemented, there was already significant community spread of the SARS-CoV-2 virus. One of the more comprehensive examples we have of this spread is a study from April 2020 estimating the seroprevalence rate of the SARS-CoV-2 virus in Los Angeles County to be approximately 4.34%. As of the 2020 census, Los Angeles County contained 10,014,009 people. 4.34% of that number is 434,608 people. If even 10% of those people are classified as "essential," that is 43,461 people. This Grand Jury is not aware of any NASA-modified Airstream trailer that can hold that many individuals.

Given that there is no way to effectively quarantine a population of this size, according to the SEIR model, with no other inputs, these 43,461 people will inevitably interact with susceptible hosts, exposing them to the virus and infecting them at a rate defined by the R0. Even if we chose a conservative R0 estimate of 2.28, within one disease cycle, 43,461 sick individuals would multiply to 99,091. Within two generations, it multiplies again to 225,927, and so on. Within five generations, if nothing changes, all 10,014,009 people in Los Angeles County will be infected.

This, of course, leads us into the other widely-claimed benefit of government-mandated lockdowns: They may not ultimately "stop the spread" of the disease, but they can at least "flatten the curve," slowing down the infection growth rate and allowing our healthcare system to keep up with the influx of serious cases. The evidence for this effect is mixed. One prominent journal found in January of 2021 that "while small benefits cannot be excluded," more restrictive NPIs did not confer significant benefits in terms of case growth, and that similar reductions may be achievable with "less restrictive interventions." Similarly, a meta-analysis conducted on lockdowns in the Spring of 2020 showed "little to no effect on COVID-19 mortality." On the other hand, age-adjusted charts from multiple European nations do echo the early Chinese claims, showing the same stalling or reversing of overall case growth during the pendency of the lockdown. This begs the question: Assuming the Chinese and European case growth data is accurate, is a lockdown that merely postpones case growth a worthwhile endeavor?

Collateral Consequences

In order to comprehensively answer that question, we must examine the significant collateral consequences of lockdowns which lie outside the boundaries of SEIR-based analyses.

First, one must consider the underlying economics: Lockdowns have been accurately called a "luxury of the laptop class" in that the benefits of these NPIs inure to the population who can afford to stay at home, not to the "essential workers" who cannot. The result is an income and class stratification that sees SARS-CoV-2 spread well-controlled among certain income strata while case growth remains rampant in others. Case growth data from low versus high income neighborhoods during the pandemic clearly demonstrates this distinction.

This is to say nothing of the overall impact of reduced economic activity in first-world countries like the United States and in Europe on other areas of the world. While many American workers, especially small business owners and those in the service sector, certainly felt the economic brunt of lockdown-related business closures, the CARES act did provide United States citizens with at least some economic protection. By contrast, many third world countries with more precarious economic prospects suffered far worse consequences but were not able to provide similar benefits. Pandemic-related economic depression produced a marked increase in extreme poverty (the number of people living on less than $1.90 a day). This statistic had been declining for years before it spiked in 2020. As of 2022, the number had returned to the same levels it had been in 2018, but almost five years of worldwide declining poverty had been erased. Similar effects were observed on the global food supply, where food shortages associated with COVID-19-related economic fallout have been modeled to have contributed to thousands of deaths. Likewise, global vaccination programs have seen the largest decline in childhood vaccinations in the last 30 years, resulting in a resurgence of diseases like measles that had previously all but disappeared. Clearly, the pandemic itself was going to cause global disruption. Is it fair to lay these consequences at the foot of lockdowns alone? No, but they certainly did not help.

Another aspect of lockdowns that deserves distinct consideration is that these NPIs effectively paused much of what would be considered "routine" healthcare like checkups, physicals, other health-related screenings and minor surgeries. This is an important point, because much of what one would consider "routine" is meant to detect conditions that could become serious in the future. A missed mammogram may be the difference between catching breast cancer at stage 1 versus stage 3 or 4. A routine checkup that would have revealed serious heart disease may be missed, resulting in a heart attack at some future date. There are thousands of potential scenarios, but even just these two adequately underscore our point: By pausing "routine" healthcare, lockdowns may have serious, unintended and unanticipated health consequences.

These collateral consequences will not be written in the language of SEIR. Rather, they will be written in the language of increased excess mortality—defined as the number of actual deaths over a given period of time versus the number of expected deaths—that can persist for months or even years after a lockdown is lifted. According to actuarial estimates based on data released by the CDC, excess mortality was indeed well above expected throughout the pandemic ***even when COVID-19-related deaths were excluded.*** Furthermore, excess mortality has remained dramatically higher through 2023 in age groups which—according to the IFR table we presented above—are at a greatly decreased risk of illness and death from SARS-CoV-2 infection.

These persistent excess deaths may not all be attributable to physical health problems. Mental health also declined precipitously during the pandemic. The WHO estimated in 2022 that anxiety and depression increased by 25% between 2020 and 2021. Even today, the NIH states that "[b]oth SARS-CoV-2 and the COVID-19 pandemic have significantly affected the mental health of adults and children[,]" describing that impact as follows:

> If you get COVID-19, you may experience a number of symptoms related to brain and mental health, including:
>
> - Cognitive and attention deficits (brain fog)
> - Anxiety and depression
> - Psychosis
> - Seizures
> - Suicidal behavior
>
> Data suggest that people are more likely to develop mental illnesses or disorders in the months following infection, including symptoms of post-traumatic stress disorder (PTSD). People with Long COVID may experience many symptoms related to brain function and mental health.

We included this text because it aptly demonstrates one of the key problems with analyzing collateral consequences: ***It conflates the consequences of SARS-CoV-2 with the consequences of our reaction to it.*** Is this Grand Jury really supposed to believe—as the text above suggests—that ***all*** the mental health symptoms described therein are attributable to the virus, while ***none*** of them are attributable to the fact that heavy-handed, government-mandated lockdowns, stay-at-home orders and school closures turned people's lives upside down for the better part of three years? That surmise not only offends common sense, it is also contradicted by CDC data from June of

2020 where a cross-section of Americans reported dramatically increased levels of anxiety, depression and PTSD at a time when—at the most—1 out of 20 of them had contracted the SARS-CoV-2 virus, but when NPIs across the nation had already been in place for months.

In the same vein, drug abuse deaths rose precipitously during the pandemic. No one has yet attempted to blame those on the SARS-CoV-2 virus itself, but they would fall squarely within the realm of a collateral consequence of lockdowns in that these deaths often tend to follow hand-in-glove with mental health issues. Once again, CDC data shows deaths relating to substance abuse rising beginning in early 2020 and only beginning to level out (but still rising) in 2022.

The final collateral consequences we wish to place on the scale are those related to one of the most controversial facets of lockdowns: School closures. One analytical model from a peer reviewed journal concluded that there was a median of 54 days of school instruction lost by children in the United States ages 5-11 during 2020. That may be a conservative estimate, and we plan to gather further empirical and anecdotal evidence about the collateral impacts of school closures and, if necessary, provide a deeper analysis of their consequences in a future Presentment. We include the concept here because school closures are perhaps the most important collateral consequence of lockdowns, and we did not wish to ignore their impact—even if that impact is difficult, at this point, to quantify—in our analysis.

As we gather and examine these consequences, an analogy starts to emerge. A government-mandated lockdown is like a credit card: It allows leaders to buy a period of depressed case growth, but that benefit is temporary and ends when the lockdown is lifted. The "interest" of this benefit—written in the language of excess mortality—is paid for in future months and years of economic hardship, mental & physical health consequences, and loss of educational attainment.

No one understood this relationship more clearly than one of the world's most famous epidemiologists, Dr. Donald Henderson. Widely credited with eradicating smallpox, Henderson had this to say about large-scale quarantines in 2006:

> As experience shows, there is no basis for recommending quarantine either of groups or individuals. The problems in implementing such measures are formidable, and secondary effects of absenteeism and community disruption as well as possible adverse consequences, such as loss of public trust in government and stigmatization of quarantined people and groups, are likely to be considerable.

Somehow, because of panic, hubris, ineptitude or some unfortunate combination of the three, this widely rejected idea not only made its way back into scientific discourse in 2020, it became the

law of the land in most of the United States between 2020 and 2022. It is clear to this Grand Jury that whatever benefits inured from these mandates, they were not worth the price.

The Use of Masks and Social Distancing

As of the writing of this Interim Presentment, the CDC provides the following "Key Messages" on using facemasks to prevent or limit the spread of the SARS-CoV-2 virus:

- Masking is a critical public health tool for preventing spread of COVID-19, and it is important to remember that any mask is better than no mask.
- To protect yourself and others from COVID-19, CDC continues to recommend that you wear the most protective mask you can that fits well and that you will wear consistently.
- Masks and respirators are effective at reducing transmission of SARS-CoV-2, the virus that causes COVID-19, when worn consistently and correctly.
- Some masks and respirators offer higher levels of protection than others, and some may be harder to tolerate or wear consistently than others. It is most important to wear a well-fitting mask or respirator correctly that is comfortable for you and that provides good protection.
- While all masks and respirators provide some level of protection, properly fitting respirators provide the highest level of protection. Wearing a highly protective mask or respirator may be most important for certain higher risk situations, or by some people at increased risk for severe disease.
- CDC's mask recommendations provide information that people can use to improve how well their masks protect them.

The substance of these recommendations has not been monolithic. In early 2020, the director of NIAID opined that masks would be ineffective at mitigating SARS-CoV-2 infection, only changing his opinion later to match newly-published federal public health guidance. In May of 2021, the CDC temporarily reversed itself on masks (in a now-deleted press release), citing observational studies showing lower viral transmissibility among vaccinated individuals as grounds to reconsider its prior guidance, only to reiterate its previous recommendation in July of that year (in another now-deleted press release) as the SARS-CoV-2 Delta Variant began to show higher transmissibility among vaccinated and unvaccinated individuals. As of today, the "Key

Messages" we cite above are part of a section entitled "Types of Masks and Respirators," the first in a confusing multi-page labyrinth of advice which indicates it was last updated on May 11, 2023.

To make these public health policy recommendations, our understanding is that the CDC relies on two primary sources of scientific literature: (1) Studies & trials published in major, peer-reviewed journals; and (2) studies published in its own journal, Morbidity and Mortality Weekly Report (MMWR). It is also our understanding that unlike major peer-reviewed journals, studies and trials published in MMWR are reviewed internally for rigor and accuracy by scientists and policymakers from the CDC.

MMWR did publish several studies on masks in the early part of the pandemic. Here are three prominent examples:

(1) "Absence of Apparent Transmission of SARS-CoV-2 from Two Stylists After Exposure at a Hair Salon with a Universal Face Covering Policy — Springfield, Missouri, May 2020" (known colloquially as the "Great Clips Study");

(2) "Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020" (known colloquially as the "Kansas Study"); and

(3) "Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021" (known colloquially as the "Dummy Study").

The Great Clips Study was among the first published in MMWR touting the utility of masking in preventing SARS-CoV-2 transmission. It involved two hairstylists who developed symptoms of COVID-19 and continued servicing clients for several days while wearing cloth or surgical masks. All in all, they exposed a total of 139 clients to potential SARS-CoV-2 transmission, but after a two-week period, none of the clients developed COVID-19 symptoms.

From the perspective of a layperson, 139-0 looks compelling. Nobody got infected. What else is there to know? There is even a made-for-media infographic of 139 barber chairs interspersed with two hairdryers to underscore the findings. From a scientific perspective, however, the data is riddled with potential confounders. To begin with, there is no control group of people who had their hair cut by one of the two barbers who was not wearing a mask. Because zero people developed symptoms, there is also no rate from which we can begin to determine the degree of protection afforded by the mask, and because no one was PCR tested for SARS-CoV-2, the study does not at all account for potential asymptomatic transmission. Even if there was a potential rate,

there are an astounding number of confounders that could have dramatically influenced the outcome, dwarfing the impact of the masks. How well-ventilated was the area? How many clients required the use of a blow-dryer? Had some of the clients previously been infected with SARS-CoV-2? When were cloth versus surgical masks used and by whom? Other than being "well-fitted," how were they worn? At some point in the ten-day period would these symptomatic hairdressers have ceased to be contagious? We could go on, but the point should be clear: ***This is not quality science.***

MMWR attempted to address some of the deficiencies from the Great Clips Study in the Kansas study, which identified trends in the rolling average of new COVID-19 cases in every county in the state of Kansas from June 1 to August 23, 2020. Once again, the graphs and trendlines seem to tell a compelling story: Rolling averages went up in both sets of counties before the implementation of the mandate, and then there was a split, with case counts continuing to rise in non-mandated counties but stabilizing and falling in mandated counties. The study's authors concluded from this data that "[c]ountywide mask mandates appear to have contributed to the mitigation of COVID-19 transmission in mandated counties."

Once again, however, even moderate scientific scrutiny renders those conclusions suspect. The data shows that the 7-day rolling average was never higher in counties with no mask mandate for the entire period of the study. Rather, the rolling averages appear to have exploded in mandate counties prior to the mandate and leveled off afterward. These data raise questions that seem to confound even the study's authors. Why were the mask mandate counties higher in the first place? Were there other interventions like stay-at-home orders in place that could have also affected the rolling average? Were there substantial differences between the people in the 81 non-mandated counties versus the 24 mandated counties? Were urban density or wealth taken into account? All in all, ***this study, too, is problematic.***

Finally, we get to the Dummy Study, where CDC scientists strapped various single and dual mask configurations on a "pliable elastomeric headform" (that looks a lot like the head of a CPR dummy), pointed it at another "pliable elastomeric headform" six feet away, and tested the ability of various mask configurations to filter out a mixture of exhaled potassium chloride with particles ranging in size from 100 to 7,000 nanometers. The study concluded that masks were effective at filtering out these particles, and that situations where both "pliable elastomeric headforms" were equipped with double masks (where a cloth mask is worn over a surgical mask)

or knotted/tucked surgical masks offered even greater protection, filtering out an impressive 96.4% and 95.9% of particles, respectively.

There is a significant problem, however, with this analysis. The size of the SARS-CoV-2 virus is approximately 90 nanometers, the very bottom of the range of particle sizes tested. Other studies from 2020 have estimated the minimum amount of liquid necessary to sustain the virus for any length of time in air to be somewhere in the range of 250-1,000 nanometers. Still, at best, this would fall within the bottom 1/7 of the tested particle sizes. Importantly, as we will explore in detail below, particles of this size are not droplets, but aerosols, which can remain in the air for extended periods of time provided they are not blown away or evaporated. The study did not specify what ratios of particle sizes were tested, but it would be reasonable to expect that these smaller aerosol-type particles were the 3.4% and 4.1% of particles that went through both masks.

Additionally, testing various mask configurations on two dummy heads in a laboratory really can't tell us much about the protection offered by these masks in a real-world environment. ***Human beings are not "pliable elastomeric headforms."*** We move. We talk. We eat. We sweat. We vary in age. We vary in size. We vary in mask-wearing behavior. Some of us have beards. Most importantly, perhaps, we inhale, causing negative pressure behind our masks that sucks in air through every available gap, provided there are any. All of these factors and many others influence the effectiveness of masks for real human beings in the real world.

These three are far from the only studies MMWR has published on masks, but they are good examples of the type of flawed observational and laboratory data the CDC has published to justify its Guidance. This is a "quality" problem, not a "quantity" problem. The number of published studies available cannot serve as a substitute for the quality of the underlying science upon which they are based.

The situation has gotten so convoluted with MMWR, that there is science on the science. A preprint posted in July 2023 concluded—after reviewing 77 studies published by MMWR on the issue of masking—that:

> MMWR publications pertaining to masks drew positive conclusions about mask effectiveness over 75% of the time despite only 30% testing masks and <15% having statistically significant results. No studies were randomized, yet over half drew causal conclusions. The level of evidence generated was low and the conclusions drawn were most often unsupported by the data. Our findings raise concern about the reliability of the journal for informing health policy.

How does what should be the leading journal on infectious disease in the world, sponsored by the United States government, in the midst of a global pandemic, find itself seemingly unable to publish sound science on such a critical and controversial question? In this particular situation, the best way to determine the reliability of masks—especially the all-important question of whether to mask children—would be to conduct a properly designed Randomized Controlled Trial (RCT). The structure of an RCT would call for researchers to take a number of steps beyond what we see in the observational and laboratory studies above: Create a control group; define endpoints in advance; limit the time period of the study; account for as many external variables as possible; and ultimately, we would all be able to see what the data have to say. So why not conduct one? In sworn testimony before the United States House of Representatives on February 8, 2023, the CDC Director described her agency's position on that question as follows:

> In order to do a randomized clinical trial you need to have equipoise in the question, and ultimately what would happen... what happened is that there were so many studies that demonstrated time and time again in the height of covid transmission that masks were working to prevent transmission, that I'm not sure anybody would have proposed a clinical trial because in fact there wasn't equipoise to the question anymore.

In medicine, "equipoise" is defined as "a state of uncertainty as to the balance of benefits and harm that may result from two or more therapeutic regimens[,]" indicating the appropriateness of an RCT. Is there equipoise on the question of masking? In one sense, the Director is correct, outside her sandbox of MMWR, there are indeed RCTs that precisely address the question her agency refused to ask in that format: Do masks work?

We have the beginnings of an answer. The Cochrane Library is a U.K. nonprofit that specializes in the collection and synthesis of scientific research data "for anyone interested in using high-quality information to make health decisions." Much of this research is published in the form of "meta-analyses," where Cochrane researchers analyze and weigh available scientific studies in order to form a conclusion on some issue of interest. In the world of medicine and scientific research, Cochrane is considered the "gold standard," respected for its careful and considered treatment of the topics it addresses. After examining available studies from around the world, including several all-important RCTs regarding the effectiveness of masks, here is what Cochrane's researchers concluded and published in January 2023, approximately one week before the congressional testimony of the CDC Director we cited above:

> ***There is uncertainty about the effects of face masks.*** The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. . . . ***There is a need for large, well-designed RCTs addressing the effectiveness of many of these interventions in multiple settings and populations, as well as the impact of adherence on effectiveness, especially in those most at risk*** . . . .

(emphasis added). Once again, we are not physicians, but we do not believe years of medical school education or an advanced degree is required to read the paragraph above as confirmation that there is indeed equipoise in the question of whether masks are an effective NPI for SARS-CoV-2. If the best meta-analysis we have says there needs to be more RCTs, someone should do those RCTs. The NIH and CDC receive billions of our tax dollars every year to elucidate these important questions in public health for the American people.

With all these resources at their disposal and given the importance of the question, why did these agencies not just do the RCTs? Frankly, we do not believe equipoise had much to do with it. Rather, after reading between the lines of the scientific data involving the structure of the SARS-CoV-2 virus and how it spreads, we believe at least some of the officials in these agencies were acutely aware that a properly conceived and administered RCT where the effects of masking are isolated from the effects of other NPIs is very likely to show that mask mandates—if not masks themselves—have little to no efficacy in stopping or slowing the spread of SARS-CoV-2 virus. This, of course, would invite further criticism of the CDC and other federal agencies who championed these broad mask mandates, and on the federal, state and local agencies who codified and enforced them.

Before explaining why we believe such a study would not show efficacy, we acknowledge the conventional wisdom that masks, which limit the outflow of fluids associated with respiration, should limit transmission of a respiratory virus like SARS-CoV-2. Viewed through that lens, the "Key Messages" we cited at the beginning of this section make sense: Wearing masks limits droplets and limiting droplets prevents viral spread. That analysis is not exactly wrong, *per se*, it is just incomplete.

There are two reasons for this. The first comes down to the fact that humans are almost invariably imperfect mask wearers. The SARS-CoV-2 virus does not know we just sat down at a restaurant for lunch, or that we have a big speech to make, or that grandpa needs a hug. Even if we were to find the right kind of mask with exactly the right kind of fit, shave every day and change filters diligently, it would still be virtually impossible for us to conduct our affairs with the rigidity necessary to receive the full measure of benefits the mask would provide to a CPR dummy in a laboratory. The CDC Director argued in her February 2023 testimony that one of the primary obstacles to an effective RCT involving mask-wearing was that it would be difficult to get study participants to adhere to the protocols. She has a good point, but we offer a counterpoint: If the protocols are such that a large number of study participants who are compensated for their time and effort in an RCT cannot adhere to them, what use will they be to the rest of us?

The second reason is less well-known, but perhaps equally significant. Unlike many other respiratory diseases, it appears that SARS-CoV-2's primary mode of transmission is via aerosol. To understand why this matters, we must delve into the science of aerosols. As we mentioned above, humans emit respiratory ejecta of various sizes, all of which could theoretically contain some concentration of SARS-CoV-2 viruses, and all of which are subject to environmental effects like gravity and air circulation based on their size. The largest droplets, measuring some 42,000 nanometers, drift to the ground within seconds and are therefore unable to travel more than a few feet. As the particles get smaller, however, gravity has less of an impact. Particles from 9,000 to 1,900 nanometers can hang in the air for anywhere from a few minutes to a half hour like mist from a fog machine at a rock concert. Particles of 400 nanometers or smaller can hang in the air for hours provided they do not evaporate (as they certainly would in sunny, exterior areas). SARS-CoV-2 itself is approximately 90 nanometers. It does require some liquid in order not to desiccate before it reaches a new host, but normal respiration by an infected person could produce any number of small aerosol particles that are surprisingly persistent in the right environmental conditions. Moreover, time would be a factor, a few seconds in such an environment might not be enough time to build the viral load necessary to cause an infection, but as the number of respiratory expressions increase, so goes the number of droplets inhaled and the viral load.

The concept of aerosol-based transmission of SARS-CoV-2 is not at all a new idea. We were able to trace the earliest research papers discussing it to around mid-2020. They also discussed, in detail, the considerations that would arise from different daily activities like riding in cars, planes, or even just having normal conversations. For whatever reason, however, the

concept of aerosol-based spread never came to significantly inform public health science communication. The word "aerosol" and its attendant properties should have become part of the zeitgeist. People should have been told that masks, like any protective device, have limitations. Surgical and cloth masks have limited utility against aerosol particles. Well-fitted N95 masks will protect only the wearer, not anyone else, and only for as long as the filter remains viable and the mask remains dry. It would have underscored the minimal utility of the ubiquitous plastic shielding that persists in the retail and food service sector today. Were aerosol-based spread taken account, we believe the CDC guidance cited at the top of this section would look very different.

This incomplete, inaccurate advice is not without its own potential consequences. High-risk individuals who have been misled into believing masks offered more protection than they did may have been encouraged to do activities they should not have done or to go places they should not have gone. People who got sick with COVID-19 may have persisted in their daily activities in a misplaced belief that wearing a mask—even an N95 mask—would protect those around them from potential transmission. "Isolation bubbles" that appeared around exterior restaurant tables in some states may have increased the risk of viral spread between whoever was inside the bubble by limiting sources of potential ventilation. For that matter, congregating in open-air spaces should have been encouraged back in 2020, not shunned.

SARS-CoV-2's primary mode of transmission being aerosolized also sheds light on another oft-criticized area of CDC advice—not updated since July 2020—which reads as follows:

> Social distancing, also called "physical distancing," means keeping a safe space between yourself and other people who are not from your household.
>
> To practice social or physical distancing, stay at least 6 feet (about 2 arms' length) from other people who are not from your household in both indoor and outdoor spaces.
>
> . . . .
>
> COVID-19 spreads mainly among people who are in close contact (within about 6 feet) for a prolonged period. Spread happens when an infected person coughs, sneezes, or talks, and droplets from their mouth or nose are launched into the air and land in the mouths or noses of people nearby. The droplets can also be inhaled into the lungs.

The CDC's six-foot guideline was drafted based on the prevalence of SARS-CoV-1 on a single airline flight in 2003. The WHO based its recommendation of three feet between people on

even older research from influenza in the 1930s. Neither are based on the particularities of SARS-CoV-2. The problem, once again, is that when one is dealing with an aerosol, the primary concern is not the distance between people, it is whether one is dealing with an interior or exterior space, and, in an interior space, whether there is sufficient air filtration to prevent the accumulation of aerosol clouds containing SARS-CoV-2 virus. In enclosed interior spaces for extended periods of time, a distance of six feet or sixty feet is not going to make any difference. By fall of 2020, there was peer-reviewed, published scientific data available containing all of these facts. Public policy should have been focused on taking advantage of exterior spaces. Instead, many states and municipalities did the opposite, closing parks, taping up playgrounds and confining people to interior spaces—where viral transmission was more likely—with stay-at-home orders.

Not only was most of the information involving aerosol-based spread available in 2020, there was also a contemporaneous, large and growing body of scientific research showing the effectiveness of High-Efficiency Particulate Air (HEPA) and other air exchange and filtration systems in limiting SARS-CoV-2 spread in indoor settings. Planes, for example, which have robust air circulation systems, had unusually low spread given the proximity of passengers to one another on flights. Hospital transmission was also low. Even MMWR did a study on air filtration systems in hospitals reducing transmission. One peer-reviewed paper detected zero SARS-CoV-2 pathogens in one of its wards after installing an air/UV filter, but detected the virus in the air both before those filters were turned on and after they were shut down again a week later. Perhaps instead of runs on hand sanitizer, toilet paper and N95 masks, there should have been runs on HEPA filters.

To their credit, the CDC's website does contain significant information about the importance of air filtration in indoor spaces. Our critique is that the relationship between this information and the social distancing guidelines should have been much more a matter of public discourse, and the guidelines should have been updated to reflect our emerging understanding of how the disease moves in indoor versus outdoor spaces. Institutional public health experts had this science at their disposal but continued to stick to advice that bore only a cursory resemblance to the contrary scientific evidence presented in the emerging data. That, coupled with heavy-handed directives from state and local actors, essentially turned scientific inquiry—the very basis of which is asking questions and doubting priors—into a form of civil disobedience. The world could have had a very different approach, where people understood that the protection offered by masks was at-best limited and speculative, but the outdoors could have essentially been at their disposal. How

many more quality air filtration systems could we have installed in 2020-21 as opposed to pointless plastic shields, social distancing stickers, and hand-sanitizer dispensers? We have no way to know.

CONCLUSION

This brings us back to our original question: How did these nonpharmaceutical interventions affect the overall risk presented by the SARS-CoV-2 virus?

With respect to lockdowns, there does exist a pattern in the data showing a short-term stabilization of case growth that persists until the lockdown is lifted, followed by months or even years of excess mortality that can partially be attributed to collateral consequences concentrated in the groups at lowest risk from COVID-19 disease. There is a case to be made that these lockdowns enabled others in high-risk groups to "bridge the gap" until 2021 when they had access to vaccines—a subject which this Grand Jury will undoubtedly examine in future presentments. On average, however, when one includes all age groups, lockdowns were not a good trade. Comparative data showed that jurisdictions that held to them tended to end up with higher overall excess mortality. This is especially evident when compared to jurisdictions that targeted their protective efforts towards the highest-risk groups instead of mandating large-scale, extended periods of quarantine for everyone. Effectively, lockdowns traded the immediate welfare of a smaller, affluent, well-represented group of older Americans who could afford to stay home for the longer-term welfare of a larger, less-affluent, poorly-represented group of children, teens, twenty-, thirty- and forty-somethings who could not. If anything, the result of this was a modest benefit to the former group at the expense of the latter.

With respect to masks, we have never had sound evidence of their effectiveness against SARS-CoV-2 transmission in the form of reliable RCTs that demonstrated statistically significant benefits. There have always been legitimate questions around the impracticality of individual adherence to mask recommendations, but once it became clear that the primary transmission vector of SARS-CoV-2 was via aerosol, their potential efficacy was further diminished. Public health agencies failed to adequately explain this important distinction to the American public in favor of a broad mask recommendation that did not make nearly enough distinction between the types of masks available and put at risk those it sought to help. Well-financed federal agencies chose to fill the discourse with flawed observational and laboratory studies, hiding behind their conclusion of "no equipoise" to avoid the potential embarrassment of the public health advice they championed being invalidated by evidence.

Likewise, the aerosol-based spread of SARS-CoV-2 changes the equation with respect to social distancing. It is not nearly as important how far away people are from one another as it is whether they are in an interior or exterior environment and whether that environment is subject to adequate airflow. Even today, this important information is missing from the CDC's Social Distancing Guidelines.

As for their effect on overall SARS-CoV-2 risk, we cannot ignore the fact that these NPIs were not administered based on the best available scientific data. In fact, many public health recommendations and their attendant mandates departed significantly from scientific research that was contemporaneously available to everyone: Individuals, scientists, corporations and governments alike. Often this research was ignored by institutional policymakers. Occasionally it was even attacked. It is a sad state of affairs when something as simple as following the science constitutes an act of heresy, but here we are. Importantly, while some of these NPIs may have shifted risk to later in time or from one group to another or had some speculative efficacy against viral spread when used in perfect laboratory conditions, comparative evidence suggests they did not significantly change the overall risk profile presented by the SARS-CoV-2 virus in terms of excess death, especially once collateral consequences are taken into consideration.

CERTIFICATION

THIS REPORT IS RESPECTFULLY SUBMITTED in Open Court to the HONORABLE CHRISTOPHER C. SABELLA, Presiding Judge of the Twenty-Second Statewide Grand Jury, this 2nd day of February, 2024.

Juror # 5
Foreperson
Twenty-Second Statewide Grand Jury of Florida

I, NICHOLAS B. COX, Statewide Prosecutor and Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

NICHOLAS B. COX
Statewide Prosecutor
Legal Adviser

I, JEREMY B. SCOTT, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

JEREMY B. SCOTT
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, BRIAN L. FERNANDES, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

BRIAN L. FERNANDES
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, KENNETH L. A. LINEBERGER, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

KENNETH L. A. LINEBERGER
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAMES R. HARRIS, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

JAMES R. HARRIS
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAE HEE KIM, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

JAE HEE KIM
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, NATHANIEL S. BAHILL, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 2nd day of February, 2024.

NATHANIEL S. BAHILL
Assistant Statewide Prosecutor
Assistant Legal Adviser

THE FOREGOING First Interim Report of the Twenty-Second Statewide Grand Jury was returned before me in Open Court this 2nd day of February, 2024, and is hereby sealed until further order of this Court, upon proper motion of the Statewide Prosecutor.

HONORABLE CHRISTOPHER C. SABELLA
Chief Judge of the Thirteenth Judicial Circuit
Presiding Judge, Twenty-Second Statewide Grand Jury

Received, Clerk, Supreme Court

FEB 2 2024

A True Copy
Attest:
John A. Tomasino, Clerk
Supreme Court of Florida
By
Deputy Clerk

SUPREME COURT OF THE STATE OF FLORIDA
ESSE QUAM VIDERI

Hearing on Masking

kerhood@verizon.net <kerhood@verizon.net>

Mon 2/26/2024 12:50 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>;Senator Jessica de La Cruz <jessicaforri@gmail.com>

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Report Suspicious

Good Day Mr. Garceau

I am writing to you regarding the upcoming hearing on March 15th regarding the Mask Mandate Regulation. I want to state clearly my opposition for this regulation. We have learned so much since the masking mandate - the proposed regulation defies logic.
What we know:

- Masking did not stop the spread of Covid
- Masks caused irreparable harm in children
- The masking policies at school wide events and sports made no logical sense

Let me tell you a story that shows the utter stupidity of the previous masking policy. Near the end of the pandemic, while the common citizens of RI were able to walk around without masks, my High School age children were forced to wear sweaty, dirty masks that did not work. I have three sons that all wrestle. They were forced to wrestle with a mask on. Think about that - two children wrestling on top of each other with a mask. The rules stated they could not shake hands at the beginning of the match or have their hands raised at the end of a match. Yet they wrestled with their paper mask. The only thing that the mask prevented was proper breathing. They were handed school provided masks from a box that clearly states "does not stop the transmission of...".

We are now several years past Covid. We have gained knowledge and have concrete data that supports the fact that masks do NOT work. The DoH should be working diligently to regain the trust of its citizens. We can do that by ensuring all regulations regarding health care and health restrictions be based on scientific evidence. It is shocking that this is controversial.

Thank You - I look to the hearing.

Jessica - as a parent of school age children and a Senator - I hope you can show your opposition on the proposed regulation.

Masking in School Rule

karenflora@hotmail.com <karenflora@hotmail.com>

Tue 2/27/2024 10:02 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Sent from my iPhone

Masking in School Rule

Karen Flora <karenflora@hotmail.com>

Tue 2/27/2024 10:06 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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I apologize, I sent blank emails!

I would to express that I am OPPOSED to the Department of Health making any mask mandate for any reason at any time in schools or any other location.

Aside from the fact that it has been shown that masks don't work and the mask mandate caused irreparable harm to our children, Rhode Island was founded on the principles of freedom and its citizens should be free to make their own informed choices regarding what they wear on their bodies.

Please make note of my opposition,

Thank you,
Karen Flora
North Smithfield, Rhode Island

Mask mandate

Jaclyn Ayotte <jayotte829@yahoo.com>

Wed 2/28/2024 10:53 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hi
I'm writing in opposition to the proposed mask mandate in RI. I'm a mom of three children; one in private school, one in public and one home school. Masks do not belong on children and this mandate should not even be entertained. We are prepared to pull our children out of school if they try to pass this nonsense.

Jaclyn Ayotte
East Greenwich, RI

Sent from my iPhone

February 28, 2024

Rhode Island officials,

I am writing to you as a concerned parent and citizen of East Greenwich, RI regarding 216-RICR-30-05-4, a permanent regulation for future mask mandates. In light of the dearth of evidence that masking children prevents spread of disease within the community I ask you to strike down such a regulation. As early as 2021, Paul Alexander of The Brownstone Institute writes "I present the masking 'body of evidence' below (n=167 studies and pieces of evidence), comprised of comparative effectiveness research as well as related evidence and high-level reporting. To date, the evidence has been stable and clear that masks do not work to control the virus and they can be harmful and especially to children." https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/ There has been no compelling study showing a positive effect from masking children. In fact, a paper by Sundlun et al. published in the British Medical Journal in December 2023 concludes "Real-world effectiveness of child mask mandates against SARS-CoV-2 transmission or infection has not been demonstrated with high-quality evidence. The current body of scientific data does not support masking children for protection against COVID-19." https://adc.bmj.com/content/archdischild/early/2023/12/06/archdischild-2023-326215.full.pdf

I would also like to remind you of the testimony I gave in January, 2022 regarding the negative effects of masking our children.

"Our students are suffering anxiety, learning loss, speech delays, and reading delays. They have missed important academic, developmental, social and coming-of-age milestones; they have lost time they cannot gain back. I implore you to think back on your own childhood and ask yourself if you can continue to watch our children deprived of the normalcy you were offered as a student. Children, whether in elementary, middle, or high school need to see faces and expressions. They need to sit together and socialize. While adults in our state have the freedom to have a chat with friends over brunch, our children are forced to sit apart in silence, masks off, voices off. These are policy choices, Covid did not cause this, policymakers did. These choices have been an unnecessary burden on our children for far too long."

We MUST put mandatory masking behind us for the sake of our children. They've sacrificed so much in the last 4 years. No one should be able to once again force our children (or anyone else for that matter) to once again cover their faces and hinder their breathing.

I thank you in advance for appropriately weighing the evidence (or lack thereof) and striking down any regulation that allows authorities to once again force masking.

Lisa Pomeroy
495 Stone Ridge Drive
East Greenwich, RI

Re: questions regarding 216-RICR-30-05-4 - RIDOH's March 15th hearing for its proposal of a mask mandate regulation

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Thu 2/22/2024 10:23 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good morning Zack,

Thank you for your recent responses to my questions regarding the March 15th hearing for RIDOH's proposal of a mask mandate regulation (216-RICR-30-05-4). I'm writing to follow up on the remaining unanswered questions. Have you determined what technological equipment be available for expert witnesses who wish to provide a visual presentation? We are particularly interested in the ability to project power point presentations.

Additionally, will an overflow room be provided in the event that we exceed the capacity of conference rooms A, B and C?

I'd also like to ensure that we will be able to record the hearing. All public *meetings* can be recorded by attending members of the public. Does this transparency also apply to public *hearings*? We have a professional cameraman who will be in attendance and I'd like to ensure that he will not be barred from recording on the day of the hearing.

Finally, may we visit the conference rooms with our cameraman prior to March 15th in order to adequately plan for the hearing?

Thank you for your time and for your responses.

Maddalena Cirignotta

Re: questions regarding 216-RICR-30-05-4 - RIDOH's March 15th hearing for its proposal of a mask mandate regulation

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Wed 2/28/2024 11:02 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:gregory@splawri.com <gregory@splawri.com>

1 attachments (3 KB)

Outlook-4ejukmww;

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Good Morning Zachary,

Thank you for responding to my inquiries. I'd like to ensure that I understood your response accurately. To be clear, if more than 390 people attend the march 15th hearing for RIDOH's proposed mask mandate regulation, RIDOH will turn members of the public away? This means that some people may be denied the right to make a public comment regarding the proposed regulation. Is this accurate? Please advise.

Best,
Maddalena

Another follow up question regarding 216-RICR-30-05-4 - RIDOH's March 15th hearing for its proposal of a mask mandate regulation

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Wed 2/28/2024 1:00 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:gregory@splawri.com <gregory@splawri.com>

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Hi again Zachary,

I understand that RIDOH will not provide technological equipment for our expert witnesses. Would you please confirm that RIDOH will not *bar* our expert witnesses from providing our own equipment? We do intend to present data to RIDOH and will make the necessary arrangements ourselves.

Best,

Maddalena Cirignotta

NO MORE MASK MANDATES EVER AGAIN

Becky DiStefano <becky47417@gmail.com>
Thu 2/29/2024 6:02 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:Jeffrey DiStefano <remmy474117@gmail.com>

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February 29, 2024

This is my written testimony submitted to voice our vehement opposition to any and all mask mandates in schools. As a mother who has been fighting alongside my husband and countless other parents since 2020, we will not comply with any future mandates and are speaking up against anyone who wrongly thinks they have the authority to do so.

My name is Becky DiStefano and we joined with hundreds of other Rhode Island parents against the governor and Rhode Island Department of Health over the harmful and abusive mask mandates in Rhode Island schools. The ruling of "irreparable harm" done by masks stands in the courts of Rhode Island since November 2021 and more has come to light since. It turns out the very "experts" you have listened to, without questioning them or their motives, are liars and manipulators, as we have said all along.

Here is what is going to happen:

No child will be forced to wear a mask – parents (and parents only) make that decision.

There is no legal requirement for any child to wear a mask in school, under any circumstances regardless of vaccination status, recent illness or symptoms. According to Dr. McDonald, who initially mandated masks based on his own whims, **school mask mandates are unenforceable**.

My children will not, under any circumstances, wear a mask to attend school. It is our choice as parents and our children will not be masked. My children's medical information is private and no one in any school building or capacity has the authority to ask them this private information.

If any school system tries to force masking, they can expect swift legal action.

On May 20th2022, the Department of Health distributed a memo [andrewbostom.org] to RI school superintendents in which RIDOH director incorrectly used the word "must," stating that "*On days 6-10 of their isolation period, they (*students) ***must*** *wear a well-fitting mask on the bus, in school, and at all school-associated events…If students and staff are unable to wear a mask at school, they* ***must*** *isolate at home for the full 10 days following the positive test*."

Despite this misleading memo, Dr. McDonald explicitly told the RI Superior Court this July, that the memo is "*not an enforceable document from the Department of Health… There's nothing enforceable about this. It's simply a memo. It's not a rule. It's not a regulation. It's not a law. It's not an executive order* [loom.com] ." According to Dr. McDonald's July 2022 Superior Court deposition [m.youtube.com], the intention of this memo was to inform superintendents of CDC *recommendations*

but should NOT be interpreted to mean that district leaders should require children to wear masks [loom.com].

Recently issued guidance from RIDE (slides 21 – 22) updated language regarding isolation to include the word "*must,*" presumably from RIDOH's unenforceable memo [andrewbostom.org]. **There is no legal basis for any of this guidance**.

The masking of children did irreparable harm to children as young as two years old mentally, physically and emotionally. The amount of fear and lies pumped into children for years while they were told to cover their faces is abhorrent and there is blood on the hands of many in this state.

Just so we are crystal clear:

We will never mask our kids. We will never mask ourselves. We will never comply and we will fight and never go away.

Sincerely,
Becky DiStefano

Department of Health

Three Capitol Hill
Providence, RI 02908-5097

TTY: 711
www.health.ri.gov

May 20, 2022

Dear Rhode Island Pre K-12 Families,

We are writing to remind you of the Centers for Disease Control and Prevention's (CDC) isolation protocol for those who test positive for COVID-19. Please see the specifics of the isolation protocol for school-based settings below:

- Anyone who tests positive for COVID-19, **even if they are vaccinated**, must stay home and isolate for *at least 5 days*.
- They *may* return to school on day 6, ***if*** **they don't have symptoms or their symptoms are improving, and they've been fever-free for 24 hours** (without the use of fever reducing medication), *and*
- **On days 6-10 of their isolation period**, **they must wear a well-fitting mask** on the bus, in school, and at all school-associated events. They should also wear a mask outside of school when they are around others, especially when indoors.
- **If students and staff are unable to wear a mask at school, they must isolate at home for the full 10 days following the positive test.** They can then return to school if their symptoms have improved and they've been fever-free for 24 hours (without the use of fever-reducing medication).
- The CDC recommends an isolation period of at least 10, and up to 20 days, for people who were severely ill with COVID-19 and for people with weakened immune systems.
- **Everyone must follow these isolation protocols, even if they receive a negative test result** (i.e., antigen or PCR) during their 10-day isolation period.

Additionally, **please ensure that all self-test positive test results are reported to the RIDOH** at portal.ri.gov/s/selftest. This information helps the Department of Health monitor the spread of COVID-19.

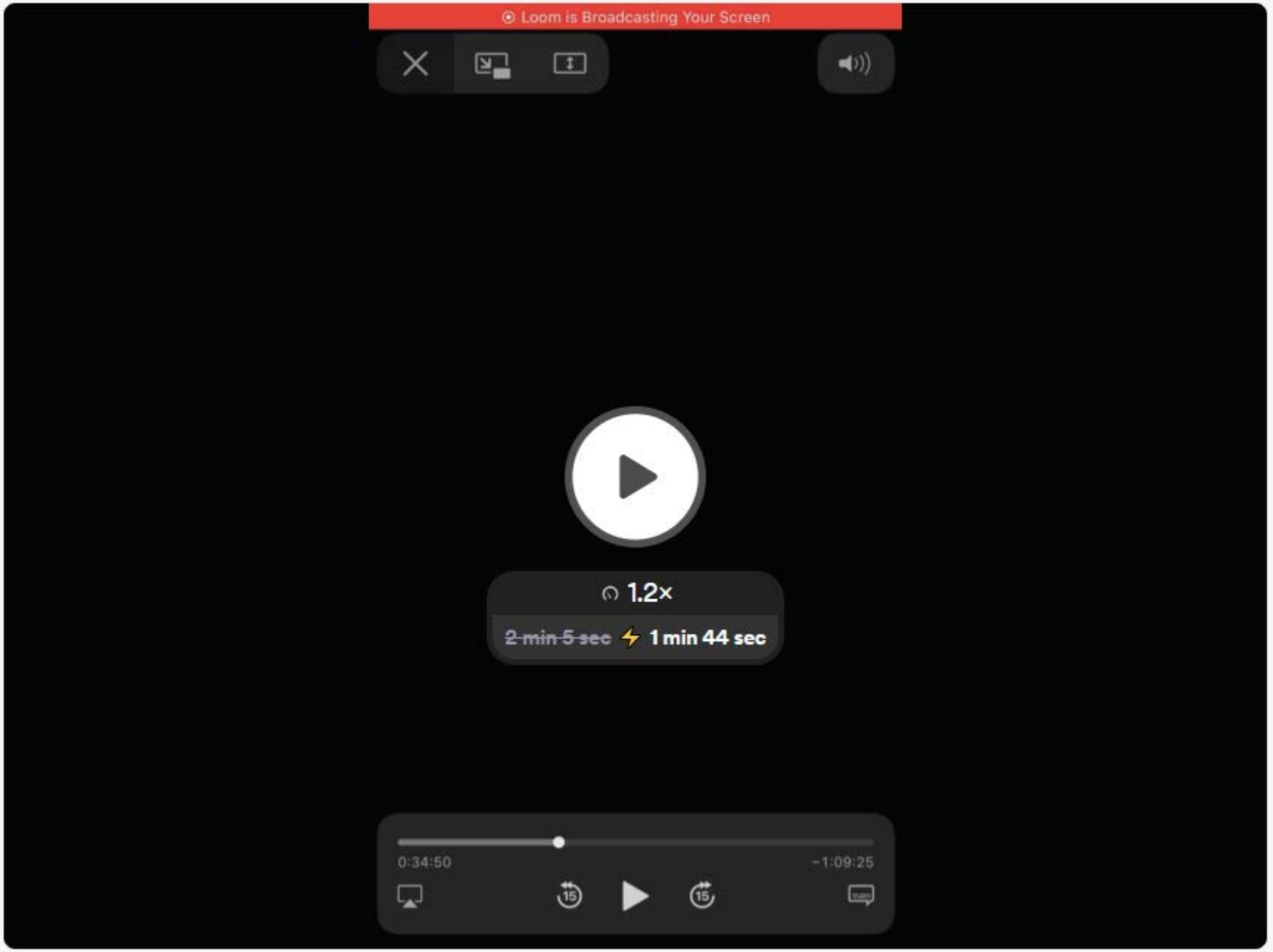
For additional information about COVID-19, visit health.ri.gov/covid or call 401-222-8022. You can find this letter available online.

Sincerely,

James V. McDonald MD, MPH
Interim Director of Health
james.mcdonald@health.ri.gov

Deposition Dr. McDonald - RIDOH's use of the word "must" Southwell vs...

Maddalena Cirignotta · almost 2 years ago





COVID-19 vaccine
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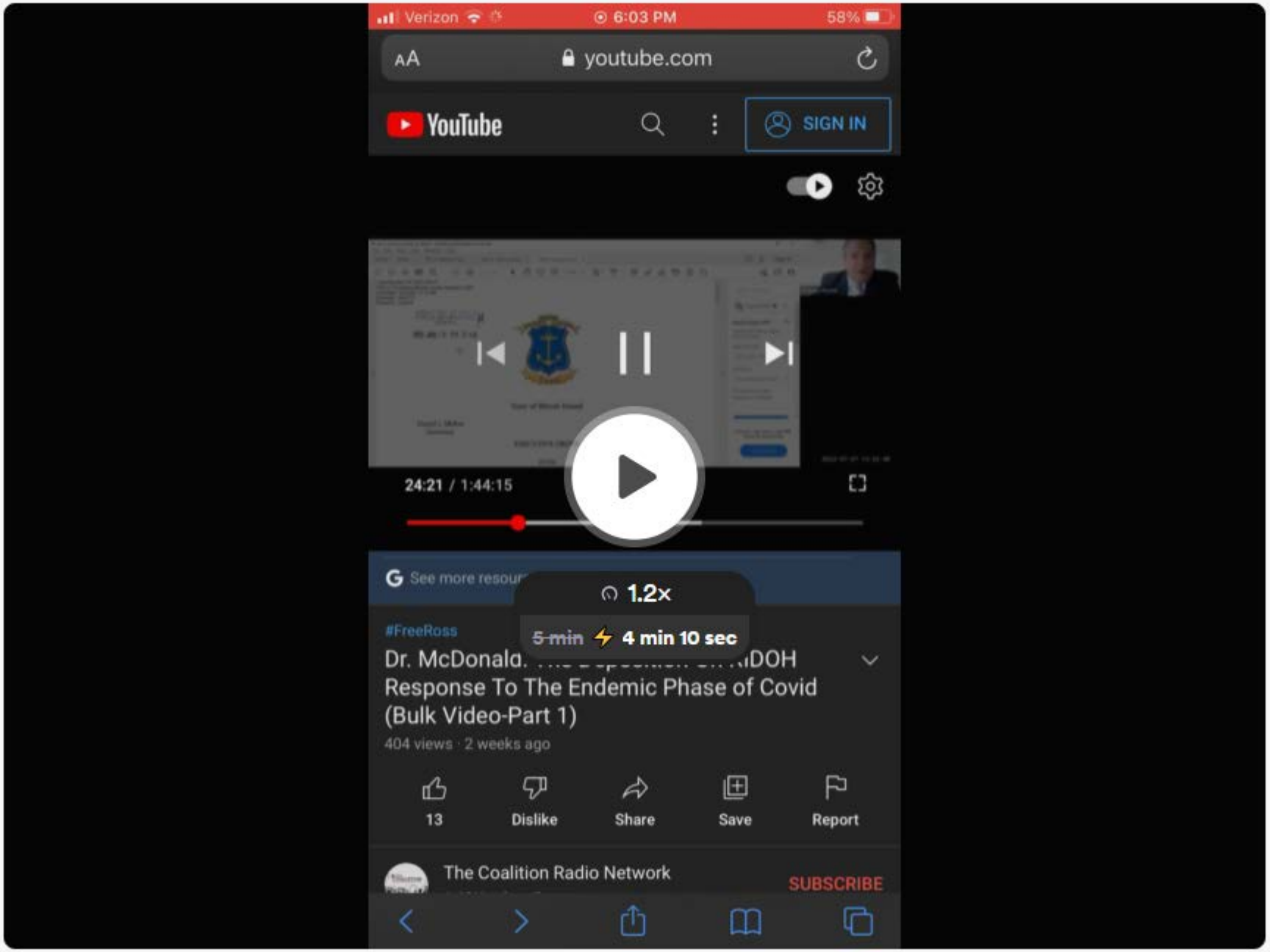
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Dr. McDonald: The Deposition On RIDOH Response To The Endemic Phase of Covid (Bulk Video-Part 1)

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iOS recording - 10 Aug 2022

Maddalena Cirignotta · almost 2 years ago



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Proposed Mask Policy

Catherine Rodgers <catherinerodgers25@gmail.com>

Thu 2/29/2024 9:11 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good evening, Mr. Garceau:

I am writing to express my concern about the proposed mask policy that would impose a mask mandate on school children in the future for any infectious disease. My daughter suffered emotionally, socially, and physically when masks were mandated in Rhode Island. She was born with a cleft lip and has had multiple surgeries to help her breathe properly, and she experienced a feeling of suffocation while wearing a mask. She also had a seizure disorder which often also caused migraines. During the Covid pandemic, my daughter got daily headaches from wearing her mask, and she could not endure more mask wearing at activities, so she could not participate in them, which was socially isolating. While everyone at school wore masks, she had trouble understanding what the teachers and students were saying during lessons. Her love of learning disappeared. I respectfully request that you take into consideration the harm that was caused when this policy was unfairly imposed on the least likely group to contract or spread this virus. Please understand that if you implement this policy, it will have negative repercussions that may never be undone. Thank you for considering the needs of children who are powerless to shape a policy that they will be most harmed by.

Sincerely,
Catherine Rodgers
15 David Court
East Greenwich, RI
360-509-1282

Testimony in opposition to proposed rule Masking in School 216-RICR-30-05-4

Kimberly Vecchio <kimberly.vecchio122@gmail.com>
Sat 3/2/2024 11:12 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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March 2, 2024
Re: Testimony in opposition to proposed rule Masking in School 216-RICR-30-05-4

To Whom it may concern,

I submit this written testimony in OPPOSITION to this proposed rule Masking in School 216-RICR-30-05-4

A mask is a medical intervention. For the past four horrific years, RIDOH has touted their commitment to "follow the science," with regard to a variety of medical interventions, including masks, while simultaneously ignoring any science presented to them that doesn't fit their needs. It would seem based on the original draft of this rule (4.3 (B) - "An absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the Department from considering a face mask requirement."), that RIDOH had no intention of considering any evidence whatsoever in this matter. Why is that? And how can they be trusted to properly review the evidence on any issue if this statement was actually consideration at all?

Here is just a fraction of the science on masks that has been ignored over the past four years.

Mask effectiveness:

October 2011: The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence. Results: "None of the studies we reviewed established a conclusive relationship between mask/respirator use and protection against influenza infection." 1

May 2020: Non Pharmaceutical Measures for Pandemic Influenza in Non Healthcare Settings— Personal Protective and Environmental Measures. Results in the area of face masks: "In our systematic review, we identified 10 Randomized Control Trials that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks." "There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory confirmed influenza."2

September 2020: Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020. Results: 84% of participants who tested positive for COVID-19 said they wore a mask most of the time or all of the time. 3

November 2020: Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers A Randomized Controlled Trial. Results: "In this community-based, randomized controlled trial conducted in a setting where mask wearing was uncommon and was not among other recommended public health measures related to COVID-19, a recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, incident SARS-CoV-2 infection compared with no mask recommendation." 4

March 2021: Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates — United States, March 1–December 31, 2020. Results: "Daily case and death growth rates before implementation of mask mandates were not statistically different from the reference period." 5

May 2021: Mask mandate and use efficacy in state-level COVID-19 containment - "Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID-19 growth surges. 6

July, 2021: Experimental investigation of indoor aerosol dispersion and accumulation in the context of COVID-19: Effects of masks and ventilation. Results: "The results show that a standard surgical and three-ply cloth masks, which see current widespread use, filter at apparent efficiencies of only 12.4% and 9.8%, respectively. " 7

November, 2021: Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review - "The available clinical evidence of face mask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle." 8

July, 2022: Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota "We observed no significant difference between student case rates while the districts had differing masking policies, nor while

they had the same mask policies…Researchers concluded that school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students." 9

January, 2023: Cochrane Review Insert Cochran review - Physical interventions to interrupt or reduce the spread of respiratory viruses. - "12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks." 10

March 2015: A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. Results: The use of cloth masks (the ones the children are most likely wearing) was found to produce the highest rates of infection with influenza like illness, clinical respiratory illness, and laboratory confirmed respiratory viruses compared to the other groups studied. The use of cloth masks is not recommended.11

That is not the only study whose results indicate that wearing a mask makes you in fact more likely to become sick.

November, 2023: Association between Face mask use and Risk of SARS-CoV-2 Infection – Cross-sectional study. - "We found that the incidence of self-reported COVID-19 was 33% higher in those wearing face masks often or sometimes, and 40% higher in those wearing face masks almost always or always, compared to participants who reported wearing face masks never or almost never." 12

Which brings me to my other area of concern, that RIDOH has completely ignored, the negative impacts and side effects of wearing a face mask for both adults and children, but especially for children.
November, 2020: Exercise with facemask; Are we handling a devil's sword?- A physiological hypothesis - "Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus." 16

February, 2022: 100) The Foegen effect A mechanism by which facemasks contribute to the COVID-19 case fatality rate - "The most important finding from this study is that contrary to the accepted thought that fewer people are dying because infection rates are reduced by masks, this was not the case. Results from this study strongly suggest that mask mandates actually caused about 1.5 times the number of deaths or ∼50% more deaths compared to no mask mandates. This means that the risk for the individual wearing the mask should even be higher, because there is an unknown number of people in MMC who either do not obey mask mandates, are exempted for medical reasons or do not go to public places where mask mandates are in effect. These people do not have an increased risk and thus the risk on the other people under a mask mandate is actually higher." 17

In a study of children conducted in October, 2020 of 20,353 students in Germany, 68% reported adverse side effects from being forced to wear a mask all day in school which included headache, difficulty concentrating, reluctance to go to school, malaise, impaired learning, drowsiness/fatigue, and less happiness. 13

Additionally, when breathing through their nose becomes impaired while wearing a mask, children often resort to breathing through their mouth. Chronic and prolonged mouth breathing can alter facial development. Children who mouth-breathe can develop a mouth deformity and elongated face. 14

A review of 65 studies examining the side effects of masks on children and adults found the following, "According to the scientific results and findings, masks have measurably harmful effects not only on healthy people, but also on sick people and their relevance is likely to increase with the duration of use." These include the following pathophysiological changes and subjective complaints
- Increase in breathing resistance
- Increase in blood carbon dioxide
- Decrease in blood oxygen saturation
- Increase in heart rate
- Decrease in cardiopulmonary capacity
- Feeling of exhaustion
- Increase in respiratory rate
- Difficulty breathing and shortness of breath
- Headache
- Dizziness
- Drowsiness

- Impaired skin barrier function with acne, itching and skin lesions

"The described mask-related changes in respiratory physiology can have an adverse effect on the wearer's blood gases sub-clinically and in some cases also clinically manifest and, therefore, have a negative effect on the basis of all aerobic life, external and internal respiration, with an influence on a wide variety of organ systems and metabolic processes with physical, psychological and social consequences for the individual human being."

With regard to children this review indicated the following: "Children are particularly vulnerable and may be more likely to receive inappropriate treatment or additional harm. It can be assumed that the potential adverse mask effects described for adults are all the more valid for children." In addition, "The masks currently used for children are exclusively adult masks manufactured in smaller geometric dimensions and had neither been specially tested nor approved for this purpose." And finally, "According to experts, masks block the foundation of human communication and the exchange of emotions and not only hinder learning but deprive children of the positive effects of smiling, laughing and emotional mimicry. The effectiveness of masks in children as a viral protection is controversial, and there is a lack of evidence for their widespread use in children." 15

Has RIDOH considered any of the following questions:
What science do they have to prove that forcing a mask on a child for 35+ hours a week is safe for their developing bodies?

How have they assessed the effects of imposed mask use on mental health, particularly in light of the temporal relationship between mandates and the exploding mental health crisis?

How much did masks contribute to the documented learning loss that our children suffered during mandates? - I work in special education in RI public schools and I can personally attest to this significant learning loss, which includes an explosion in my, and my colleagues caseloads.

In closing, this rule should not exist and the result of this hearing should be that RIDOH will not implement this rule which would allow for a mask mandate because RIDOH cannot support its regulation with quality science. Should a revision be considered instead of throwing out the rule entirely, the following revision should be made: “There will be no regulation requiring masking in schools for the alleged prevention of respiratory viral infections until evidence of their effectiveness has been demonstrated convincingly by multiple, rigorous randomized, controlled clinical trials and real world data.”

Thank you,
Kimberly Vecchio
9 Cynthia Drive
North Kingstown, RI

List of References

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Review Article

The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence

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Faisal bin-Reza, Angus Nicoll and Mary E Chamberland undertook this work whilst at the Health Protection Agency but no longer work at the HPA.
An earlier version of this review was published on-line by the Department of Health at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125425.pdf. This version has been updated and revised.

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There are limited data on the use of masks and respirators to reduce transmission of influenza. A systematic review was undertaken to help inform pandemic influenza guidance in the United Kingdom. The initial review was performed in November 2009 and updated in June 2010 and January 2011. Inclusion criteria included randomised controlled trials and quasi-experimental and observational studies of humans published in English with an outcome of laboratory-confirmed or clinically-diagnosed influenza and other viral respiratory infections. There were 17 eligible studies. Six of eight randomised controlled trials found no significant differences between control and intervention groups (masks with or without hand hygiene; N95/P2 respirators). One household trial found that mask wearing coupled with hand sanitiser use reduced secondary transmission of upper respiratory infection/influenza-like illness/laboratory-confirmed influenza compared with education; hand sanitiser alone resulted in no reduction. One hospital-based trial found a lower rate of clinical respiratory illness associated with non-fit-tested N95 respirator use compared with medical masks. Eight of nine retrospective observational studies found that mask and/or respirator use was independently associated with a reduced risk of severe acute respiratory syndrome (SARS). Findings, however, may not be applicable to influenza and many studies were suboptimal. None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene. The effectiveness of masks and respirators is likely linked to early, consistent and correct usage.

Keywords Influenza, mask, pandemic, respirator.

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Introduction

Personal protective equipment to help reduce transmission of influenza is generally advised according to the risk of exposure to the influenza virus and the degree of infectivity and human pathogenicity of the virus. The paucity of scientific evidence upon which to base guidance for the use of masks and respirators in healthcare and community settings has been a particularly vexing issue for policymakers.

The Health Protection Agency (HPA) undertook a scientific evidence-based review of the use of masks and respirators in an influenza pandemic to inform relevant guidance following the emergence of pandemic A (H1N1) 2009 influenza. The Department of Health commissioned the HPA to update the review in support of the revision of the United Kingdom (UK) influenza pandemic preparedness strategy.[1] The review was published on-line at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125425.pdf. A further update of the evidence base subsequently was performed in January 2011 and described herein.

Methods

Search strategy

We generally followed the approach detailed in the University of York's *Systematic Reviews: CRD's Guidance for Undertaking Reviews in Health* Care.[2]

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The original search of the PubMed database was conducted on 7 November 2009; subsequent updates of the PubMed database search were undertaken on 23 June 2010 and 12 January 2011.[1] The November 2009 search also included the following scientific databases: Bandolier, the Cochrane Library Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the Health Technology Assessment database, the National Health Service (NHS) Economic Evaluation database, the UK Database of Uncertainties about the Effects of Treatments, the NHS Centre for Reviews and Dissemination and the Cumulative Index to Nursing and Allied Health Literature.[2] No additional publications resulted from these databases. The initial search in November 2009 had no time period restrictions.

A limited effort was made to identify additional studies: reference lists of review articles were examined; the European Centre for Disease Prevention and Control's (ECDC) Antimicrobial Resistance and Health Care Associated Infection Programme was consulted; and MEC's and AN's hardcopy literature files were hand-searched.

Table 1. Summary of criteria for the review

Inclusion criteria
Type of study: Randomised controlled trial, quasi-experimental and observational studies
Participants: Humans
Setting: Healthcare or community
Language: English only
Abstract: Available
Outcome: Laboratory-confirmed or clinically-diagnosed influenza and other viral respiratory infections
Exclusion criteria
Type of study: Case series, case report, mathematical modelling and human/non-human experimental laboratory studies, reviews
Participants: Animals
Setting: Laboratory
Language: non-English
Abstract: not available

Study selection

We included the following types of studies listed in the hierarchical order of study design quality: randomised controlled trials (i.e. randomised cross-over trial and cluster randomised trial); quasi-experimental studies (i.e. non-randomised controlled study, before-and-after study and interrupted time series); and observational studies (cohort study and case–control study). Only human studies published in English which had an abstract were included (Table 1).

Infection with pandemic strains, seasonal influenza A or B viruses and zoonotic viruses such as swine or avian influenza were included because mask/respirator guidance is needed for all types of influenza. Studies that evaluated the effect of masks/respirators on transmission of other respiratory viruses were included as a proxy for influenza.

Study selection and validity assessment

A two-stage selection process was used to identify studies that appeared to meet the inclusion criteria. Firstly, Fb-R or VLC scanned and excluded papers on the basis of the 'title' for relevance; in the second and third searches, some relevant titles were excluded because they had been selected for review during a prior search. Secondly, to enhance the reliability of the selection process, Fb-R, VLC, MEC and AN independently reviewed the abstracts for the remaining papers.

Fb-R or VLC used a pre-designed form to perform an initial data extraction of the full article and make an initial determination regarding its eligibility. MEC or AN subsequently reviewed all of the papers, supplemented Fb-R's and VLC's initial abstraction as necessary and re-assessed

[1]Search terms for PubMed database search: [1] Respiratory viruses: influenza OR influenza[tw] OR flu OR flu[tw] OR common cold OR common cold[tw] OR rhinovirus OR rhinovirus*[tw] OR adenoviridae OR adenovirus*[tw] OR coronavirus OR coronavirus infections OR coronavirus*[tw] OR respiratory syncytial viruses OR respiratory syncytial virus infections OR respiratory syncytial virus*[tw] OR respiratory syncitial virus[tw] OR parainfluenza virus 1 OR parainfluenza virus 2 OR parainfluenza virus 3 OR parainfluenza virus 4 OR parainfluenza[tw] OR parainfluenza[tw] OR parainfluenza[tw] OR severe acute respiratory syndrome OR severe acute respiratory syndrome[tw] OR SARS[tw] OR acute respiratory infection*[tw] OR acute respiratory tract infection*[tw] OR influenza-like illness OR influenza-like illness[tw] OR ILI OR Severe acute respiratory infection OR Severe acute respiratory infection[tw] OR pandemic influenza OR pandemic flu
[2] Interventions and population groups: masks OR mask*[tw] OR patient isolators OR personal protective equipment OR face protection OR N95 OR FFP2 OR FFP3 OR respirator OR home OR household* OR community OR nursing home OR nosocomial OR HCAI OR healthcare associated infection OR healthcare associated infections OR airborne precautions OR droplet precautions OR nonpharmaceutical intervention OR nonpharmaceutical intervention OR aerosol-generating procedures OR healthcare workers OR healthcare workers OR HCW OR healthcare personnel OR healthcare personnel.

[2]Search terms for the additional databases were respiratory viruses, mask, respirator, N95, FFP, FFP2, FFP3, influenza.

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each paper for inclusion in the review. Any differences were resolved by mutual agreement. MEC and AN assessed the quality of the eligible studies using the Critical Appraisal Skills Programme tools[3] for randomised controlled trials, case–control studies and cohort studies.

Results

The three separate database searches yielded a total of 6015 titles; five articles were identified by scanning the reference lists of review articles and three articles were from MEC's hard copy collection (Figure 1). Full papers were obtained for 76 articles; of these, 17 studies were eligible for inclusion. Descriptions, findings and comments for these studies are detailed in Tables 2–4.

Randomised controlled trials

Three of the randomised trials were hospital-based studies,[4–6] and five were conducted in community settings.[7–11] Two of these studies compared N95 respirators (designed to seal tightly to the wearer's face and filter out very small particles or aerosols that may contain viruses) and surgical masks (used to block large droplets from coming into contact with the wearer's mouth or nose) amongst healthcare workers; one trial found a lower rate of clinical respiratory illness associated with the use of non-fit-tested N95 respirators compared with medical masks,[6] whilst a non-inferiority trial found that masks and respirators offered similar protection to nurses against laboratory-confirmed influenza infection.[5] A trial conducted amongst crowded, urban households found that, despite poor compliance, mask wearing coupled with hand sanitiser use, reduced secondary transmission of upper respiratory infection/influenza-like illness/laboratory-confirmed influenza compared with education; hand sanitiser alone resulted in no reduction in this aggregated outcome.[11]

Although the remaining five trials found no significant differences between control and intervention groups, there were some notable findings. Household contacts who wore a P2 respirator (considered to have an equivalent rating to an N95 respirator) 'all' or 'most' of the time for the first 5 days were less likely to develop an influenza-like illness compared with less frequent users in one study.[9] Another study found a significant reduction in laboratory-confirmed influenza amongst household contacts that began hand hygiene or hand hygiene plus a mask within 36 hours of the index case's illness.[8] A trial conducted amongst resident university students detected significant reductions in influenza-like illness during weeks 4–6 in the mask and hand hygiene group after adjusting for vaccine receipt and other potential confounders.[10]

The requirements for mask/respirator wearing and subsequent compliance varied by study (Table 2); for example, in MacIntyre's study of healthcare workers in China in December 2008 through January 2009[6] 'participants wore the mask or respirator on every shift for 4 consecutive weeks after being shown when to wear it', whilst nurses in Canada wore a mask or respirator during the 2008/09 influenza season when caring for patients with febrile respiratory illness and during aerosol-generating procedures.[5]

Observational studies

All of the observational studies evaluated mask and respirator use following the outbreaks of severe acute respiratory syndrome (SARS) in 2003;[12–20] seven studies were conducted amongst healthcare workers and two were community-based. All but two[12,13] of the case–control studies in healthcare workers reported that wearing masks and/or respirators appeared to protect workers from acquiring SARS.[14–17] A retrospective cohort study of nurses who worked in two Toronto hospital intensive care units found that the relative risk of SARS for nurses who consistently wore a N95 respirator was half that for nurses who consistently wore a surgical mask; however, the difference was not significant because of a small sample size.[18]

Discussion

None of the studies we reviewed established a conclusive relationship between mask/respirator use and protection against influenza infection. Some useful clues, however, could be gleaned. Subanalyses performed for one of the larger randomised controlled studies in a household setting found evidence of reduced rates of influenza-like illness if household contacts consistently wore the mask or respirator.[9] The authors of a randomised trial of mask plus alcohol-based sanitiser and mask-only group amongst U.S. university students living in residence halls noted that their study may have been better positioned to identify a protective effect because participants initiated the interventions at the beginning of the influenza season.[10] Cowling's[8] finding that there was a significant reduction in the secondary attack ratio if the hand hygiene and mask plus hand hygiene interventions were begun within 36 hours of the index case lends support to this hypothesis.

Anticipating the paucity of studies that focused solely on influenza, we included the effect of masks/respirators on respiratory viruses other than influenza. Such studies have often been used to support infection control guidance for influenza. However, the difficulties in interpreting the observational studies of SARS suggest that they are of limited use for guiding policy on influenza. Firstly, SARS is an unusual acute viral respiratory infection with a very different epidemiology to almost all other respiratory viral infections. It is fundamentally different from human influenza: it rarely infects children, has a long incubation period, transmits little early on, mostly transmits in

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Table 2. Synopsis of randomised controlled trials evaluating mask and respirator use for influenza

Author/country/ year of exposure/ (reference)	Study design and participants	Reported results	Limitations
Jacobs/Japan 2008 (4)	Block randomisation to 2 arms and analysed as mask group (17 HCWs wore surgical mask on duty) and no mask group (15 HCWs only wore mask if job-required e.g. surgical nurse). Outcome measure: Self-reported cold symptoms scaled to severity.	No difference between two groups; HCWs living with children reported higher severity scores. 84·3% of participants reported full compliance with mask use and non-use.	Underpowered study; no exposure data; compliance self-reported; no confirmatory laboratory testing.
Loeb/Canada 2008/09 (5)	Non-inferiority randomisation of 446 nurses in emergency departments and medical and paediatric units in 8 hospitals to 2 arms and analysed as surgical mask group (212 nurses) and fit-tested N95 respirator group (210 nurses); mask/respirator worn when caring for patients with febrile respiratory illness during influenza season; assigned respiratory device worn for aerosol-generating procedures. Outcome measure: Laboratory confirmed influenza by PCR; serology only if no receipt of 2008/09 vaccine.	No difference in influenza infection: 50 (23·6%) of 212 in mask group versus 48 (22·9%) of 210 in N95 group (absolute risk difference, –0·73%; 95% CI –8·8% to 7·3%; $P = 0·86$). Limited audit found high compliance.	Hard to generalise findings given lack of control arm. Incomplete assessment of compliance and lack of detailed descriptions of exposures.
Cowling/China - Hong Kong 2007 (7)	Cluster randomisation of 198 HHs (index case and HH contacts) to 3 arms and analysed as control (71 HHs and 205 contacts), surgical masks (21 HHs and 61 contacts) or hand hygiene (30 HHs and 84 HH contacts); index cases and contacts asked to wear masks as often as possible at home during the 7-day follow-up period (including when with index patient outside of the household). Outcome measure: Culture-confirmed influenza; self-reported influenza symptoms.	No difference in laboratory-confirmed secondary attack ratios in controls 0·06 (95% CI 0·03–0·10), mask 0·07(95% CI 0·02–0·16) and hand hygiene groups 0·06 (95% CI 0·02–0·13), $P = 0·99$.	Underpowered pilot study; some index cases wore masks in control and hand hygiene arms; difficulty in starting the intervention quickly may have underestimated its true effect. Compliance low: 45% (21%) of index cases (HH contacts) wore mask often/always.
Cowling/China - Hong Kong 2008 (8)	Cluster randomisation of 407 HHs (index case and HH contacts) to 3 arms and analysed as control (91 HHs and 279 contacts), surgical masks and hand hygiene by both index case and contacts (83 HHs and 258 contacts) or hand hygiene (85 HHs and 257 contacts); index cases and contacts asked to wear masks as often as possible at home during the 7-day follow-up period (including when with index patient outside of the household). Outcome measure: RT-PCR positive confirmed influenza; self-reported influenza symptoms.	No difference in laboratory-confirmed secondary attack ratios in controls 10% (95% CI 6–14), hand hygiene 5% (95% CI 3–9) and mask plus hand hygiene groups 7% (95% CI 4–11); $P = 0·22$. Significant reduction in secondary attack ratio if either intervention applied within 36 hours of index case's onset.	Control and hand hygiene arms 'contaminated' as some index cases wore masks; delay in starting intervention quickly may have underestimated its true effect Adherence low: 49% (26%) of index cases (HH contacts) wore mask often/always. Cannot distinguish relative contributions of hand hygiene and mask as they were combined.

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Table 2. (Continued)

Author/country/ year of exposure/ (reference)	Study design and participants	Reported results	Limitations
MacIntyre/Australia 2006/07 (9)	Cluster randomisation of 145 HHs (index case and HH contacts >16 years) to 3 arms and analysed as control (50 HHs and 100 contacts) or surgical mask (47 HHs and 94 contacts) or P2 respirator (46 HHs and 92 contacts); mask/respirator to be worn at all times when in room with index case. Outcome measure: ILI or laboratory- confirmed respiratory virus infection.	No significant differences between ILI rates in controls 16 (16·0%) of 100, in surgical mask group 21 (22·3%) of 94 (RR 1·29, 95%.CI 0·69–2·31, $P = 0·46$) and in P2 respirator group 14 (15·2%) of 92 (RR 0·95, 95%.CI = 0·49–1·84, $P = 1$); no difference in respiratory virus isolation rates in controls 3 (3·0%) of 100; in surgical mask group 6 (6·4%) of 94 (RR 2·13, 95% CI 0·55–8·26, $P = 0·32$); and in P2 respirator group 8 (8·7%) of 92 (RR 2·90, 95% CI 0·79–10·6, $P = 0·12$). Reduced risk for ILI with adherent mask or respirator use (hazard ratio 0·26, CI 0·09–0·77, $P = 0·015$).	Underpowered to detect differences between 2 interventions; low level of self-reported adherence (21% of contacts in the surgical mask and respirator arms wore mask often/always). Interval between index case's symptom onset and start of intervention not stated; if delayed may have underestimated true effect of intervention.
Aiello/USA, 2006/07 (10)	Cluster parallel randomisation of 1437 students living in university residence halls to 3 arms and analysed as control group (552 students); mask plus hand sanitiser group (367 students); and mask-only group (378 students); instructed to wear mask as much as possible in residence hall during 6 week intervention period; encouraged to wear outside residence hall also. Outcome measure: self-reported ILI.	Adjusted analyses found ILI significantly reduced in mask plus hand sanitiser hygiene group compared with controls (during weeks 4–6), ranging from 35% (95% CI 9–53%) to 51% (95% CI 13–73%); reductions in the mask group not significant at $P < 0·025$.	Hard to generalise given limited age group and specialised setting. Study underpowered to detect small reductions in ILI across arms and the relative contributions of hand hygiene and masks.
Larson/USA 2006/08 (11)	Block randomisation of 617 urban HHs allocated into education (control) group (174 HHs); hand sanitiser group (169 HHs); and hand sanitiser and mask group (166 HHs); household caretaker to wear mask when within 3 feet of person with ILI for 7 days or until symptoms disappeared and to change mask between interactions; ill person encouraged to wear mask when within 3 feet of other HH members. Outcome measure: Self-reported ILI/URI symptoms and viral culture.	Hand sanitiser group more likely to report no symptomatic HH members (545/946 [57·6%] compared with education (447/904 [49·4%] and hand sanitiser/mask (363/938 [38·7%] groups, $P < 0·01$; no significant differences in rates of URI, ILI or influenza infection by intervention group in multivariate analyses. Hand sanitiser/mask group had significant reduction in secondary attack rates for URI/ILI/influenza infection (OR 0·82, 95% CI 0·70–0·97) compared with education. No reduction with hand sanitiser alone (OR 1·01, 95% CI 0·85–1·21).	Poor self-reported compliance with mask use: 22 (50%) of 44 HHs reporting ILI used masks within 48 hours of episode onset; average of 2 (range 0–9) masks/day/ILI episode used. Limited power to detect differences amongst 3 groups; some use of hand sanitiser in control group in response to media reports about methicillin-resistant *Staphylococcus aureus*.

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Table 2. (Continued)

Author/country/ year of exposure/ (reference)	Study design and participants	Reported results	Limitations
MacIntyre/ China –Beijing/ 2008/09 (6)	Cluster, stratified (by size of hospital and level of infection control) randomisation of 1441 HCWs in 15 Beijing hospitals into mask group (492 HCWs/5 hospitals); N95 fit-tested group (461 HCWs/5 hospitals; and N95 non-fit-tested group (488 HCWs/5 hospitals); supplemented with convenience sample of non-mask-wearing HCWs from 9 hospitals; participants wore the mask/respirator on every shift for 4 consecutive weeks after being shown when/how to wear it. Outcome measure: Self-reported CRI, ILI and laboratory-confirmed viral infection by PCR.	For all outcomes N95 respirators had lower, but not significant, rates compared with masks. Intention-to-treat analysis adjusted for clustering of hospitals found only non-fit-tested N95s protective against CRI (16/488 [3·3%], OR 0·48, 95% CI 0·24–0·98, $P = 0{\cdot}045$) compared with mask group (33/492 [6·7%]) as ref. Multivariate analysis found wearing N95s and hospital level each reduced odds of CRI and laboratory-confirmed infection.	Monitored and self-reported compliance good (68–76%) in the 3 arms; however, monitoring by HCWs' supervisors not optimal method. Limited power to detect differences amongst 3 groups as observed attack rates low. Authors note 46% probability of incorrectly finding one significant difference. Despite stratified randomisation, mask group comprised of only level 3 (most sophisticated) hospitals. Hard to generalise beyond unique study population. Detailed data on potential exposures and information on community levels of influenza not provided.

HCW, healthcare worker; PPE, personal protective equipment; RT-PCR, reverse transcription-polymerase chain reaction; ILI, influenza-like illness; HH, household; URI, upper respiratory infection; CRI, clinical respiratory illness; ref, reference group.

healthcare settings, is not prone to extensive global spread and has only appeared once. Secondly, the studies were poorly designed, had many weaknesses and so were very difficult to interpret. Issues of concern include the use of a non-specific definition for exposure to a SARS patient (e.g. coming within one metre of a patient), inconsistency in providing information about the comparability of cases and controls and collection of data after a lengthy period following the outbreak. Several lacked microbiological confirmation of cases or controls and it would seem likely that a number of the SARS cases were not cases at all. Because all the cases knew they were cases, recall bias was highly likely. The single case–control study that tried to address some of these limitations did not find that inconsistent use of masks or respirators was associated with SARS infection.[13]

It is important to note three considerations when assessing the practical implications of the review's findings. Firstly, development of evidence-based guidance about mask/respirator use is inextricably linked to what is known about how influenza is spread and specific risk factors that can affect transmissibility (e.g. host factors, pathogen factors, environmental factors and particle size). However, this is an area equally fraught with uncertainty; there are limited and conflicting evidence regarding the relative importance and frequency of direct contact, indirect contact, droplet and aerosol modes of transmission.[21,22] Historically, transmission has been thought to occur principally through respiratory droplets and masks have been used as a barrier against droplets emitted by coughing and sneezing. In the last decade, there has been increasing interest in a possible role for aerosol transmission of influenza and the advisability of filtering respirators to block such transmission. For example, studies have found that infected patients can produce aerosol particles containing influenza virus[23] and that hospital airflow patterns can influence influenza transmission via aerosols.[24]

Secondly, although the focus of this review has been on masks and respirators, limiting transmission of influenza in both healthcare and community settings requires a multifaceted approach, of which masks and respirators are but one component. In the healthcare setting, this 'hierarchy of controls' includes administrative controls help to reduce the introduction and spread of infection (e.g. policies to restrict entrance of ill visitors and workers, vaccination of healthcare workers); environmental/ engineering controls (e.g. adequate ventilation); and lastly, use of personal protective equipment and hand hygiene.[25] In the community setting, a similarly structured approach is advised. However, during both the planning for an eventual pandemic and the subsequent public health response to the H1N1 pandemic, concern over policy and guidance related to mask/respirator use has at times seemed to overshadow

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Table 3. Synopsis of observational case–control studies evaluating mask and respirator use for SARS

Author/country (reference)	Study design and participants	Reported results	Comments
Chen/China (12)	91 SARS IgG positive HCWs compared with 657 SARS IgG negative HCWs who cared for SARS patients in two hospitals.	Double-layer cotton mask (versus a single-layer cotton mask) protective against SARS infection in univariate analysis (OR 2·53, 95% CI 1·57–4·07); not significant in multivariate analysis.	Possible recall bias as questionnaire survey conducted 4 months after outbreak; limited data on frequency and type of exposures to SARS patients.
Lau/China-Hong Kong (13)	72 HCWS with SARS from 5 hospitals compared with 144 matched controls; PPE use examined during (i) direct contact with SARS patient; (ii) general contact with SARS and non-SARS patients; and (iii) no patient contact.	Almost all HCWs wore N95 respirator or surgical mask in all patient settings. Unadjusted univariate analysis found inconsistent use of masks or respirators not associated with higher risk of SARS in any of the 3 contact settings; multivariate analysis found inconsistent use of >1 type of PPE during direct contact independent risk for SARS.	No serological testing of controls; reporting bias possible.
Nishiura/Viet Nam (14)	Period 1: Time from admission of index case to occurrence of secondary cases in one hospital: 25 laboratory-confirmed SARS cases compared with 90 controls (HCWs and relatives of patients). Period 2: During a nosocomial outbreak in the hospital with strict isolation procedures, quarantine of HCWs and increased use of PPE: 4 laboratory-confirmed SARS cases compared with 26 controls with only physicians and nurses in both groups.	Period 1: univariate analysis found masks (OR 0·3, 95%CI 0·1–0·7) and gowns (OR 0·2, 95%CI 0·0–0·8) protective; in logistic regression analyses, only masks protective (OR = 0·29, 95% CI 0·11–0·73) Period 2: use of masks (OR < 0·1, 95% CI 0·0–0·3) and gowns (P = 0·010, OR and CI not calculable) associated with non-infection for doctors and nurses.	Possible recall bias; exposures imprecisely quantified; no serological testing of controls.
Nishiyama/Viet Nam (15)	Risk factors for serologically-confirmed SARS infection assessed for 85 case and control HCWs who had direct contact with SARS patients.	Multivariate logistic regression analysis found significant risk for SARS amongst HCWs who never wore mask compared with those who always wore a mask (OR 12·6, 95% CI 2·0–80·0, P < 0·01)	Possible reporting bias as interview conducted 7 months after outbreak; nature of exposures to SARS not specified; community exposures not assessed.
Seto/China - Hong Kong (16)	13 SARS-infected HCWs with no community exposures compared with 241 HCWs without clinical SARS; all reported direct contact with 11 SARS patients in 5 hospitals.	Univariate analysis found HCWs who used surgical masks or N95 respirators, gowns or hand washing less likely to develop SARS; logistic regression analysis found use of any mask significant (OR 13, 95% CI 3–60).	No serological testing of controls; reporting bias possible as interviews conducted a month after cases identified; community exposures not assessed.
Teleman/ Singapore (17)	Evaluated risk factors for serologically-confirmed SARS amongst 36 ill case-HCWs exposed to 3 highly infectious source patients and 50 well control-HCWs that came within 1 m of serologically-confirmed SARS patients.	Adjusted logistic regression analyses found that wearing N95 respirator during each patient contact (adj OR 0·1, 95% CI 0·02–0·86, P = 0·04) and hand washing after patient contact (adj OR 0·07, 95% CI 0·008–0·66, P = 0·02) protective.	Small sample size; no serological testing of the controls; limited recall of precise exposure data; no assessment of community/household exposures.

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Table 3. (*Continued*)

Author/country (reference)	Study design and participants	Reported results	Comments
Lau/China - Hong Kong (19)	330 probable SARS cases with 'undefined' source of infection compared with 660 controls recruited by random telephone survey matched for age, sex and reference time for behaviours in question.	Matched multivariate analyses found using mask frequently in public places 27·9% of 330 cases versus 58·7% of 660 controls (OR = 0·36, 95% CI 0·25–0·52); washing one's hands >10 times a day (OR = 0·58, 95% CI 0·38–0·87) and disinfecting living quarters (OR = 0·41, 95% CI 0·29–0·58) protective.	Likely misclassification because no laboratory testing for most cases and no testing of controls; non-specific questions about exposures and potential protective measures.
Wu/China (20)	94 unlinked, probable clinical SARS cases without reported contact with other SARS cases and 281 community-based age- and sex-matched controls in Beijing recruited by sequential digit dialling.	Multivariate analysis found 'sometimes' and 'always' wearing mask when outside home protective (matched OR 0·4, 95% CI 0·2–0·9, $P = 0·03$ and OR 0·3, 95% CI 0·1–0·6, $P = 0·002$, respectively).	Likely misclassification because no laboratory testing for most cases and no testing of controls; lack of information about community exposures; recall and self-selection bias possible.

SARS, severe acute respiratory syndrome; HCW, healthcare worker.

Table 4. Synopsis of an observational cohort study evaluating mask and respirator use for SARS

Author/country (reference)	Study design and participants	Reported results	Comments
Loeb/Canada (18)	Retrospective cohort of 43 nurses who worked in ICU or CCU when laboratory-confirmed SARS patient in unit; analysis limited to 32 nurses who entered patient's room at least once.	3 (13%) of 23 nurses who consistently wore mask (either surgical or N95 respirator) developed SARS compared with 5 (56%) of 9 nurses who did not consistently wear either (RR 0·23, $P = 0·02$). 2 (13%) of 16 nurses who consistently wore N95 respirator developed SARS compared with 1 (25%) of 4 nurses who consistently wore a surgical mask (RR = 0·50, $P = 0·51$).	Underpowered study; recall bias possible; community exposure not explored; no serological testing of controls.

SARS, severe acute respiratory syndrome; PPE, personal protective equipment; ILI, influenza-like illness; ICU, intensive care unit; CCU, coronary care unit.

other important controls.[26] It is somewhat paradoxical that whilst continued effort and resources are needed to assess the independent effect of masks and respirators on influenza transmission, their use would always be recommended in combination with other control measures.

Thirdly the practical implications of policy, guidance and recommendations on mask/respirator use and other infection control measures must be considered. The only two studies that compared mask and respirators to protect healthcare workers from influenza infection essentially reached different conclusions[5,6] illustrating the difficulties facing policymakers.[27] Further, a simulation study found that strict adherence to guidance about personal protective equipment (which included masks and respirators) compromised normal ward functioning in a UK hospital setting.[28]

This review had a prescribed narrow focus that permitted us to examine a relatively small number of studies. We considered employing quantitative techniques, but on analysis found the studies comprised a range of study designs, pathogens, participants, interventions and opportunities for bias and confounding would render any meta-

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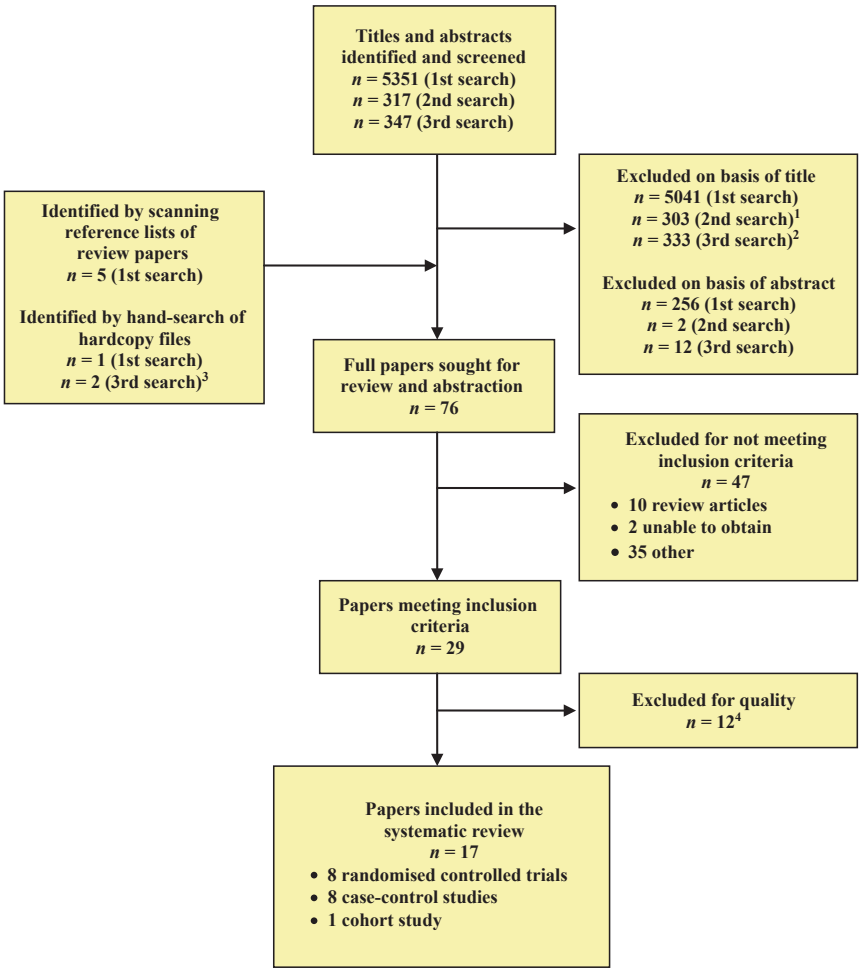


Figure 1. Diagram of search strategy results and article selection for three searches. [1]Includes 3 papers that were sought for review and abstraction in the first search. [2]Includes 6 papers that were sought for review and abstraction in the second search. [3]One of these papers (reference no. 6) became available on-line on 27 January 2011. [4]Reasons for exclusion included an inability to distinguish the effect of mask use from other personal protective equipment or lack of quantitative data.

analysis findings open to criticism. A review that included interventions other than mask/respirator use, experimental laboratory and/animal–human studies on mask/respirator efficacy, cost-effectiveness studies and the occurrence of adverse events would present a more comprehensive picture.

Several systematic reviews of interventions to limit the transmission of respiratory viral infections and/or specifically influenza have been undertaken. Most have considered a range of interventions;[29–33] one focused specifically on respiratory protection.[34] Within the boundaries established by our inclusion criteria, our search strategy captured essentially the same studies on masks and respirators that others have identified. Jefferson *et al* derived pooled estimates of the effectiveness of wearing an N95 respirator (91%) and wearing a mask (68%) for any respiratory viral infection;[29] however, these estimates were derived from the analyses of six SARS studies whose methodology was problematic. We carefully noted how well exposures in various studies were detailed and if cases and controls were laboratory-confirmed to avoid misclassification bias. We did not feel that such a heterogeneous group of studies could be combined even for SARS.

In conclusion, there is a limited evidence base to support the use of masks and/or respirators in healthcare or community settings. Mask use is best undertaken as part of a package of personal protection, especially including hand hygiene in both home and healthcare settings. Early initiation and correct and consistent wearing of masks/respirators may improve their effectiveness. However, this remains a major challenge – both in the context of a formal study and in everyday practice.

Continued research on the effectiveness masks/respirators use and other closely associated considerations remains an urgent priority with emphasis being on carefully designed observational studies and trials best conducted

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outside a crisis situation.[35] However, examination of the literature has highlighted that well-designed studies in this field are challenging.[27] Studies need to be adequately powered to assess potentially small differences between interventions and the independent effect of mask/respirator wearing when a second intervention (e.g. hand hygiene) is employed; an appropriate control group must be identified (e.g. no use of masks/respirators). Most of the studies we examined were too small to reliably detect what would be anticipated to be moderate effects. Perhaps, one solution is to fund large multi-centre trials with similar protocols in different sites for multiple years to achieve sufficient power. Protocols should include the collection of detailed exposure data, objective monitoring of compliance and assessment of potential confounders. It may be difficult to design studies employing a control group that does not use any protective equipment (including masks/respirators), particularly in healthcare settings, as such precautions are routinely recommended. Finally, there is a striking paucity of published studies with microbiologically proven influenza infection as an outcome; inclusion of laboratory outcomes is essential in any future study of masks/respirators on transmission of influenza.

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Declarations of interest

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Authors' contributions

Fb-R, VLC, AN and MEC analysed the data. Fb-R and MEC were the principal writers of the manuscript with contributions from AN and VLC.

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Policy Review

Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures

On This Page

Methods and Results

Discussion

Cite This Article

Figures

Figure 1

Figure 2

Tables

Table 1

Table 2

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Appendix

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Abstract

There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

Influenza pandemics occur at irregular intervals when new strains of influenza A virus spread in humans (*1*). Influenza pandemics cause considerable health and social impact that exceeds that of typical seasonal (interpandemic) influenza epidemics. One of the characteristics of influenza pandemics is the high incidence of infections in all age groups because of the lack of population immunity. Although influenza vaccines are the cornerstone of seasonal influenza control, specific vaccines for a novel pandemic strain are not expected to be available for the first 5–6 months of the next pandemic. Antiviral drugs will be available in some locations to treat more severe infections but are unlikely to be available in the quantities that might be required to control transmission in the general community. Thus, efforts to control the next pandemic will rely largely on nonpharmaceutical interventions.

Most influenza virus infections cause mild and self-limiting disease; only a small fraction of case-patients require hospitalization. Therefore, influenza virus infections spread mainly in the community. Influenza virus is believed to be transmitted predominantly by respiratory droplets, but the size distribution of particles responsible for transmission remains unclear, and in particular, there is a lack of consensus on the role of fine particle aerosols in transmission (*2*,*3*). In healthcare settings, droplet precautions are recommended in addition to standard precautions for healthcare personnel when interacting with influenza patients and for all visitors during influenza seasons (*4*). Outside healthcare settings, hand hygiene is recommended in most national pandemic plans (*5*), and medical face masks were a common sight during the influenza pandemic in 2009. Hand hygiene has been proven to prevent many infectious diseases and might be considered a major component in influenza pandemic plans, whether or not it has proven effectiveness against influenza virus transmission, specifically because of its potential to reduce other infections and thereby reduce pressure on healthcare services.

In this article, we review the evidence base for personal protective measures and environmental hygiene measures, and specifically the evidence for the effectiveness of these measures in reducing transmission of laboratory-confirmed influenza in the community. We also discuss the implications of the evidence base for inclusion of these measures in pandemic plans.

Methods and Results

We conducted systematic reviews to evaluate the effectiveness of personal protective measures on influenza virus transmission, including hand hygiene, respiratory etiquette, and face masks, and a systematic review of surface and object cleaning as an environmental measure (Table 1). We searched 4 databases (Medline, PubMed, EMBASE, and CENTRAL) for literature in all languages. We aimed to identify randomized controlled trials (RCTs) of each measure for laboratory-confirmed influenza outcomes for each of the measures because RCTs provide the highest quality of evidence. For respiratory etiquette and surface and object cleaning, because of a lack of RCTs for laboratory-confirmed influenza, we also searched for RCTs reporting effects of these interventions on influenza-like illness (ILI) and respiratory illness outcomes and then for observational studies on laboratory-confirmed influenza, ILI, and respiratory illness outcomes. For each review, 2 authors (E.Y.C.S. and J.X.) screened titles and abstracts and reviewed full texts independently.

We performed meta-analysis for hand hygiene and face mask interventions and estimated the effect of these measures on laboratory-confirmed influenza prevention by risk ratios (RRs). We used a fixed-effects model to estimate the overall effect in a pooled analysis or subgroup analysis. No overall effect would be generated if there was considerable heterogeneity on the basis of I^2 statistic ≥75% (*6*). We performed quality assessment of evidence on hand hygiene and face mask interventions by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (*7*). We provide additional details of the search strategies, selection of articles, summaries of the selected articles, and quality assessment (Appendix).

Personal Protective Measures

Hand Hygiene

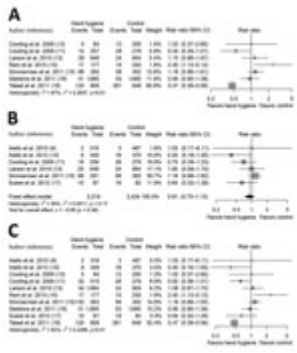


Figure 1. Meta-analysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza from 10 randomized controlled trials with >11,000 participants. A) Hand hygiene alone;…

We identified a recent systematic review by Wong et al. on RCTs designed to assess the efficacy of hand hygiene interventions against transmission of laboratory-confirmed influenza (*8*). We used this review as a starting point and then searched for additional literature published after 2013; we found 3 additional eligible articles published during the search period of January 1, 2013–August 13, 2018. In total, we identified 12 articles (*9*–*20*), of which 3 articles were from the updated search and 9 articles from Wong et al. (*8*). Two articles relied on the same underlying dataset (*16*,*19*); therefore, we counted these 2 articles as 1 study, which resulted in 11 RCTs. We further selected 10 studies with >10,000 participants for inclusion in the meta-analysis (Figure 1). We excluded 1 study from the meta-analysis because it provided estimates of infection risks only at the household level, not the individual level (*20*). We did not generate an overall pooled effect of hand hygiene only or of hand hygiene with or without face mask because of high heterogeneity in individual estimates (I^2 87 and 82%, respectively). The effect of hand hygiene combined with face masks on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73–1.13; I^2 = 35%, p = 0.39). Some studies reported being underpowered because of limited sample size, and low adherence to hand hygiene interventions was observed in some studies.

We further analyzed the effect of hand hygiene by setting because transmission routes might vary in different settings. We found 6 studies in household settings examining the effect of hand hygiene with or without face masks, but the overall pooled effect was not statistically significant (RR 1.05, 95% CI 0.86–1.27; I^2 = 57%, p = 0.65) (Appendix Figure 4) (*11*–*15*,*17*). The findings of 2 studies in school settings were different (Appendix Figure 5). A study conducted in the United States (*16*) showed no major effect of hand hygiene, whereas a study in Egypt (*18*) reported that hand hygiene reduced the risk for influenza by >50%. A pooled analysis of 2 studies in university residential halls reported a marginally significant protective effect of a combination of hand hygiene plus face masks worn by all residents (RR 0.48, 95% CI 0.21–1.08; I^2 = 0%, p = 0.08) (Appendix Figure 6) (*9*,*10*).

In support of hand hygiene as an effective measure, experimental studies have reported that influenza virus could survive on human hands for a short time and could transmit between hands and contaminated surfaces (*2*,*21*). Some field studies reported that influenza A(H1N1)pdm09 and influenza A(H3N2) virus RNA and viable influenza virus could be detected on the hands of persons with laboratory-confirmed influenza (*22*,*23*), supporting the potential of direct and indirect contact transmission to play a role in the spread of influenza. Other experimental studies also demonstrated that hand hygiene could reduce or remove infectious influenza virus from human hands (*24*,*25*). However, results from our meta-analysis on RCTs did not provide evidence to support a protective effect of hand hygiene against transmission of laboratory-confirmed influenza. One study did report a major effect, but in this trial of hand hygiene in schools in Egypt, running water had to be installed and soap and hand-drying material had to be introduced into the intervention schools as part of the project (*18*). Therefore, the impact of hand hygiene might also be a reflection of the introduction of soap and running water into primary schools in a lower-income setting. If one considers all of the evidence from RCTs together, it is useful to note that some studies might have underestimated the true effect of hand hygiene because of the complexity of implementing these intervention studies. For instance, the control group would not typically have zero knowledge or use of hand hygiene, and the intervention group might not adhere to optimal hand hygiene practices (*11*,*13*,*15*).

Hand hygiene is also effective in preventing other infectious diseases, including diarrheal diseases and some respiratory diseases (*8*,*26*). The need for hand hygiene in disease prevention is well recognized among most communities. Hand hygiene has been accepted as a personal protective measure in >50% of national preparedness plans for pandemic influenza (*5*). Hand hygiene practice is commonly performed with soap and water, alcohol-based hand rub, or other waterless hand disinfectants, all of which are easily accessible, available, affordable, and well accepted in most communities. However, resource limitations in some areas are a concern when clean running water or alcohol-based hand rub are not available. There are few adverse effects of hand hygiene except for skin irritation caused by some hand hygiene products (*27*). However, because of certain

social or religious practices, alcohol-based hand sanitizers might not be permitted in some locations (*28*). Compliance with proper hand hygiene practice tends to be low because habitual behaviors are difficult to change (*29*). Therefore, hand hygiene promotion programs are needed to advocate and encourage proper and effective hand hygiene.

Respiratory Etiquette

Respiratory etiquette is defined as covering the nose and mouth with a tissue or a mask (but not a hand) when coughing or sneezing, followed by proper disposal of used tissues, and proper hand hygiene after contact with respiratory secretions (*30*). Other descriptions of this measure have included turning the head and covering the mouth when coughing and coughing or sneezing into a sleeve or elbow, rather than a hand. The rationale for not coughing into hands is to prevent subsequent contamination of other surfaces or objects (*31*). We conducted a search on November 6, 2018, and identified literature that was available in the databases during 1946–November 5, 2018. We did not identify any published research on the effectiveness of respiratory etiquette in reducing the risk for laboratory-confirmed influenza or ILI. One observational study reported a similar incidence rate of self-reported respiratory illness (defined by ≥1 symptoms: cough, congestion, sore throat, sneezing, or breathing problems) among US pilgrims with or without practicing respiratory etiquette during the Hajj (*32*). The authors did not specify the type of respiratory etiquette used by participants in the study. A laboratory-based study reported that common respiratory etiquette, including covering the mouth by hands, tissue, or sleeve/arm, was fairly ineffective in blocking the release and dispersion of droplets into the surrounding environment on the basis of measurement of emitted droplets with a laser diffraction system (*31*).

Respiratory etiquette is often listed as a preventive measure for respiratory infections. However, there is a lack of scientific evidence to support this measure. Whether respiratory etiquette is an effective nonpharmaceutical intervention in preventing influenza virus transmission remains questionable, and worthy of further research.

Face Masks

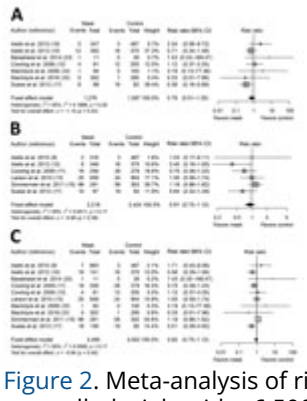


Figure 2. Meta-analysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza from 10 randomized controlled trials with >6,500 participants. A) Face mask…

In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25) (Figure 2). One study evaluated the use of masks among pilgrims from Australia during the Hajj pilgrimage and reported no major difference in the risk for laboratory-confirmed influenza virus infection in the control or mask group (*33*). Two studies in university settings assessed the effectiveness of face masks for primary protection by monitoring the incidence of laboratory-confirmed influenza among student hall residents for 5 months (*9*,*10*). The overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies (*9*,*10*). Study designs in the 7 household studies were slightly different: 1 study provided face masks and P2 respirators for household contacts only (*34*), another study evaluated face mask use as a source control for infected persons only (*35*), and the remaining studies provided masks for the infected persons as well as their close contacts (*11*–*13*,*15*,*17*). None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group (*11*–*13*,*15*,*17*,*34*,*35*). Most studies were underpowered because of limited sample size, and some studies also reported suboptimal adherence in the face mask group.

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids (*36*). There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory-confirmed influenza.

We did not consider the use of respirators in the community. Respirators are tight-fitting masks that can protect the wearer from fine particles (*37*) and should provide better protection against influenza virus exposures when properly worn because of higher filtration efficiency. However, respirators, such as N95 and P2 masks, work best when they are fit-tested, and these masks will be in limited supply during the next pandemic. These specialist devices should be reserved for use in healthcare settings or in special subpopulations such as immunocompromised persons in the community, first responders, and those performing other critical community functions, as supplies permit.

In lower-income settings, it is more likely that reusable cloth masks will be used rather than disposable medical masks because of cost and availability (*38*). There are still few uncertainties in the practice of face mask use, such as who should wear the mask and how long it should be used for. In theory, transmission should be reduced the most if both infected members and other contacts wear masks, but compliance in uninfected close contacts could be a problem (*12*,*34*). Proper use of face masks is essential because improper use might increase the risk for transmission (*39*). Thus, education on the proper use and disposal of used face masks, including hand hygiene, is also needed.

Environmental Measures

Surface and Object Cleaning

For the search period from 1946 through October 14, 2018, we identified 2 RCTs and 1 observational study about surface and object cleaning measures for inclusion in our systematic review (*40*–*42*). One RCT conducted in day care nurseries found that biweekly cleaning and disinfection of toys and linen reduced the detection of multiple viruses, including adenovirus, rhinovirus, and respiratory syncytial virus in the environment, but this intervention was not significant in reducing detection of influenza virus, and it had no major protective effect on acute respiratory illness (*41*). Another RCT found that hand hygiene with hand sanitizer together with surface disinfection reduced absenteeism related to gastrointestinal illness in elementary schools, but there was no major reduction in absenteeism related to respiratory illness (*42*). A cross-sectional study found that passive contact with bleach was associated with a major increase in self-reported influenza (*40*).

Given that influenza virus can survive on some surfaces for prolonged periods (*43*), and that cleaning or disinfection procedures can effectively reduce or inactivate influenza virus from surfaces and objects in experimental studies (*44*), there is a theoretical basis to believe that environmental cleaning could reduce influenza transmission. As an illustration of this proposal, a modeling study estimated that cleaning of extensively touched surfaces could reduce influenza A infection by 2% (*45*). However, most studies of influenza virus in the environment are based on detection of virus RNA by PCR, and few studies reported detection of viable virus.

Although we found no evidence that surface and object cleaning could reduce influenza transmission, this measure does have an established impact on prevention of other infectious diseases (*42*). It should be feasible to implement this measure in most settings, subject to the availability of water and cleaning products. Although irritation caused by cleaning products is limited, safety remains a concern because some cleaning products can be toxic or cause allergies (*40*).

Top

Discussion

In this review, we did not find evidence to support a protective effect of personal protective measures or environmental measures in reducing influenza transmission. Although these measures have mechanistic support based on our knowledge of how influenza is transmitted from person to person, randomized trials of hand hygiene and face masks have not demonstrated protection against laboratory-confirmed influenza, with 1 exception (*18*). We identified only 2 RCTs on environmental cleaning and no RCTs on cough etiquette.

Hand hygiene is a widely used intervention and has been shown to effectively reduce the transmission of gastrointestinal infections and respiratory infections (*26*). However, in our systematic review, updating the findings of Wong et al. (*8*), we did not find evidence of a major effect of hand hygiene on laboratory-confirmed influenza virus transmission (Figure 1). Nevertheless, hand hygiene might be included in influenza pandemic plans as part of general hygiene and infection prevention.

We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility (Figure 2). However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and

therefore have value in an influenza pandemic when healthcare resources are stretched.

It is essential to note that the mechanisms of person-to-person transmission in the community have not been fully determined. Controversy remains over the role of transmission through fine-particle aerosols (*3*,*46*). Transmission by indirect contact requires transfer of viable virus from respiratory mucosa onto hands and other surfaces, survival on those surfaces, and successful inoculation into the respiratory mucosa of another person. All of these components of the transmission route have not been studied extensively. The impact of environmental factors, such as temperature and humidity, on influenza transmission is also uncertain (*47*). These uncertainties over basic transmission modes and mechanisms hinder the optimization of control measures.

In this review, we focused on 3 personal protective measures and 1 environmental measure. Other potential environmental measures include humidification in dry environments (*48*), increasing ventilation (*49*), and use of upper-room UV light (*50*), but there is limited evidence to support these measures. Further investigations on the effectiveness of respiratory etiquette and surface cleaning through conducting RCTs would be helpful to provide evidence with higher quality; evaluation of the effectiveness of these measures targeting specific population groups, such as immunocompromised persons, would also be beneficial (Table 2). Future cost-effectiveness evaluations could provide more support for the potential use of these measures. Further research on transmission modes and alternative interventions to reduce influenza transmission would be valuable in improving pandemic preparedness. Finally, although our review focused on nonpharmaceutical measures to be taken during influenza pandemics, the findings could also apply to severe seasonal influenza epidemics. Evidence from RCTs of hand hygiene or face masks did not support a substantial effect on transmission of laboratory-confirmed influenza, and limited evidence was available on other environmental measures.

Top

Ms. Xiao is a postgraduate student at the School of Public Health, University of Hong Kong, Hong Kong, China. Her primary research interests are influenza epidemiology and the dynamics of person-to-person transmission.

Top

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Top

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Top

Figures

Figure 1. Meta-analysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza from 10 randomized controlled trials with >11,000 participants. A) Hand…

Figure 2. Meta-analysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza from 10 randomized controlled trials with >6,500 participants. A)…

Tables

Table 1. Summary of literature searches for systematic review on personal and environmental nonpharmaceutical interventions for pandemic influenza

Table 2. Knowledge gaps for personal protective and environmental nonpharmaceutical interventions for pandemic influenza

Top

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Table of Contents – Volume 26, Number 5—May 2020

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Top

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Morbidity and Mortality Weekly Report (*MMWR*)

Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020

Weekly / September 11, 2020 / 69(36);1258–1264

Summary

What is already known about the topic?

Community and close contact exposures contribute to the spread of COVID-19.

What is added by this report?

Findings from a case-control investigation of symptomatic outpatients from 11 U.S. health care facilities found that close contact with persons with known COVID-19 or going to locations that offer on-site eating and drinking options were associated with COVID-19 positivity. Adults with positive SARS-CoV-2 test results were approximately twice as likely to have reported dining at a restaurant than were those with negative SARS-CoV-2 test results.

What are the implications for public health practice?

Eating and drinking on-site at locations that offer such options might be important risk factors associated with SARS-CoV-2 infection. Efforts to reduce possible exposures where mask use and social distancing are difficult to maintain, such as when eating and drinking, should be considered to protect customers, employees, and communities.

Related Materials

Identifying COVID-19 Risk Through Observational Studies to Inform Control Measures

MMWR Article PDF

Please note: *This report has been corrected. An erratum has been published.*

Kiva A. Fisher, PhD[1]; Mark W. Tenforde, MD, PhD[1,2]; Leora R. Feldstein, PhD[1]; Christopher J. Lindsell, PhD[3,4]; Nathan I. Shapiro, MD[3,5]; D. Clark Files, MD[3,6]; Kevin W. Gibbs, MD[3,6]; Heidi L. Erickson, MD[3,7]; Matthew E. Prekker, MD[3,7]; Jay S. Steingrub, MD[3,8]; Matthew C. Exline, MD[3,9]; Daniel J. Henning, MD[3,10]; Jennifer G. Wilson, MD[3,11]; Samuel M. Brown, MD[3,12]; Ithan D. Peltan, MD[3,12]; Todd W. Rice, MD[3,4]; David N. Hager, MD, PhD[3,13]; Adit A. Ginde, MD[3,14]; H. Keipp Talbot, MD[3,4]; Jonathan D. Casey, MD[3,4]; Carlos G. Grijalva, MD[3,4]; Brendan Flannery, PhD[1]; Manish M. Patel, MD[1]; Wesley H. Self, MD[3,4]; IVY Network Investigators; CDC COVID-19 Response Team (VIEW AUTHOR AFFILIATIONS)

View suggested citation

Community and close contact exposures continue to drive the coronavirus disease 2019 (COVID-19) pandemic. CDC and other public health authorities recommend community mitigation strategies to reduce transmission of SARS-CoV-2, the virus that causes COVID-19 (*1*,*2*). Characterization of community exposures can be difficult to assess when widespread

transmission is occurring, especially from asymptomatic persons within inherently interconnected communities. Potential exposures, such as close contact with a person with confirmed COVID-19, have primarily been assessed among COVID-19 cases, without a non-COVID-19 comparison group (*3*,*4*). To assess community and close contact exposures associated with COVID-19, exposures reported by case-patients (154) were compared with exposures reported by control-participants (160). Case-patients were symptomatic adults (persons aged ≥18 years) with SARS-CoV-2 infection confirmed by reverse transcription–polymerase chain reaction (RT-PCR) testing. Control-participants were symptomatic outpatient adults from the same health care facilities who had negative SARS-CoV-2 test results. Close contact with a person with known COVID-19 was more commonly reported among case-patients (42%) than among control-participants (14%). Case-patients were more likely to have reported dining at a restaurant (any area designated by the restaurant, including indoor, patio, and outdoor seating) in the 2 weeks preceding illness onset than were control-participants (adjusted odds ratio [aOR] = 2.4; 95% confidence interval [CI] = 1.5–3.8). Restricting the analysis to participants without known close contact with a person with confirmed COVID-19, case-patients were more likely to report dining at a restaurant (aOR = 2.8, 95% CI = 1.9–4.3) or going to a bar/coffee shop (aOR = 3.9, 95% CI = 1.5–10.1) than were control-participants. Exposures and activities where mask use and social distancing are difficult to maintain, including going to places that offer on-site eating or drinking, might be important risk factors for acquiring COVID-19. As communities reopen, efforts to reduce possible exposures at locations that offer on-site eating and drinking options should be considered to protect customers, employees, and communities.

This investigation included adults aged ≥18 years who received a first test for SARS-CoV-2 infection at an outpatient testing or health care center at one of 11 Influenza Vaccine Effectiveness in the Critically Ill (IVY) Network sites* during July 1–29, 2020 (*5*). A COVID-19 case was confirmed by RT-PCR testing for SARS-CoV-2 RNA from respiratory specimens. Assays varied among facilities. Each site generated lists of adults tested within the study period by laboratory result; adults with laboratory-confirmed COVID-19 were selected by random sampling as case-patients. For each case-patient, two adults with negative SARS-CoV-2 RT-PCR test results were randomly selected as control-participants and matched by age, sex, and study location. After randomization and matching, 615 potential case-patients and 1,212 control-participants were identified and contacted 14–23 days after the date they received SARS-CoV-2 testing. Screening questions were asked to identify eligible adults. Eligible adults for the study were symptomatic at the time of their first SARS-CoV-2 test.

CDC personnel administered structured interviews in English or five other languages† by telephone and entered data into REDCap software (*6*). Among 802 adults contacted and who agreed to participate (295 case-patients and 507 control-participants), 332 reported symptoms at the time of initial SARS-CoV-2 testing and were enrolled in the study. Eighteen interviews were excluded because of nonresponse to the community exposure questions. The final analytic sample (314) included 154 case-patients (positive SARS-CoV-2 test results) and 160 control-participants (negative SARS-CoV-2 test results). Among nonparticipants, 470 were ineligible (i.e., were not symptomatic or had multiple tests), and 163 refused to participate. This activity was reviewed by CDC and participating sites and conducted consistent with applicable federal law and CDC policy.§

Data collected included demographic characteristics, information on underlying chronic medical conditions,¶ symptoms, convalescence (self-rated physical and mental health), close contact (within 6 feet for ≥15 minutes) with a person with known COVID-19, workplace exposures, mask-wearing behavior, and community activities ≤14 days before symptom onset. Participants were asked about wearing a mask and possible community exposure activities (e.g., gatherings with ≤10 or >10 persons in a home; shopping; dining at a restaurant; going to an office setting, salon, gym, bar/coffee shop, or church/religious gathering; or using public transportation) on a five-point Likert-type scale ranging from “never” to “more than once per day” or “always”; for analysis, community activity responses were dichotomized as never versus one or more times during the 14 days before illness onset. For each reported activity, participants were asked to quantify degree of adherence to recommendations such as wearing a face mask of any kind or social distancing among other persons at that location, with response options ranging from “none” to “almost all.” Descriptive and statistical analyses were performed to compare case-patients with control-participants, assessing differences in demographic characteristics, community exposures, and close contact. Although an effort was made initially to match case-patients to control-participants based on a 1:2 ratio, not all potential participants were eligible or completed an interview, and therefore an unmatched analysis was performed. Unconditional logistic regression models with generalized estimating equations with exchangeable correlation structure correcting standard error estimates for site-level clustering were used to assess differences in community exposures between case-patients and control-participants, adjusting for age, sex, race/ethnicity, and presence of one or more underlying chronic medical conditions. In each model, SARS-CoV-2 test result (i.e., positive or negative) was the outcome variable, and each community exposure activity was the predictor variable. The first model included the full

analytic sample (314). A second model was restricted to participants who did not report close contact to a person with COVID-19 (89 case-patients and 136 control-participants). Statistical analyses were conducted using SAS software (version 9.4; SAS Institute).

Compared with case-patients, control-participants were more likely to be non-Hispanic White (p<0.01), have a college degree or higher (p<0.01), and report at least one underlying chronic medical condition (p = 0.01) (Table). In the 14 days before illness onset, 71% of case-patients and 74% of control-participants reported always using cloth face coverings or other mask types when in public. Close contact with one or more persons with known COVID-19 was reported by 42% of case-patients compared with 14% of control-participants (p<0.01), and most (51%) close contacts were family members. Approximately one half of all participants reported shopping and visiting others inside a home (in groups of ≤10 persons) on ≥1 day during the 14 days preceding symptom onset. No significant differences were observed in the bivariate analysis between case-patients and control-participants in shopping; gatherings with ≤10 persons in a home; going to an office setting; going to a salon; gatherings with >10 persons in a home; going to a gym; using public transportation; going to a bar/coffee shop; or attending church/religious gathering. However, case-patients were more likely to have reported dining at a restaurant (aOR = 2.4, 95% CI = 1.5–3.8) in the 2 weeks before illness onset than were control-participants (Figure). Further, when the analysis was restricted to the 225 participants who did not report recent close contact with a person with known COVID-19, case-patients were more likely than were control-participants to have reported dining at a restaurant (aOR = 2.8, 95% CI = 1.9–4.3) or going to a bar/coffee shop (aOR = 3.9, 95% CI = 1.5–10.1). Among 107 participants who reported dining at a restaurant and 21 participants who reported going to a bar/coffee shop, case-patients were less likely to report observing almost all patrons at the restaurant adhering to recommendations such as wearing a mask or social distancing (p = 0.03 and p = 0.01, respectively).

Top

Discussion

In this investigation, participants with and without COVID-19 reported generally similar community exposures, with the exception of going to locations with on-site eating and drinking options. Adults with confirmed COVID-19 (case-patients) were approximately twice as likely as were control-participants to have reported dining at a restaurant in the 14 days before becoming ill. In addition to dining at a restaurant, case-patients were more likely to report going to a bar/coffee shop, but only when the analysis was restricted to participants without close contact with persons with known COVID-19 before illness onset. Reports of exposures in restaurants have been linked to air circulation (*7*). Direction, ventilation, and intensity of airflow might affect virus transmission, even if social distancing measures and mask use are implemented according to current guidance. Masks cannot be effectively worn while eating and drinking, whereas shopping and numerous other indoor activities do not preclude mask use.

Among adults with COVID-19, 42% reported close contact with a person with COVID-19, similar to what has been reported previously (*4*). Most close contact exposures were to family members, consistent with household transmission of SARS-CoV-2 (*8*). Fewer (14%) persons who received a negative SARS-CoV-2 test result reported close contact with a person with known COVID-19. To help slow the spread of SARS-CoV-2, precautions should be implemented to stay home once exposed to someone with COVID-19,** in addition to adhering to recommendations to wash hands often, wear masks, and social distance.†† If a family member or other close contact is ill, additional prevention measures can be taken to reduce transmission, such as cleaning and disinfecting the home, reducing shared meals and items, wearing gloves, and wearing masks, for those with and without known COVID-19.§§

The findings in this report are subject to at least five limitations. First, the sample included 314 symptomatic patients who actively sought testing during July 1–29, 2020 at 11 health care facilities. Symptomatic adults with negative SARS-CoV-2 test results might have been infected with other respiratory viruses and had similar exposures to persons with cases of such illnesses. Persons who did not respond, or refused to participate, could be systematically different from those who were interviewed for this investigation. Efforts to age- and sex-match participating case-patients and control-participants were not maintained because of participants not meeting the eligibility criteria, refusing to participate, or not responding, and this was accounted for in the analytic approach. Second, unmeasured confounding is possible, such that reported behaviors might represent factors, including concurrently participating in activities where possible exposures could have taken place, that were not included in the analysis or measured in the survey. Of note, the question assessing dining at a restaurant did not distinguish between indoor and outdoor options. In addition, the question about going to a bar or coffee shop did not distinguish between the venues or service delivery methods, which might represent different exposures. Third, adults in the study were from one of 11 participating health care facilities and might not be representative of the United States

population. Fourth, participants were aware of their SARS-CoV-2 test results, which could have influenced their responses to questions about community exposures and close contacts. Finally, case or control status might be subject to misclassification because of imperfect sensitivity or specificity of PCR-based testing (*9*,*10*).

This investigation highlights differences in community and close contact exposures between adults who received a positive SARS-CoV-2 test result and those who received a negative SARS-CoV-2 test result. Continued assessment of various types of activities and exposures as communities, schools, and workplaces reopen is important. Exposures and activities where mask use and social distancing are difficult to maintain, including going to locations that offer on-site eating and drinking, might be important risk factors for SARS-CoV-2 infection. Implementing safe practices to reduce exposures to SARS-CoV-2 during on-site eating and drinking should be considered to protect customers, employees, and communities[¶¶] and slow the spread of COVID-19.

Top

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Top

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Top

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Top

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Top

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† Other languages included Spanish, Arabic, Vietnamese, Portuguese, and Russian.

§ Activity was determined to meet the requirements of public health surveillance as defined in 45 CFR 46.102(l)(2).

¶ Cardiac condition, hypertension, asthma, chronic obstructive pulmonary disease, immunodeficiency, psychiatric condition, diabetes, or obesity.

** https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.

†† https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html.

§§ https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html.

¶¶ https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/personal-social-activities.html#restaurant; https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/business-employers/bars-restaurants.html; https://www.cdc.gov/coronavirus/2019-ncov/images/community/Rest_Bars_RiskAssessment.jpg .

Top

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Top

TABLE. Characteristics of symptomatic adults ≥18 years who were outpatients in 11 academic health care facilities and who received positive and negative SARS-CoV-2 test results (N = 314)* — United States, July 1–29, 2020

Return

Characteristic	No. (%)		P-value
	Case-patients (n = 154)	Control participants (n = 160)	
Age group, yrs			
18–29	44 (28.6)	39 (24.4)	0.18
30–44	46 (29.9)	62 (38.7)	
45–59	46 (29.9)	35 (21.9)	
≥60	18 (11.7)	24 (15.0)	
Sex			
Men	75 (48.7)	72 (45.0)	0.51
Women	79 (51.3)	88 (55.0)	
Race/Ethnicity†			
White, non-Hispanic	92 (59.7)	124 (77.5)	<0.01
Hispanic/Latino	29 (18.8)	12 (7.5)	
Black, non-Hispanic	27 (17.5)	19 (11.9)	
Other, non-Hispanic	6 (3.9)	5 (3.1)	
Education (missing = 3)			
Less than high school	16 (10.5)	3 (1.9)	<0.01
High school degree or some college	60 (39.2)	48 (30.4)	
College degree or more	77 (50.3)	107 (67.7)	
At least one underlying chronic medical condition§	75 (48.7)	98 (61.2)	0.01
Community exposure 14 days before illness onset¶			

Characteristic	No. (%)		P-value
	Case-patients (n = 154)	Control participants (n = 160)	
Shopping	131 (85.6)	141 (88.1)	0.51
Home, ≤10 persons	79 (51.3)	84 (52.5)	0.83
Restaurant	63 (40.9)	44 (27.7)	0.01
Office setting	37 (24.0)	47 (29.6)	0.27
Salon	24 (15.6)	28 (17.6)	0.63
Home, >10 persons	21 (13.6)	24 (15.0)	0.73
Gym	12 (7.8)	10 (6.3)	0.60
Public transportation	8 (5.2)	10 (6.3)	0.68
Bar/Coffee shop	13 (8.5)	8 (5.0)	0.22
Church/Religious gathering	12 (7.8)	8 (5.0)	0.32
Restaurant: others following recommendations such as wearing a face covering or mask of any kind or social distancing (n = 107)			
None/A few	12 (19.0)	1 (2.3)	0.03
About half/Most	25 (39.7)	21 (47.7)	
Almost all	26 (41.3)	22 (50.0)	
Bar: others following recommendations such as wearing a face covering or mask of any kind or social distancing (n = 21)			
None/A few	4 (31.8)	2 (25.0)	0.01
About half/Most	7 (53.8)	0 (0.0)	
Almost all	2 (15.4)	6 (75.0)	
Previous close contact with a person with known COVID-19 (missing = 1)			
No	89 (57.8)	136 (85.5)	<0.01
Yes	65 (42.2)	23 (14.5)	
Relationship to close contact with known COVID-19 (n = 88)			

Characteristic	No. (%)		P-value
	Case-patients (n = 154)	Control participants (n = 160)	
Family	33 (50.8)	5 (21.7)	<0.01
Friend	9 (13.8)	4 (17.4)	
Work colleague	11 (16.9)	6 (26.1)	
Other**	6 (9.2)	8 (34.8)	
Multiple	6 (9.2)	0 (0.0)	
Reported use of cloth face covering or mask 14 days before illness onset (missing = 2)			
Never	6 (3.9)	5 (3.1)	0.86
Rarely	6 (3.9)	6 (3.8)	
Sometimes	11 (7.2)	7 (4.4)	
Often	22 (14.4)	23 (14.5)	
Always	108 (70.6)	118 (74.2)	

* Respondents who completed the interview 14–23 days after their test date. Five participants had significant missingness for exposure questions and were removed from the analysis. Patients were randomly sampled from 11 academic health care systems that are part of the Influenza Vaccine Effectiveness in the Critically Ill Network sites (Baystate Medical Center, Springfield, Massachusetts; Beth Israel Deaconess Medical Center, Boston, Massachusetts; University of Colorado School of Medicine, Aurora, Colorado; Hennepin County Medical Center, Minneapolis, Minnesota; Intermountain Healthcare, Salt Lake City, Utah; Ohio State University Wexner Medical Center, Columbus, Ohio; Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina; Vanderbilt University Medical Center, Nashville, Tennessee; John Hopkins Hospital, Baltimore, Maryland; Stanford University Medical Center, Palo Alto, California; University of Washington Medical Center, Seattle, Washington). Participating states include California, Colorado, Maryland, Massachusetts, Minnesota, North Carolina, Ohio, Tennessee, Utah, and Washington.

† Other race includes responses of Native American/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, and other; these were combined because of small sample sizes.

§ Reported at least one of the following underlying chronic medical conditions: cardiac condition, hypertension, asthma, chronic obstructive pulmonary disease, immunodeficiency, psychiatric condition, diabetes, or obesity.

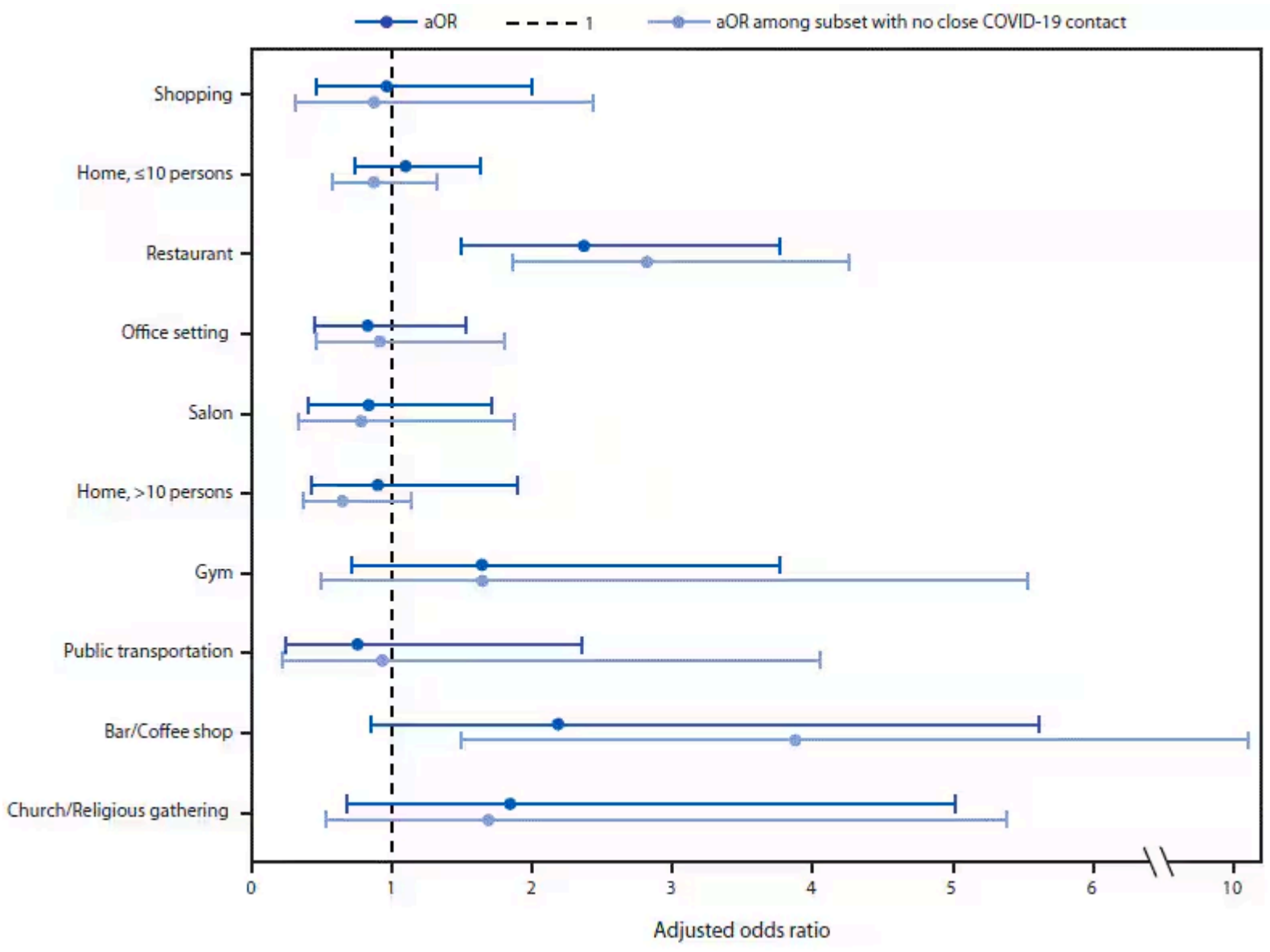
¶ Community exposure questions asked were “In the 14 days before feeling ill about how often did you:” with options of “shop for items (groceries, prescriptions, home goods, clothing, etc.)” (missing = 1); “have people visit you inside your home or go inside someone else’s home where there were more than 10 people”; “have people visit you inside your home or go inside someone else’s home where there were 10 people or less”; “go to church or a religious gathering/place of worship” (missing = 1); “go to a restaurant (dine-in, any area designated by the restaurant including patio seating)” (missing = 1); “go to a bar or coffee shop (indoors)” (missing = 2); “use public transportation (bus, subway, streetcar, train, etc.)” (missing = 1); “go to an office setting (other than for healthcare purposes)” (missing = 1); “go to a gym or fitness center” (missing = 1); and “go to a salon or barber (e.g., hair salon, nail salon, etc.)” (missing = 1). Response options were coded as never versus at least once in the 14 days prior to illness onset. Some participants had missing data for exposure questions.

** Other includes patients of health care workers (9), patron of a restaurant (1), spouse of employee (1), day care teacher (1), member of a religious congregation (1), and unspecified (1).

Top

FIGURE. Adjusted odds ratio (aOR)* and 95% confidence intervals for community exposures† associated with confirmed COVID-19 among symptomatic adults aged ≥18 years (N = 314) — United States, July 1–29, 2020

Return



Abbreviation: COVID-19 = coronavirus disease 2019.

* Adjusted for race/ethnicity, sex, age, and reporting at least one underlying chronic medical condition. Odds ratios were estimated using unconditional logistic regression with generalized estimating equations, which accounted for Influenza Vaccine Effectiveness in the Critically Ill Network site-level clustering. A second model was restricted to participants who did not report close contact to a person known to have COVID-19 (n = 225).

† Community exposure questions asked were "In the 14 days before feeling ill about how often did you: shop for items (groceries, prescriptions, home goods, clothing, etc.); have people visit you inside your home or go inside someone else's home where there were more than 10 people; have people visit you inside your home or go inside someone else's home where there were 10 people or less; go to church or a religious gathering/place of worship; go to a restaurant (dine-in, any area designated by the restaurant including patio seating); go to a bar or coffee shop (indoors); use public transportation (bus, subway, streetcar, train, etc.); go to an office setting (other than for healthcare purposes); go to a gym or fitness center; go to a salon or barber (e.g., hair salon, nail salon, etc.)." Response options were coded as never versus at least once in the 14 days before illness onset.

Top

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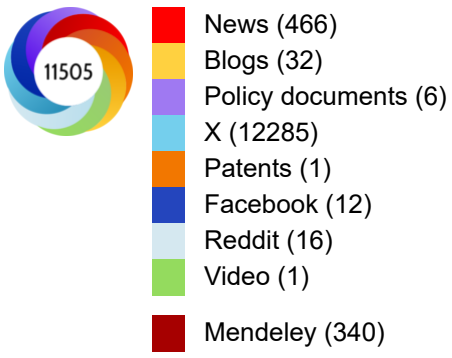
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Abstract

Background:

Observational evidence suggests that mask wearing mitigates transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is uncertain if this observed association arises through protection of uninfected wearers (protective effect), via reduced transmission from infected mask wearers (source control), or both.

Objective:

To assess whether recommending surgical mask use outside the home reduces wearers' risk for SARS-CoV-2 infection in a setting where masks were uncommon and not among recommended public health measures.

Design:

Randomized controlled trial (DANMASK-19 [Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection]). (ClinicalTrials.gov: NCT04337541)

Setting:

Denmark, April and May 2020.

Participants:

Adults spending more than 3 hours per day outside the home without occupational mask use.

Intervention:

Encouragement to follow social distancing measures for coronavirus disease 2019, plus either no mask recommendation or a recommendation to wear a mask outside the home among other persons together with a supply of 50 surgica and instructions for proper use.

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Measurements:

The primary outcome was SARS-CoV-2 infection in the mask wearer at 1 month by antibody testing, polymerase chain reaction (PCR), or hospital diagnosis. The secondary outcome was PCR positivity for other respiratory viruses.

Results:

A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point (95% CI, −1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio, 0.82 [CI, 0.54 to 1.23]; $P = 0.33$). Multiple imputation accounting for loss to follow-up yielded similar results. Although the difference observed was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection.

Limitation:

Inconclusive results, missing data, variable adherence, patient-reported findings on home tests, no blinding, and no assessment of whether masks could decrease disease transmission from mask wearers to others.

Conclusion:

The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use. The data were compatible with lesser degrees of self-protection.

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Primary Funding Source:

The Salling Foundations.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the cause of coronavirus disease 2019 (COVID-19), has infected more than 54 million persons (1, 2). Measures to impede transmission in health care and community settings are essential (3). The virus is transmitted person-to-person, primarily through the mouth, nose, or eyes via respiratory droplets, aerosols, or fomites (4, 5). It can survive on surfaces for up to 72 hours (6), and touching a contaminated surface followed by face touching is another possible route of transmission (7). Face masks are a plausible means to reduce transmission of respiratory viruses by minimizing the risk that respiratory droplets will reach wearers' nasal or oral mucosa. Face masks are also hypothesized to reduce face touching (8, 9), but frequent face and mask touching has been reported among health care personnel (10). Observational evidence supports the efficacy of face masks in health care settings (11, 12) and as source control in patients infected with SARS-CoV-2 or other coronaviruses (13).

An increasing number of localities recommend masks in community settings on the basis of this observational evidence, but recommendations vary and controversy exists (14). The World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (15) strongly recommend that persons with symptoms or known infection wear masks to prevent transmission of SARS-CoV-2 to others (source control) (16). However, WHO acknowledges that we lack evidence that wearing a mask protects healthy persons from SARS-CoV-2 (prevention) (17). A systematic

review of observational studies reported that mask use reduced risk for SARS, Middle East respiratory syndrome, and COVID-19 by 66% overall, 70% in health care workers, and 44% in the community (12). However, surgical and cloth masks were grouped in preventive studies, and none of the 3 included non–health care studies related directly to COVID-19. Another systematic review (18) and American College of Physicians recommendations (19) concluded that evidence on mask effective respiratory infection prevention is stronger in health care than community se

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Observational evidence suggests that mask wearing mitigates SARS-CoV-2 transmission, but whether this observed association arises because masks protect uninfected wearers (protective effect) or because transmission is reduced from infected mask wearers (source control) is uncertain. Here, we report a randomized controlled trial (20) that assessed whether a recommendation to wear a surgical mask when outside the home among others reduced wearers' risk for SARS-CoV-2 infection in a setting where public health measures were in effect but community mask wearing was uncommon and not recommended.

Methods

Trial Design and Oversight

DANMASK-19 (Danish Study to Assess Face Masks for the Protection Against COVID-19 Infection) was an investigator-initiated, nationwide, unblinded, randomized controlled trial (ClinicalTrials.gov: NCT04337541). The trial protocol was registered with the Danish Data Protection Agency (P-2020-311) (Part 10 of the Supplement) and published (21). The researchers presented the protocol to the independent regional scientific ethics committee of the Capital Region of Denmark, which did not require ethics approval (H-20023709) in accordance with Danish legislation (Parts 11 and 12 of the Supplement). The trial was done in accordance with the principles of the Declaration of Helsinki.

Participants and Study Period

During the study period (3 April to 2 June 2020), Danish authorities did not recommend use of masks in the community and mask use was uncommon (<5%) outside hospitals (22). Recommended public health measures included quarantining persons with SARS-CoV-2 infection, social distancing (including in shops and public transportation, which remained open), limiting the number of persons seen, frequent hand hygiene and cleaning, and limiting visitors to hospitals and nu homes (23, 24). Cafés and restaurants were closed during the study until 18 M

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Eligible persons were community-dwelling adults aged 18 years or older without current or prior symptoms or diagnosis of COVID-19 who reported being outside the home among others for at least 3 hours per day and who did not wear masks during their daily work. Recruitment involved media advertisements and contacting private companies and public organizations. Interested citizens had internet access to detailed study information and to research staff for questions (Part 3 of the Supplement). At baseline, participants completed a demographic survey and provided consent for researchers to access their national registry data (Parts 4 and 5 of the Supplement). Recruitment occurred from 3 through 24 April 2020. Half of participants were randomly assigned to a group on 12 April and half on 24 April.

Intervention

Participants were enrolled and data registered using Research Electronic Data Capture (REDCap) software (25). Eligible participants were randomly assigned 1:1 to the mask or control group using a computer algorithm and were stratified by the 5 regions of Denmark (Supplement Table 1). Participants were notified of allocation by e-mail, and study packages were sent by courier (Part 7 of the Supplement). Participants in the mask group were instructed to wear a mask when outside the home during the next month. They received 50 three-layer, disposable, surgical face masks with ear loops (TYPE II EN 14683 [Abena]; filtration rate, 98%; made in China). Participants in both groups received materials and instructions for antibody testing on receipt and at 1 month. They also received materials and instructions for collecting an oropharyngeal/nasal swab sample for polymerase chain reaction (PCR) testing at 1

month and whenever symptoms compatible with COVID-19 occurred during follow-up. If symptomatic, participants were strongly encouraged to seek medical care. They registered symptoms and results of the antibody test in the online REDCap system. Participants returned the test material by prepaid express courier.

Written instructions and instructional videos guided antibody testing, oropharyngeal/nasal swabbing, and proper use of masks (Part 8 of the Suppl and a help line was available to participants. In accordance with WHO recommendations for health care settings at that time, participants were instructed to change the mask if outside the home for more than 8 hours. At baseline and in weekly follow-up e-mails, participants in both groups were encouraged to follow current COVID-19 recommendations from the Danish authorities.

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Antibody and Viral PCR Testing

Participants tested for SARS-CoV-2 IgM and IgG antibodies in whole blood using a point-of-care test (Lateral Flow test [Zhuhai Livzon Diagnostics]) according to the manufacturer's recommendations and as previously described (26). After puncturing a fingertip with a lancet, they withdrew blood into a capillary tube and placed 1 drop of blood followed by 2 drops of saline in the test chamber in each of the 2 test plates (IgM and IgG). Participants reported IgM and IgG results separately as “1 line present” (negative), “2 lines present” (positive), or “I am not sure, or I could not perform the test” (treated as a negative result). Participants were categorized as seropositive if they had developed IgM, IgG, or both. The manufacturer reported that sensitivity was 90.2% and specificity 99.2%. A previously reported internal validation using 651 samples from blood donors before November 2019 and 155 patients with PCR-confirmed SARS-CoV-2 infection estimated a sensitivity of 82.5% (95% CI, 75.3% to 88.4%) and specificity of 99.5% (CI, 98.7% to 99.9%) (26). We (27) and others (28) have reported that oropharyngeal/nasal swab sampling for SARS-CoV-2 by participants, as opposed to health care workers, is clinically useful. Descriptions of RNA extraction, primer and probe used, reverse transcription, preamplification, and microfluidic quantitative PCR are detailed in Part 6 of the Supplement.

Data Collection

Participants received 4 follow-up surveys (Parts 4 and 5 of the Supplement) by e-mail to collect information on antibody test results, adherence to recommendations on time spent outside the home among others, development of symptoms, COVID-19 diagnosis based on PCR testing done in public hospitals, and known COVID-19 exposures.

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Outcomes

The primary outcome was SARS-CoV-2 infection, defined as a positive result on an oropharyngeal/nasal swab test for SARS-CoV-2, development of a positive SARS-CoV-2 antibody test result (IgM or IgG) during the study period, or a hospital-based diagnosis of SARS-CoV-2 infection or COVID-19. Secondary end points included PCR evidence of infection with other respiratory viruses (Supplement Table 2).

Sample Size Calculations

The sample size was determined to provide adequate power for assessment of the combined composite primary outcome in the intention-to-treat analysis. Authorities estimated an incidence of SARS-CoV-2 infection of at least 2% during the study period. Assuming that wearing a face mask halves risk for infection, we estimated that a sample of 4636 participants would provide the trial with 80% power at a significance level of 5% (2-sided α level). Anticipating 20% loss to follow-up in this community-based study, we aimed to assign at least 6000 participants.

Statistical Analysis

Participants with a positive result on an antibody test at baseline were excluded from the analyses. We calculated CIs of proportions assuming binomial distribution (Clopper–Pearson).

The primary composite outcome (intention-to-treat) was compared between groups using the χ^2 test. Odds ratios and confidence limits were calculated using logistic

regression. We did a per protocol analysis that included only participants reporting complete or predominant use of face masks as instructed. A conservative sensitivity analysis assumed that participants with a positive result on an antibody test at the end of the study who had not provided antibody test results at study entrance had had a positive result at entrance. To further examine the uncertainty of loss to follow-up, we did (post hoc) 200 imputations using the R package smcfcs, version 1. to impute missing values of outcome. We included sex, age, type of work, tim home, and outcome in this calculation.

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Prespecified subgroups were compared by logistic regression analysis. In a post hoc analysis, we explored whether there was a subgroup defined by a constellation of participant characteristics for which a recommendation to wear masks seemed to be effective. We included sex, age, type of work, time out of home, and outcome in this calculation.

Two-sided *P* values less than 0.05 were considered statistically significant. Analyses were done using R, version 3.6.1 (R Foundation).

Role of the Funding Source

An unrestricted grant from the Salling Foundations supported the study, and the BESTSELLER Foundation donated the Livzon tests. The funders did not influence study design, conduct, or reporting.

Results

Participants

A total of 17 258 Danish citizens responded to recruitment, and 6024 completed the baseline survey and fulfilled eligibility criteria. The first participants (group 1; *n* = 2995) were randomly assigned on 12 April 2020 and were followed from 14 to 16 April through 15 May 2020. Remaining participants (group 2; *n* = 3029) were randomly assigned on 24 April 2020 and were followed from 2 to 4 May through 2 June 2020. A

total of 3030 participants were randomly assigned to the recommendation to wear face masks, and 2994 were assigned not to wear face masks (Figure); 4862 participants (80.7%) completed the study. Table 1 shows baseline characteristics, which were well balanced between groups. Participants reported having spent a median of 4.5 hours per day outside the home.

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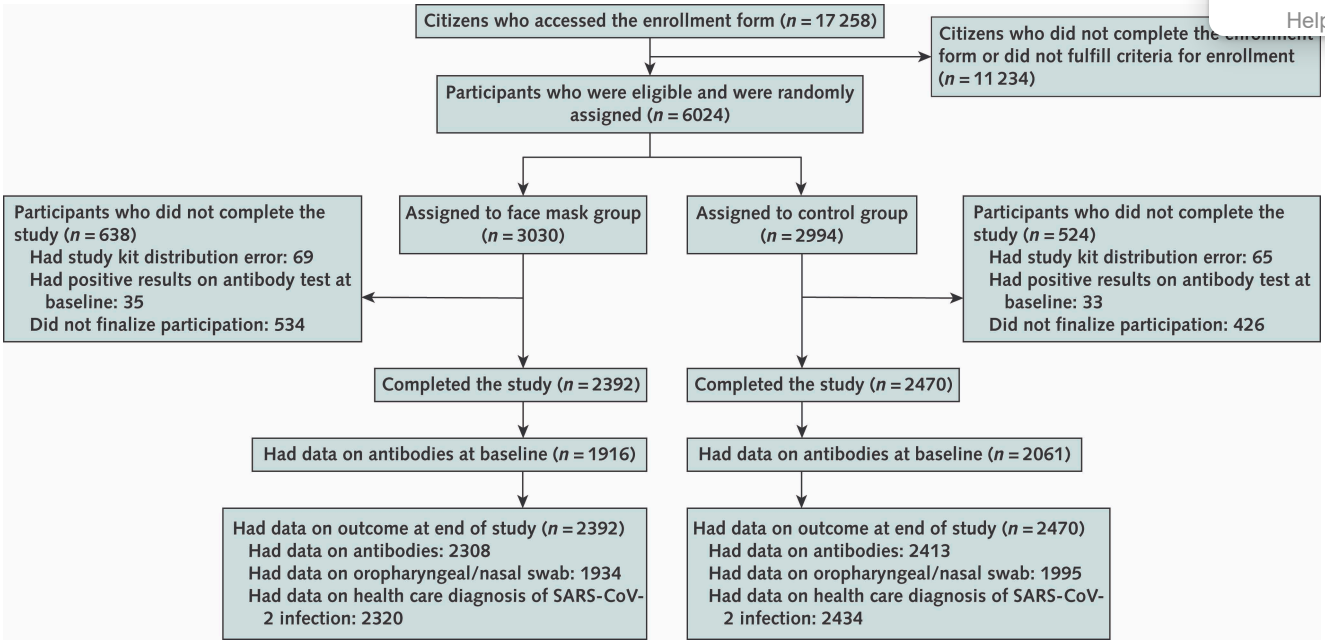


Figure. Study flow diagram.

Inclusion and exclusion criteria are described in the Methods section, and criteria for completion of the study are given in the Supplement. SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Table 1. Characteristics of Participants Completing the Study

Table 1. Characteristics of Participants Completing the Study

Characteristic	Face Mask Group (*n* = 2392)	Control Group (*n* = 2470)
Mean age (SD), *y*	47.4 (14)	47.0 (13)
Female sex, *n (%)*	1545 (64.6)	1571 (63.6)
Smoker, *n (%)*	478 (20.0)	499 (20.2)
Wears eyeglasses daily, *n (%)*	956 (40.0)	929 (37.6)
Capital Region resident, *n (%)**	1220 (51.0)	1289 (52.2)
Provided antibody test results at baseline, *n (%)*	1916 (80.1)	2061 (83.4)
Occupation, *n (%)*		
Shop employee	108 (4.5)	85 (3.4)
Cashier	101 (4.2)	96 (
Craftsperson	110 (4.6)	103 (
Office employee	265 (11.1)	312 (
Manager	111 (4.6)	108 (
Transportation employee	617 (25.8)	625 (
Service employee	107 (4.5)	104 (
Home care/nursing home employee	197 (8.2)	229 (9.3)
Early childhood care staff	89 (3.7)	88 (3.6)
Salesperson	37 (1.5)	47 (1.9)
Other	650 (27.2)	673 (27.2)

* According to national authority data, the Capital Region had a higher frequency of coronavirus disease 2019 than other Danish regions; see subgroup analyses in **Supplement Figure 2** (available at Annals.org).

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Adherence

Based on the lowest adherence reported in the mask group during follow-up, 46% of participants wore the mask as recommended, 47% predominantly as recommended, and 7% not as recommended.

Primary Outcome

The primary outcome occurred in 42 participants (1.8%) in the mask group and 53 (2.1%) in the control group. In an intention-to-treat analysis, the between-group difference was −0.3 percentage point (CI, −1.2 to 0.4 percentage point; $P = 0.38$) (odds ratio [OR], 0.82 [CI, 0.54 to 1.23]; $P = 0.33$) in favor of the mask group (Supplement Figure 1). When this analysis was repeated with multiple imputation for missing data due to loss to follow-up, it yielded similar results (OR, 0.81 [CI, 0.53 to 1.23]; $P = 0.32$). Table 2 provides data on the components of the primary end point, which were similar between groups.

Table 2. Distribution of the Components of the Composite Primary Outcome

Table 2. Distribution of the Components of the Composite Primary Outcome

Outcome Component	Face Mask Group (*n* = 2392), *n* (%)	Control Group (*n* = 2470), *n* (%)	Odds Ratio (95% CI)*
Primary composite end point	42 (1.8)	53 (2.1)	0.82 (0.54-1.23)
Positive antibody test result†			
IgM	31 (1.3)	37 (1.5)	0.87 (0.54-1.41)
IgG	33 (1.4)	32 (1.3)	1.07 (0.66-1.75)
Positive SARS-CoV-2 RT-PCR	0 (0)	5 (0.2)	–
Health care–diagnosed SARS-CoV-2 or COVID-19	5 (0.2)	10 (0.4)	0.52 (0.18-1.53)

COVID-19 = coronavirus disease 2019; RT-PCR = reverse transcriptase polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
* Calculated using logistic regression. The between-group differences in frequencies of positive SARS-CoV-2 RT-PCR were not statistically
(*P* = 0.079).
† 124 participants in the mask group and 140 in the control group registered "not done" or unclear results of the antibody test–i.e
included in the analysis because they sent an oropharyngeal swab for PCR.

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In a per protocol analysis that excluded participants in the mask group who reported nonadherence (7%), SARS-CoV-2 infection occurred in 40 participants (1.8%) in the mask group and 53 (2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.2 to 0.5 percentage point]; *P* = 0.40) (OR, 0.84 [CI, 0.55 to 1.26]; *P* = 0.40). Supplement Figure 2 provides results of the prespecified subgroup analyses of the primary composite end point. No statistically significant interactions were identified.

In the preplanned sensitivity analysis, those who had a positive result on an antibody test at 1 month but had not provided antibody results at baseline were considered to have had positive results at baseline (*n* = 18)—that is, they were excluded from the analysis. In this analysis, the primary outcome occurred in 33 participants (1.4%) in the face mask group and 44 (1.8%) in the control group (between-group difference, −0.4 percentage point [CI, −1.1 to 0.4 percentage point]; *P* = 0.22) (OR, 0.77 [CI, 0.49 to 1.22]; *P* = 0.26).

Three post hoc (not preplanned) analyses were done. In the first, which included only participants reporting wearing face masks "exactly as instructed," infection (the primary outcome) occurred in 22 participants (2.0%) in the face mask group and 53 (2.1%) in the control group (between-group difference, −0.2 percentage point [CI, −1.3 to 0.9 percentage point]; *P* = 0.82) (OR, 0.93 [CI, 0.56 to 1.54]; *P* = 0.78). The second post hoc analysis excluded participants who did not provide antibody test results at baseline; infection occurred in 33 participants (1.7%) in the face mask group and 44

(2.1%) in the control group (between-group difference, −0.4 percentage point [CI, −1.4 to 0.4 percentage point]; $P = 0.33$) (OR, 0.80 [CI, 0.51 to 1.27]; $P = 0.35$). In the third post hoc analysis, which investigated constellations of patient characteristics, we did not find a subgroup where face masks were effective at conventional levels of statistical significance (data not shown).

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A total of 52 participants in the mask group and 39 control participants repor COVID-19 in their household. Of these, 2 participants in the face mask group and 1 in the control group developed SARS-CoV-2 infection, suggesting that the source of most observed infections was outside the home. Reported symptoms did not differ between groups during the study period (Supplement Table 3).

Secondary Outcomes

In the mask group, 9 participants (0.5%) were positive for 1 or more of the 11 respiratory viruses other than SARS-CoV-2, compared with 11 participants (0.6%) in the control group (between-group difference, −0.1 percentage point [CI, −0.6 to 0.4 percentage point]; $P = 0.87$) (OR, 0.84 [CI, 0.35 to 2.04]; $P = 0.71$). Positivity for any virus, including SARS-CoV-2, occurred in 9 mask participants (0.5%) versus 16 control participants (0.8%) (between-group difference, −0.3 percentage point [CI, −0.9 to 0.2 percentage point]; $P = 0.26$) (OR, 0.58 [CI, 0.25 to 1.31]; $P = 0.19$).

Discussion

In this community-based, randomized controlled trial conducted in a setting where mask wearing was uncommon and was not among other recommended public health measures related to COVID-19, a recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, incident SARS-CoV-2 infection compared with no mask recommendation. We designed the study to detect a reduction in infection rate from 2% to 1%. Although no statistically significant difference in SARS-CoV-2 incidence was observed, the 95% CIs are compatible with a possible 46% reduction to 23% increase

in infection among mask wearers. These findings do offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings, however, should not be used to conclude that a recommendation for everyone to wear masks in the community would not be effective in reducing SARS-CoV-2 infections, because the trial did not test the masks in source control of SARS-CoV-2 infection. During the study period, au did not recommend face mask use outside hospital settings and mask use was rare in community settings (22). This means that study participants' exposure was overwhelmingly to persons not wearing masks.

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The observed infection rate was similar to that reported in other large Danish studies during the study period (26, 30). Of note, the observed incidence of SARS-CoV-2 infection was higher than we had estimated when planning a sample size that would ensure more than 80% power to detect a 50% decrease in infection. The intervention lasted only 1 month and was carried out during a period when Danish authorities recommended quarantine of diagnosed patients, physical distancing, and hand hygiene as general protective means against SARS-CoV-2 transmission (23). Cafés and restaurants were closed through 18 May, but follow-up of the second randomized group continued through 2 June.

The first randomized group was followed while the Danish society was under lockdown. Reopening occurred (18 May 2020) during follow-up of the second group of participants, but it was not reflected in the outcome because infection rates were similar between groups (Supplement Figure 2). The relative infection rate between mask wearers and those not wearing masks would most likely be affected by changes in applied protective means or in the virulence of SARS-CoV-2, whereas the rate difference between the 2 groups would probably not be affected solely by a higher—or lower—number of infected citizens.

Although we saw no statistically significant difference in presence of other respiratory viruses, the study was not sufficiently powered to draw definite

conclusions about the protective effect of masks for other viral infections. Likewise, the study had limited power for any of the subgroup analyses.

The primary outcome was mainly defined by antibodies against SARS-CoV-2. This definition was chosen because the viral load of infected patients may be only transiently detectable (31, 32) and because approximately half of persons infe… with SARS-CoV-2 are asymptomatic (26, 33). Masks have been hypothesized t… inoculum size (34) and could increase the likelihood that infected mask users are asymptomatic, but this hypothesis has been challenged (35). For these reasons, we did not rely solely on identification of SARS-CoV-2 in oropharyngeal/nasal swab samples. As mentioned in the Methods section, an internal validation study estimated that the point-of-care test has 82.5% sensitivity and 99.5% specificity (26).

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The observed rate of incident SARS-CoV-2 infection was similar to what was estimated during trial design. These rates were based on thorough screening of all participants using antibody measurements combined with PCR, whereas the observed official infection rates relied solely on PCR test–based estimates during the period. In addition, authorities tested only a small subset of primarily symptomatic citizens of the entire population, yielding low incidence rates. On this basis, the infection rates we report here are not comparable with the official SARS-CoV-2 infection rates in the Danish population. The eligibility requirement of at least 3 hours of exposure to other persons outside the home would add to this difference. Between 6 April and 9 May 2020, we found a similar seroprevalence of SARS-CoV-2 of 1.9% (CI, 0.8% to 2.3%) in Danish blood donors using the Livzon point-of-care test and assessed by laboratory technicians (36). Testing at the end of follow-up, however, may not have captured any infections contracted during the last part of the study period, but this would have been true in both the mask and control groups and was not expected to influence the overall findings.

The face masks provided to participants were high-quality surgical masks with a filtration rate of 98% (37). A published meta-analysis found no statistically significant difference in preventing influenza in health care workers between respirators (N95

[American standard] or FFP2 [European standard]) and surgical face masks (38). Adherence to mask use may be higher than observed in this study in settings where mask use is common. Some mask group participants (14%) reported adverse reactions from other citizens (Supplement Table 4). Although adherence may influence the protective effect of masks, sensitivity analyses had similar results across reported adherence.

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How SARS-CoV-2 is transmitted—via respiratory droplets, aerosols, or (to a lesser extent) fomites—is not firmly established. Droplets are larger and rapidly fall to the ground, whereas aerosols are smaller (≤5 μm) and may evaporate and remain in the air for hours (39). Transmission of SARS-CoV-2 may take place through multiple routes. It has been argued that for the primary route of SARS-CoV-2 spread—that is, via droplets—face masks would be considered effective, whereas masks would not be effective against spread via aerosols, which might penetrate or circumnavigate a face mask (37, 39). Thus, spread of SARS-CoV-2 via aerosols would at least partially explain the present findings. Lack of eye protection may also have been of importance, and use of face shields also covering the eyes (rather than face masks only) has been advocated to halt the conjunctival route of transmission (40, 41). We observed no statistically significant interaction between wearers and nonwearers of eyeglasses (Supplement Figure 2). Recent reports indicate that transmission of SARS-CoV-2 via fomites is unusual (42), but masks may alter behavior and potentially affect fomite transmission.

The present findings are compatible with the findings of a review of randomized controlled trials of the efficacy of face masks for prevention (as personal protective equipment) against influenza virus (18). A recent meta-analysis that suggested a protective effect of face masks in the non–health care setting was based on 3 observational studies that included a total of 725 participants and focused on transmission of SARS-CoV-1 rather than SARS-CoV-2 (12). Of 725 participants, 138 (19%) were infected, so the transmission rate seems to be higher than for SARS-CoV-2. Further, these studies focused on prevention of infection in healthy mask wearers

from patients with a known, diagnosed infection rather than prevention of transmission from persons in their surroundings in general. In addition, identified comparators (control participants) not wearing masks may also have missed other protective means. Recent observational studies that indicate a protective association between mandated mask use in the community and SARS-CoV-2 transmission are limited by study design and simultaneous introduction of other public health interventions (14, 43).

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Several challenges regarding wearing disposable face masks in the community exist. These include practical aspects, such as potential incorrect wearing, reduced adherence, reduced durability of the mask depending on type of mask and occupation, and weather. Such circumstances may necessitate the use of multiple face masks during the day. In our study, participants used a mean of 1.7 masks per weekday and 1.3 per weekend day (Supplement Table 4). Wearing a face mask may be physically unpleasant, and psychological barriers and other side effects have been described (44). "Face mask policing" between citizens might reinforce use of masks but may be challenging. In addition, the wearer of a face mask may change to a less cautious behavior because of a false sense of security, as pointed out by WHO (17); accordingly, our face mask group seemed less worried (Supplement Table 4), which may explain their increased willingness to wear face masks in the future (Supplement Table 5). These challenges, including costs and availability, may reduce the efficacy of face masks to prevent SARS-CoV-2 infection.

The potential benefits of a community-wide recommendation to wear masks include combined prevention and source control for symptomatic and asymptomatic persons, improved attention, and reduced potential stigmatization of persons wearing masks to prevent infection of others (17). Although masks may also have served as source control in SARS-CoV-2–infected participants, the study was not designed to determine the effectiveness of source control.

The most important limitation is that the findings are inconclusive, with CIs compatible with a 46% decrease to a 23% increase in infection. Other limitations

include the following. Participants may have been more cautious and focused on hygiene than the general population; however, the observed infection rate was similar to findings of other studies in Denmark (26, 30). Loss to follow-up was 19%, but results of multiple imputation accounting for missing data were similar to the main results. In addition, we relied on patient-reported findings on home antibody tests, and blinding to the intervention was not possible. Finally, a randomized cont trial provides high-level evidence for treatment effects but can be prone to re external validity.

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Our results suggest that the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers in a setting where social distancing and other public health measures were in effect, mask recommendations were not among those measures, and community use of masks was uncommon. Yet, the findings were inconclusive and cannot definitively exclude a 46% reduction to a 23% increase in infection of mask wearers in such a setting. It is important to emphasize that this trial did not address the effects of masks as source control or as protection in settings where social distancing and other public health measures are not in effect.

Reduction in release of virus from infected persons into the environment may be the mechanism for mitigation of transmission in communities where mask use is common or mandated, as noted in observational studies. Thus, these findings do not provide data on the effectiveness of widespread mask wearing in the community in reducing SARS-CoV-2 infections. They do, however, offer evidence about the degree of protection mask wearers can anticipate in a setting where others are not wearing masks and where other public health measures, including social distancing, are in effect. The findings also suggest that persons should not abandon other COVID-19 safety measures regardless of the use of masks. While we await additional data to inform mask recommendations, communities must balance the seriousness of

COVID-19, uncertainty about the degree of source control and protective effect, and the absence of data suggesting serious adverse effects of masks (45).

Supplemental Material

Supplement. Supplementary Material

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Dr Rosamond A K Jones • #UsforThemUK • 18 November 2020

Will mandatory mask usage be scaled back in light of these results?

Dr Bundgaard and colleagues are to be congratulated on this well-constructed randomis
a time when much policy has been based on weak observational or laboratory-based stu
results highlight the dilemma that lack of evidence for benefit is unlikely to alter public policy. The suggestion that mask wearing is for the protection of others, rather than of the wearer, has created a climate of discrimination against those with genuine medical exemptions. This is especially worrying when applied to school children, known to play a very small role in transmission of Sars-Cov-2. In particular, the creeping use of masks in classrrooms in the UK, has resulted in many reports of children feeling alienated and unable to understand their teachers. Parents of primary school children are being instructed to wear masks when collecting their children from the school playground, giving children a potent message that they and their parents are all a danger to one another. The long-term mental health impacts of this are yet to be fully realised.

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Brenda Marfin • Not affiliate. I have a Ph.D. In educational leadership • 18 November 2020

Mis-representation of research purpose

Members of the general public are referencing this research as a battle cry that communities do not need to wear masks in public. After reading the entire article, I ascertained that telling the general public to stop wearing masks was not the purpose or outcome of this research.
During these tumultuous times it might be a moral imperative to include some type of explanation with this research. Very few individuals outside of the medical profession will take the time to thoroughly read the article and analyze the outcomes.

Sincerely,

Brenda Marfin, Ph.D.
Unassociated at this time while caring for my husband with end stage renal disease and Alzheimer's. I depend on the kindness (and myself) of others to wear a mask.

Ambuj Kumar, MD, MPH • Professor, Department of Internal Medicine Director, Morsani College of Medicine, University of South Florida, Tampa • 19 November 2020

In absence of an objective mechanism to track the intervention what are we counting?

The effort by Dr. Bundgaard and colleagues is commendable. However, the trial design and the associated results remind me of the randomized controlled trials assessing the efficacy of a "prayer" intervention. The fundamental issue with mask intervention and social distancing, like prayer, is the lack of objective mechanisms to ensure and track compliance or non-compliance (lack of an accurate method to track who is praying or not praying). As an example, the authors state that only "46% of participants wore the mask as recommended" in the mask group but failed to ask participants in the no mask group about their usage of the mask. Furthermore, a mask is considered an added layer of protection with social distancing and therefore the mask's a effects would be challenging to deduce. Accordingly, given this basic challenge of deliver intervention without tracking/confirmation mechanism, the results, at best, can be considered anecdotal. The desire for evidence from a randomized controlled trial for an intervention question is understandable. However, logistical challenges associated with the reliable implementation of the intervention (i.e., mask) and tracking of adherence makes the conduct of a randomized trial to assess the efficacy of mask a non-starter. The efficacy of a mask needs to be framed in the context of reducing the risk and not binary choices of works or does not work.

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Eric Thompson • Independent Researcher • 18 November 2020

Please *clarify* your policy recommendations

In light of your recent research, will you please **clarify** your policy recommendations? Thank-you

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El Rowan • Private • 19 November 2020

Tested recommendation, not adherence to recommendation

While I commend the researchers and it does demonstrate whether *recommending* masks provides benefit, the experiment does not demonstrate whether mask-wearing *actually* took place. Research in other arenas has shown people are not honest when providing answers to surveys, and these people would have likely had reason to be less than honest about the frequency with which they wore a mask and the coverage of their mouth and nose while wearing one. It may be better to find people with serious concern about NOT wearing a mask to act as the experimental group, and those who are entirely opposed to mask-wearing as the control group. This would be answer the question of whether wearing a mask provides benefit. I think people are misunderstanding the intent of this study, which was to test the power of recommendation with the hope that those in the experimental group would be honest in their responses. We will never know if they were honest or used the masks properly.

Hans Gaines • Karolinska Institute, Stockholm, Sweden • 18 November 2020

Risk for bias?

An important large-scale study investigating the benefit of bearing a mask to reduce the risk of aquiring COVID-19 during an daily average of 4,5 hours stay outside the home during one month.

To be able to do that, one must eliminate the possible bias that the participants are instead infected during the daily 19,5 hours they stay at home.

A total of 52 participants in the mask group and 39 control participants reported COVID-19 in their household. Of these, 2 participants in the face mask group and 1 in the control group dev… SARS-CoV-2 infection...'

PDF

Help

However, more participants may have been exposed and infected by household membe…, without participants reporting COVID-19 in their household, if the members experienced asymptomatic infection or only mild disease, not suspected to be due to COVID-19.

The possible inclusion of misdiagnosed subjects - infected trough household contact but estimated as infected during outside the home should influence both groups - with or without masks - equally. And the true difference between the groups, and thus the benefit of wearing a mask, should increase if this bias had been controlled, although with wide confidence intervals, due to the relatively low number of infection.

The reported finding of only 3% (3/95) infected through household contacts during the study appear to be surprisingly low, supporting the proposed risk for bias, due to misdiagnosis.

Eemil Zhang • Independent Researcher • 18 November 2020

Perceptual error in viewing COVID-19 spread as linear, not exponential.

In the discussion section the authors state that "Testing at the end of follow-up, however, may not have captured any infections contracted during the last part of the study period, but this would have been true in both the mask and control groups and was not expected to influence the overall findings.". This statement assumes a linear spread of infection among both groups. COVID-19 however has been spread exponentially (Lammers, Crusuis, Gast 2020). As such infections contracted during the last part of the study period would be largely significant to the overall findings.

Brendan Moran • NHS COVID Clinical Assessment Service • 19 November 2020

Timing is everything

This study pooled participants from two cohorts split two weeks apart in the months following the peak of first wave of infections in Denmark.

Self-reported pre-study baseline seropositive prevalence was 1.7% and these participants were excluded from the study.

Of those with unknown baseline seropositivity, 2% were positive at the end of the study.

Of those with known baseline seropositivity, around 1.7% appear to have seroconverted during the month of the study.

Do these very similar percentages spread across time raise concerns about the false posit
the self-reported antibody test used in a low prevalence population?

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Even without false positive rate, to achieve 80% sensitivity, this lateral flow antibody test has to be performed at least 15 days after symptom onset. It takes an average of 5-6 days to develop symptoms following exposure, so this creates at least a 3 week lag. Given the study only lasted 1 month in each cohort, any protective effect of mask-wearing will be diluted by late sero-conversions infected prior to the study. This effect will be balanced in the control group, but still increases the OR towards 1 even if masks were having an effect when both groups are pre-loaded equally. Taking this into account and any post-study seroconversions missed in the control group could possibly have led to a significant result. The PCR and clinically diagnosed outcomes will not suffer from this lag so much, and it is noteworthy that mask wearers scored 0 and 5 cases respectively versus 5 and 10 for controls, whilst IgG seropositivity was higher than IgM in mask wearers and vice versa in controls.

The study was also underpowered for detecting a protective-to-wearer effect of somewhere less than 50% which could be a more reasonable estimate of efficacy.

Janet Rand, OD • Concerned US citizen • 20 November 2020

Mis-leading study . Results need to be made more clear.*" Exposure was to persons NOT wearing masks"*

This study does NOT show that mask wearing in ineffective in mitigating the spread of Corona Virus / COVID-19 / SARS-CoV-2. It shows (what we already knew) that wearing a mask does not protect the person wearing the mask as much as we would like. The reason you wear a mask is to keep your viral particles to yourself - don't spread them to others. Unfortunately, anti-maskers are using this study as "prof" that they don't need to wear masks. This is irresponsible and should be made clear in the title of the study. From the discussion: "The findings, however, should not be used to conclude that a recommendation for everyone to wear masks in the community would not be effective in reducing SARS-CoV-2 infections, because the trial did not test the role of masks in source control of SARS-CoV-2 infection. During the study period, authorities did not recommend face mask use outside hospital settings and mask use was rare in community settings (22). This means that study participants' exposure was overwhelmingly to persons not wearing masks."

Tuan Nguyen • Garvan Institute of Medical Research • 23 November 2020

A Bayesian interpretation of the effect of face mask on SARS-Cov-2 infection

Dear Editor:

I would like to offer an alternative interpretation of the DANMASK-19's data [1]. My interpretation centers on the question: *what is the probability that face mask wearing reduces the risk of SARS-Cov-2 infection*. This question can only be answered by a Bayesian approach that updates existing knowledge with new evidence [2].

PDF

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Our pre-existing knowledge is informed by a recent meta-analysis which shows that surgical face mask is associated with a 13% reduction in the risk of acute respiratory infection (risk ratio [RR], 0.87; 95% confidence interval [CI], 0.74 to 1.04) [3]. Note that the average risk reduction reported in this meta-analysis is statistically comparable with that observed in the DANMASK-19 study (i.e., 18% risk reduction; RR, 0.82; 95% CI, 0.54 to 1.23).

When the distribution of relative risks obtained from the meta-analysis [3] is updated by the DANMASK-19's relative risk [1] by the Bayesian theorem [4], the new relative risk is 0.85, with 95% credible interval ranging from 0.72 to 0.99. Moreover, the probability that face mask wearing reduces the risk of SARS-Cov-2 infection by at least 50% is zero. Nevertheless, there is a 93% chance that face mask wearing reduces the risk SARS-Cov-2 infection by at least 5%.

Thus, in settings with moderate Covid-19 infection (such as Denmark) the updated evidence suggests that wearing face mask may modestly protect the wearers from infection with SARS-Cov-2.

References:

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[4] R codes available here: https://github.com/tuanvnguyen/Bayesian-analysis/blob/main/Normal-Normal%20model

Constantine Manthous • Yale New Haven Health • 21 November 2020

Masks didn't work? Not so fast

In the November 18 issue of *Annals*, Bundgaard et al conclude: "The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers . . . (1)" Not so quick. Study subjects were not required to wear masks at home. Their family members/visitors were neither taxed to wear masks in public nor were they tested for asymptomatic Covid, which is often spread in homes (2). Accordingly, it is plausible, if not likely, that some study subjects caught Covid in their own homes. This critical design flaw prevents any conclusion about the efficacy of masks for preventing Covid; a nuance that will be lost on non-scientists. Nonetheless, the erroneous conclusion was immediately trumpeted, using the *imprimatur* of *Annals*, to challenge mask-wearing. The effect – albeit inadvertent – is almost to be greater morbidity and mortality.

PDF
Help

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Hadi Ali, MS , Gunce Kaya, MPhil [1], Khameinei Ali, MD, MBA [2][3] • [1] Ferkauf Graduate School of Psychology: Yeshiva University [2] Northwell Health [3] Zucker School of Medicine at Hofstra/ Northwell • 22 November 2020

Regarding "Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers"

We commend the authors of the study on broaching a much-debated subject in the current environment. The trial was designed to obtain the most power to detect a difference. Unfortunately, there were confounding variables that were unaccounted for and unmeasured.

There is a flaw in primary outcome ascertainment. False-negative rate and false positive rate of antibody testing, PCR, and diagnosis all vary widely. For example, sensitivity (IgM and IgG) of the antibody kit in this study (86.7% and 66.7%, respectively) is equivalent to a 64.6% PPV with a 5.0% prevalence [1]. This is even more pertinent in the low prevalence (1.2%) Danish population [2], [3].

Individuals who could not correctly perform the test were assumed negative, which would further skew the data. Additionally, the intention group attrition was higher than the control group (638 vs. 524). The characteristics of the study participants' households would heavily affect the data set as

well. If family or house members were COVID-19 positive, mask-wearing outside of their homes would not protect them from their highest risk source (their homes).

We contest that an intent-to-treat analysis is inappropriate, given the authors' own published intervention adherence rate (46%). Multiple imputation analysis is simply an amplification of the data set and agreement between the original data set is a moot point. The homogeneous Danish population would make it difficult to externally validate this to other much more heterogeneous populations (i.e. New York).

PDF

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It is questionable if the study is a true RCT as it lacked blinding and utilized a self-reporte measured primary outcome which opens it up to a majority of biases. Although the researchers cited their study for the equivalence of self-testing with healthcare professional testing, this may be inappropriate for research purposes and better suited for pandemic infection control [5].

Although the goal of the study was to publish the researchers' heard-earned data, contextualization in these volatile times is paramount. This study received 90,000 tweets by 60,000 users within 4 days of publication [4]. The majority of these tweets championed the study as evidence of the impotence of masks in the control of the COVID-19 pandemic. The authors of the study would agree that this is a gross misinterpretation of the research, which further points to the fact that the wording of the conclusion should have been chosen slightly more judiciously.

References:

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Disclosures:

No disclosure to claim.

Edward Siguel, MD, PhD • Self employed in biomedical research, MD, USA. • 23 November 2020

Thought experiments and science predict that facemasks reduce viral loads and reduce severity of infection

The study is misleading; it did not consider adequately too many critical variables (factors) that have major impact on measured outcomes. Thought experiments from science predict t' facemasks reduce viral loads and severity of infection.

PDF

Help

Statistics describe outcomes, but does not explain causes. It is impossible to conduct experiments on all possible observations and outcomes, and it is not necessary. We can use "thought experiments", which Einstein used to create Relativity. We had data on the movement of planets for over 100 years, but it took "thought" experiments for Newton to predict planetary movement via equations.

We understand enough about viruses to know the body produces and expels them, mostly via mouth and nose. We know an infected person can expel many viruses. A well-designed mask, and substantial obstruction, will reduce the number of virus expelled far into the air. A mask will absorb viruses. This is not "genius" physics. I knew about it since I was about 6 yo. My parents taught me to use a handkerchief, hold it to my nose, to prevent spreading "stuff" when I cough. It worked. There is no doubt that holding a paper towel or similar paper or cloth to the mouth reduces the amount of "stuff" going out when I cough.

To those who doubt it and need more "studies", I propose they put themselves in front of people coughing without covering their mouth. Although it may not infect them, the fluids they get in the face and mouth will provide evidence of how facemasks work.

Thus, a thought experiment and science provide probative evidence that facemasks can reduce the amount of "stuff" an infected person sends to the air. How much of a reduction depends on the nature of the facemask, how tight it is, how much it absorbs and retains fluid, etc. If everybody used facemasks in public places, viral loads in public places are reduced.

We do not need more studies of the obvious; we do not need a sample size of 1,000 people thrown out of 10th story windows to predict broken bones when they hit the concrete sidewalk. If a study of 10,000 people who took Vitamin EZY434 proved they fly like birds, I would not believe it because my thought experiment says it cannot be true.

Similarly, facemasks reduce particles absorbed from air. Known for years in construction, surgery, labs, etc.

Matthew A. Spinelli, David V. Glidden, Efstathios D. Gennatas, George W. Rutherford, Monica Gandhi • Departments of Medicine and Epidemiology, University of California, San Francisco • 20 November 2020

Cluster randomization and adherence assessment are needed to test masks' true potential

We read with interest the study evaluating mask mandates in Denmark by Bundgaard and colleagues.[1] We commend the authors for performing a randomized trial of a non-pharmaceutical intervention in the midst of the pandemic. However, the study makes it difficult to draw conclusions about the impact of masks in preventing incident infection or severe COVID-19. Although masks were provided and recommended to participants, masking was not commonplace in Denmark at the time, and 14% of participants reported experiencing so due to masking. Only 46% of participants reported wearing a mask as recommended, an overreporting of adherence, as has been seen in previous prevention studies for stigmatizing interventions,[2] likely occurred. Notably, due to the complexity of interpreting self-reported adherence, HIV and sexually-transmitted infection prevention trials are now designed to incorporate objective assessment of adherence.

PDF
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The study would have benefitted from inclusion of implementation science principles: understanding the desired behavior in its social context, cluster randomization, and assessment of intervention fidelity.[3] Recommending a potentially stigmatizing intervention in a minority of individuals within a community is, we believe, a major flaw in a study designed to evaluate a policy intervention. Cluster randomization would have allowed an entire community to be randomized to the recommendation, minimizing social harms to the individual and likely increasing intervention adherence. Assessment of intervention fidelity and acceptability, such as through direct observation within the community, would allow a more accurate interpretation of self-reported adherence data.

Use of cluster-randomization has other benefits. Masks are likely to be more effective in preventing forward transmission, in the context of high community uptake and adherence. By randomizing isolated members in the community to the mask recommendation, this study design cannot answer if "masks protect you."[4] Second, given the high proportion of asymptomatic COVID-19 infections, we do not know how many individuals were infected within their household bubbles. An optimal design would pursue a cluster-randomized approach, with sufficient power to detect incident (with PCR) rather than prevalent (with serology) infections, and assess disease severity via cataloging clinical outcomes (do masks lead to less severe infections via reduced inoculum?[5]). A mask recommendation for isolated members of a community is unlikely to be effective. We suggest that future studies assess the impact of recommendations to wear masks at the community-level, which will be more informative for public health officials trying to stem transmission and disease while awaiting an effective and widely available vaccine.

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PDF
Help

Michael Cook • Vis a vis symposiums • 22 November 2020

Authors state major limitations of study

The authors state the limitations of the study: Inconclusive results, missing data, variable adherence, patient-reported findings on home tests, no blinding, and no assessment of whether masks could decrease disease transmission from mask wearers to others. Asian countries have very low levels of COVID and for decades people wear mask if they think they have flu or a cold. The authors clearly state they could not assess this.

Simon Thompson • Independent researcher • 22 November 2020

This is extremely inadequate research to support forcing the entire world to wear masks

Before making any recomendations to wear masks adequate research would be needed but this hasn't occured. Whilst such measures are often described as a recommendation in the real world people are being forced to wear masks and in some countries quite agressively. This study finds no significant effects in relation to the alleged Sars-cov2 but does not look at the many other possible effects of wearing these. For example there has been a doubling in shootings in NY this year. Could the masks be contributing to this? What are the effects on overall health? What are the dangers of conditioning people to accept forced medication in violation of informed consent laws? Without having done any proper research to establish the long term effects it is incredibly reckless to be forcing masks on the entire world and this study shows how little is known about it. It is time to immediately end these impositions and any further experimentation on the public.

Max Longin • Dipl.Math., Denmark, private • 23 November 2020

This study design would not even proof that a 100% protection has a protective effect

Imagine a 100% perfect protection against COVID-19 (a hermetic room), what outcome should be expected for this by-definition safe group using this study design?

Here is the math only for estimating

- the false-positive antibody-tests

- positive test due to before-baseline infections

But as the study design grants protection at average only 4.5 hours/day further infections outside the room (in the study false-classified as noneffective protection) should be added to the calculated expectations.

PDF

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The study reports antibody testing has an estimated 99,2% specificity. For about 2400 tes leads to an expectation of 2400*0.008=19 false-positive tests in each antibody test group.

IgG-antibodies form very delayed and persist very long. So in non-increasing rate of new infections (as the case in 05/2020 in Denmark) about 80% of all true-positive IgG tests at study-end show infections before study-baseline. So the expectation of positive tests due to before-baseline infections in the control group is 10.4 (80% of 13 (=32-19) „true-positive“ IgG tests)

The mentioned false-detection arises solely by a test-property (specificity) and before-baseline events, so the expectations for the control group for false-positive test (19) and for true-positive tests due to before-baseline infections (10.4) equals the expectations for the safe group, adding up to: expectation(IgG-SafeGroup)=29.4

IgM-tests respond from >2-6 weeks after infection. So about 50% of the IgM true positive tests are likely due to before-baseline infections. Analogue to above 19 false positive and 9 positive IgM tests (50% of 18 (=37-19) „true-positive“ IgM tests) due to before-baseline infections sum up to: expectation(IgM-SafeGroup)=29

PCR-tests hardly suffer from specifity and time lags in the study, so no positive PCR-tests should be expected in the safe group: expectation(PCR-SafeGroup)=0

A temporally evenly distributed health care diagnosis during study will again suffer from the delay from infection to diagnosis (first 9 days (=30% of 30 days) diagnosis will likely show before-baseline infections). So 0,3*10=3 cases are likely due to before-baseline infections and have to be expected for the safe group as well: expectation(HealthCare-SafeGroup)=3

Even without additional expected infections at home, friends etc. - falsely assigned as inside the hermetic room the expected outcome in the by-definition safe group is already about 75% of the control outcome (or 90% of the face-mask-group).

Altogether this study design expects for a by-definition 100%-protection:

- measure an Odd Ratio of ≥0.75 (≤25% protection),

- include OR=1 (i.e. no-protection-at-all) in the 95%-Confidence Interval and

- exclude OR≤0.4 (≥60% protection) from 95%-CI

Elena Pezzolo 1, Simone Cazzaniga 1, Silvano Gallus 2, Luigi Naldi 1 • 1.Study Center of Italian Group for Epidemiological Research in Dermatology (GISED), Bergamo, Italy 2.Environmental Health Sciences Department, Istituto Ricerche Farmacologiche M.Negri, Milano, Italia • 26 November 2020

PDF

Help

Evidence from randomised controlled trials on the surgical masks' effect on t spread of respiratory infections in the community

Dear Editor:

In the Bundgaard et al. randomized controlled trial (RCT)[1], face mask use supplementing other public health measures did not significantly reduce SARS-CoV2 infection in people wearing the mask, albeit the results cannot exclude a 46% reduction or a 23% increase in infection among mask wearers. These findings seem to confirm the notion that recommendations on the public use of respiratory devices to prevent SARS-CoV-2 infection have low certainty evidence.[2]

Indirect supportive data can come from studies dealing with the protection offered by surgical masks in influenza-like illness (ILI). We conducted a systematic review and meta-analysis of RCTs (PROSPERO ID: CRD42020178913) on the use of surgical masks in the community as a mean to prevent the spreading of ILI. The population included students and households' members of any age and sex. The main outcome was the risk of ILI among mask users vs non-users. Eligible studies included RCTs published between January 1, 2005 and April 7, 2020 in English language. Two blinded reviewers independently screened the papers identified through a search strategy including umbrella and traditional reviews, based on PubMed/Medline and Embase libraries.[3]

Out of 422 papers, 11 RCTs assessed the role of wearing versus not wearing surgical masks on ILI prevention. Overall, the studies enrolled a total of 7469 subjects. The pooled random effect relative risk (RR) for face mask protection was 0·92 (95% CI:0·81-1·04), suggesting that wearing surgical masks in the community confer no significant protection against ILI in mask wearers. It should be noted that most studies in our meta-analysis were underpowered, and that 73% of them reported a poor adherence of participants to mask use. A sub-analysis of few high compliance studies showed a RR of 0·67, 95% CI:0·46-0·99.

Notably, the type of mask and the securing system may largely influence the filtering effectiveness of face masks, with surgical or procedural masks secured with elastic ear lobes showing the least filtration efficiency.[4]

At variance with observational studies, randomised trials have failed, up to now, to clearly document the utility of wearing masks to prevent SARS-CoV2 infection. A public health intervention promoting face mask use, is usually implemented at units larger than that of individuals. Hence, we suggest that a convenient study design would be a cluster randomised trial

assessing, in a factorial way, the impact of promoting the combination of different components of individual protection on the prevention of SARS-CoV2 spreading.

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PDF Help

ANTONIO C BANDEIRA • Director, Brazilian Society of Infectious Diseases • 25 November 2020

Multiple bias towards the Null

Any study to evaluate the effectiveness of wearing masks should be done with a very careful methodological approach in order to avoid multiple sources of error. We have learned so far that the risk of SARS-CoV-2 infection through the respiratory route is very high specially at home, at lunch and coffee-break times, where nobody uses any mask protection. In this randomized open trial, there was no control over these sources of infection. Besides, only 46% of participants wore the mask as recommended, a very low adherence level. With that in mind, I would expect the results to be biased towards no association between the use of masks and the risk of SARS-CoV-2 infection as the authors stated

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Wolfgang Uter, M.D. • Dept. of Medical Informatics, Biometry and Epidemiology, Friedrich-Alexander University Erlangen/Nürnberg, Germany • 29 November 2020

Another possible source of bias

Dear Editor:

Performing a large intervention study on the population level is surely a huge effort, and the authors must be applauded for setting out to assess the effectiveness of “medical” type face masks in addition to measures of social distancing in preventing SARS-CoV-2 infection. Thereby, they followed a conclusion from a recent meta-analysis on the topic, which had found a clear indication

of a protection from virus transmission by - particularly N95 or surgical quality - face masks, but noted considerable uncertainty of evidence [1].

The randomised controlled trial design chosen is undisputedly the gold standard method in clinical research addressing interventions. However, its application in a population setting instead of a relatively well-controlled, quasi experimental clinical setting is not without pitfalls, some of which have already been outlined by other scientific comments. Another particular confounding effect related to the intervention not being amenable to blinding, and also biasing the re towards “no effect”, is the possibility that participants in the intervention group may have their relevant behaviour once wearing masks, notwithstanding similar behaviour at base a change would most plausibly happen in terms of respecting less the fundamental rules of social distancing, feeling protected well enough by the face mask, thereby increasing infection risk.

PDF
Help

From a general perspective, the DANMASK-19 study results, independent from other issues likely biasing the results towards “no effect” as discussed in other comments, cannot quantify efficacy, i.e. the maximum possible effect of an intervention, but effectiveness, i.e., the intervention effect observed under “real life conditions”. Effectiveness is often (much) smaller than efficacy, owing to manifold interferences, perhaps including the confounding effect suggested above. As “real life conditions” largely mean the societal and historical context, the following conclusions can be drawn: (i) effectiveness as observed in the study cannot be easily generalised; (ii) efficacy of wearing adequate masks adequately is underestimated by the current results, to an unknown extent; (iii) contrary to clinical interventions, the (individually) randomised controlled trial cannot necessarily be regarded as gold standard to assess efficacy on the population level.

[1] Derek K Chu, Elie A Akl, Stephanie Duda, Karla Solo, Sally Yaacoub, Holger J Schünemann, COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet 2020 Jun 27;395(10242):1973-1987

Dr Joseph Hutchinson • St. George's Hospital, London • 29 November 2020

Data raise concerns about mask-wearing causing potentially harmful reductions in physical activity

Dear Editor,

This randomised control study by Bundgaard et al. did not find face-mask wearing to have a significant effect on SARS-COV2 infection. However, the data indicate a concerning decrease in levels of physical activity among the mask-wearing cohort, which the article does not explore.

The results of the tertiary end points published in the supplementary material suggest that levels of physical activity decreased in 40% of the mask-wearing cohort. This potential effect of mask

wearing is worthy of further study. Unfortunately, the decrease in physical activity reported in this trial cannot be compared to a control as the non-mask-wearing cohort were not asked about their level of exercise in the study period. Also, trial participants were not asked to quantify the change in their physical activity, which would indicate how much of a concern this decrease should raise.

The WHO Global Action Plan on Physical Activity 2018-2030 highlights physical inactivity as a major cost to health systems and society due to resultant ill health. If mask wearing results in reduced levels of physical exercise, and therefore worse physical health, this risk should be taken in account both by individuals and those responsible for health policy.

PDF

Help

Additionally, results regarding levels of sick leave and bacterial infection in the two groups have yet to be published. May I ask when the authors expect this information to become available?

Elena Pezzolo,1* Simone Cazzaniga,1* Silvano Gallus,2 Luigi Naldi,1 • 1.study Center of Italian Group for Epidemiological Research in Dermatology (GISED), Bergamo, Italy 2.Environmental Health Sciences Department, Istituto Ricerche Farmacologiche M.Negri, Milano, Italia • 26 November 2020

Evidence from randomized controlled trials on the surgical masks' effect on the spread of respiratory infections in the community

Dear Editor:

In the Bundgaard et al. randomized controlled trial (RCT)[1], face mask use supplementing other public health measures did not significantly reduce SARS-CoV2 infection in people wearing the mask, albeit the results cannot exclude a 46% reduction or a 23% increase in infection among mask wearers. These findings seem to confirm the notion that recommendations on the public use of respiratory devices to prevent SARS-CoV-2 infection have low certainty evidence.[2]

Indirect supportive data can come from studies dealing with the protection offered by surgical masks in influenza-like illness (ILI). We conducted a systematic review and meta-analysis of RCTs (PROSPERO ID: CRD42020178913) on the use of surgical masks in the community as a mean to prevent the spreading of ILI. The population included students and households' members of any age and sex. The main outcome was the risk of ILI among mask users vs non-users. Eligible studies included RCTs published between January 1, 2005 and April 7, 2020 in English language. Two blinded reviewers independently screened the papers identified through a search strategy including umbrella and traditional reviews, based on PubMed/Medline and Embase libraries.[3]

Out of 422 papers, 11 RCTs assessed the role of wearing versus not wearing surgical masks on ILI prevention. Overall, the studies enrolled a total of 7469 subjects. The pooled random effect relative risk (RR) for face mask protection was 0·92 (95% CI:0·81-1·04), suggesting that wearing surgical masks in the community confer no significant protection against ILI in mask wearers. It should be noted that most studies in our meta-analysis were underpowered, and that 73% of them reported

a poor adherence of participants to mask use. A sub-analysis of few high compliance studies showed a RR of 0·67, 95% CI:0·46-0·99.

Notably, the type of mask and the securing system may largely influence the filtering effectiveness of face masks, with surgical or procedural masks secured with elastic ear lobes showing the least filtration efficiency.[4]

At variance with observational studies, randomised trials have failed, up to now, to clearly document the utility of wearing masks to prevent SARS-CoV2 infection. A public health intervention promoting face mask use, is usually implemented at units larger than that of individuals. Hence, we suggest that a convenient study design would be a cluster randomised trial assessing, in a factorial way, the impact of promoting the combination of different components of individual protection on the prevention of SARS-CoV2 spreading.

PDF

Help

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Zhicheng Lin, PhD • McLean Hospital, Harvard Medical School • 2 December 2020

Maskless driving as high risk for catching coronavirus

To Editor

In the United States, the number of daily new cases with COVID-19 keeps breaking global records. After seven months of preventive measures mandated and practiced, this wrong direction should be introspecting.

PDF

Help

COVID-19 is caused by infection with the coronavirus SARS-CoV-2 and spreading mainly v… airborne transmission so that wearing face masks is the most effective prevention measu… public(1). However, Bundgaard et al reported a marginal and inclusive mask-based preve… from outdoor infection based on their randomized controlled trial(2). That study didn't consider stratified outdoor time because the outdoor activity could be situational in terms of coronavirus transmission, such as gathering and driving.

Currently in the States, there is no curfew or strict lockdown. By contrast, many working places remain active at reduced density and automobiles are running all over the streets and highways day and night. Of people with face masks, approximately a half don't wear their masks correctly in the public and most people inside their cars don't wear masks at all.

It is safe to stay inside the car, however, can be a misperception regarding SARS-CoV-2. People usually feel safe when getting into their cars so that they take off the masks immediately once inside the cars. Automobiles are equipped with cabin air filters which are designed to keep air pollutants such as dust and pollen out of the passenger compartment. However, these filters can trap particles only as small as 0.3~0.5 microns, with a filtration efficiency of 50–90% where the filtration effectiveness decreases with decreasing particle size.(3) Therefore, these cabin filters are not designed to filter out the coronavirus whose average size is 0.1 microns (with a range of 0.06~0.14 micron) so that inside the car is not coronavirus-proof.

Inadequate and insufficient mearing of face masks(4) may partly explain the current surges in daily new cases. In the peaking times of this pandemic, when one drives a car with air ventilated from outside, the risk of airborne transmission can be increased with the speed of the vehicle. SARS-CoV-2 in aerosols (with sizes similar to the coronavirus) remains infectious for hours(5) so that 10-20 fold-accelerated exposure to the public air is a high risk but was neglected by the randomized trial.

"The goal of reliably filtering coronavirus from a vehicle cabin has myriad challenges," as clarified and warned by the Society of Automotive Engineers International (https://www.sae.org/news/2020/03/coronavirus-cabin-air-filtration). Maskless driving can be searching for SARS-CoV-2.

Conflict of interest: None to declare.

Funding: None.

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Disclosures:

None to declare.

David Bardenstein • Ret • 2 December 2020

Paper may suggest that masks may indeed be effective.

Did not the article report that a much larger number of mask wearing subjects had Covid 19 in their households? If so, a significantly higher rate of Covid 19 infection would have been expected given the known household transmission. Yet Covid infection despite all the other uncertainties in the protocols, was less in the masked group.

The failure of the study to have mask wearers not be “taxed” with wearing masks at home , even if there was known Covid 19 present raises scientific, public health and ethical questions. On that basis it may be due for retraction. The imprecision due to multiple uncontrolled factors similarly makes it a study, however well intentioned, that should have been rejected as it is inconclusive and does not clearly guide the path for how a useful one might be done.

Pedro M Teixeira • School of Medicine, University of Minho • 3 December 2020

Yet another case of trial external validity demolished by incongruous intervention features.

Dear Editor,

This trial resembles in many aspects the 'Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial' published in 2018 by Robert W Yeh. (1) Both present non-statistically significant results on major outcomes. They both fail to reject the null hypothesis that state that there is no effect in using a parachute when jumping from aircraft to prevent death or major trauma (1) and there is no effect in reducing respiratory infections when using facial masks in the community (2). In Yeh's study, the aircraft was on the ground and in Bundgaard's trial, people in the community do not vastly wear facial masks, only participants in the experimental group do. SARS-CoV-2 transmission may occur by mouth, nose or eye expos
Participants in the experimental group when in close contact with other people, that do
contain air droplets by using facial masks, were exposed to similar risk of eye SARS-CoV-2 infection as the control group. If the plane was on the ground, participants from the experimental group faced the same risk as the control group. Without widespread facial mask use in the community, the protective nature of facial masks (i.e. droplets containment) remains severely compromised in close encounters. Such performance bias pose serious constrains and challenges in effectiveness trial studies design and may induce error in result interpretation and decision making in health interventions. (4) The critical appraisal of the intervention features in real life settings is warranted.

PDF
Help

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Henning Bundgaard, DMSc, MD, Kasper Iverson, MD • Copenhagen University • 4 December 2020

Authors' Response to comments

Authors Henning Bundgaard and Kasper Iversen's response to Tuan Nguyen

Thanks for this interesting analysis. It should be noted that the meta-analysis was not related to SARS-CoV-2, which might be a limitation. Also, our pre-defined statistical analysis plan did not include the Bayesian approach.

Authors Henning Bundgaard and Kasper Iversen's response to Constantine Manthous

Thank you for your comment. The study participants were not instructed to wear masks at home as this is not part of the authorities Public Health Recommendations. In the paper we accounted for reported diagnosed COVID-19 in the household, but of course – asymptomatic household members might have been missed. We consider that masking at home would not be realistic, so this potential limitation is after all just another reflection of the real-world setting of the trial.

PDF

Help

Authors Henning Bundgaard and Kasper Iversen's response to Hadi Ali, Gunce Kaya and Khameinei Ali

Thank you very much for these comments. We have been as open and clear in our reporting. We agree that randomized clinical trials (RCTs) may suffer from many limitations or biases, but still RCTs are the most widely used design to obtain clinical documentation. For the same reason, more than one trial is often requested before firm recommendations are made. This relates to circumventing some of the potential biases in one study and to ensure external validation. On this basis we most certainly hope that others are perming new trials to expand our knowledge and build a stronger foundation for future recommendations. In the paper we really tried our very best to be as judicious as possible in the conclusion.

Authors Henning Bundgaard and Kasper Iversen's response to Edward Siguel

Thank you for your interesting comments. Testing a hypothesis is the backbone of science, and although a hypothesis might be considered common sense, we still need to conduct the proper studies under the right circumstances to accept or reject a hypothesis. Here the focus is source control, i.e. whether the wearer of the face mask is protected from getting infected.

Authors Henning Bundgaard and Kasper Iversen's response Matthew A. Spinelli, David V. Glidden, Efstathios D. Gennatas, George W. Rutherford and Monica Gandhi

Thanks for these interesting comments. We agree that cluster randomization might be a good alternative to RCT's. However, in practical terms it might be difficult to perform a face mask trial clustering; will all – or just most – citizens in the towns randomized to wear masks accept to do so? – will all – or just most – citizens in the town randomized not the wear a mask accept to do so? – there are several ethical concerns. Furthermore, as SARS-CoV-2 spreads in clusters and the number of clusters should therefore be very large to ensure a nonbiased result – making a cluster study even more difficult. We instructed the participants in correct use of the masks, we provided high quality masks, delivered at home, free of charge and we assessed compliance through the email surveys 4 times during the study, and the worst reported compliance was in the analyses. Our take

is that compliance was very high – and most likely higher than what is seen during every-day use of face masks.

Authors Henning Bundgaard and Kasper Iversen's response to Michael Cook

In our study we assessed if masks offer a protective effect to uninfected wearers - and not if masks reduced the transmission of SARS-CoV-2 from infected mask wearers out into the comm

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Authors Henning Bundgaard and Kasper Iversen's response to Simon Thompson

Thank you for these comments. Our contribution was to provide research data on efficiency of face masks. Authorities have to include all other data and other aspects as referred to into consideration when developing the guidelines for the citizens.

Authors Henning Bundgaard and Kasper Iversen's response to Max Longin

Thank you for these comments. The participants in the mask group were recommended to wear masks when outside the home. At entry – and at end of study IgG and IgM were determined, and only participants reporting not to have or have had COVID-19 were eligible. IgG and/or IgM positive participants at baseline were excluded from the analyses. The primary outcome was a composite outcome of antibody test results, PCR and diagnosed COVID-19 in the healthcare system. COVID-19 diagnosed household members were accounted for. However, asymptomatic household members were not accounted for. The issue of before entry infection and just before end-of-study infection is true for both groups.

Authors Henning Bundgaard and Kasper Iversen's response to Janet Rand

Thank you for your comments. Our study demonstrate that "the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use." As you also mention, our study also highlight that "the findings, however, should not be used to conclude that a recommendation for everyone to wear masks in the community would not be effective in reducing SARS-CoV-2 infections, because the trial did not test the role of masks in source control of SARS-CoV-2 infection."

Despite these statements, we cannot control how our study is being interpreted.

Authors Henning Bundgaard and Kasper Iversen's response to Dr Rosamond A K Jones

Thank you for your comments. Our aim was to provide scientific documentation for the efficiency of face masks for the wearer. We agree that masking may have a number of side effects – including psychological side effects – also in children. However, we have not assessed the psychological aspects of wearing face masks and further studies are needed to address this.

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Authors Henning Bundgaard and Kasper Iversen's response to Brenda Marfin

Thank you for your comments. We are sorry to hear about your and your husbands' situation. Our study finding is one part of the puzzle for understanding the effects of mask. We have been very clear that we studied the efficiency of masks protection for the wearer – not the effects of face masks when used by an infected individual (source control). We have made an effort to communicate the results in an objective manner and to emphasize the limitations of the study in order to accommodate the considerations you also raise. We cannot control how our study is being interpreted by individuals.

Authors Henning Bundgaard and Kasper Iversen's response to Ambuj Kumar

Thank you for the comments. Our aim was to provide scientific documentation for the protective efficiency of face masks for the wearer in addition to other protective means. The efficiency was not assessed as a dichotomous outcome – except an expected lowest outcome had to be applied in the power calculation.

Authors Henning Bundgaard and Kasper Iversen's response to Eric Thompson

Our study finding is one part of the puzzle for understanding the effects of mask. Formulation of policy recommendations should take into account all the research and knowledge available, and we leave this to the policy makers.

Authors Henning Bundgaard and Kasper Iversen's response to El Rowan

Testing adherence to recommendations in a community-based, randomized controlled trial such as this is difficult, as the real-life setting does not allow individual control. The question of true adherence will always be a question unanswered in a community-based randomized trial where the participant is the active part in carrying out the intervention – whether it be wearing a mask, taken their medicine as recommended, doing their exercise etc. - and it will in the end always depend on the honesty and self-reflection of the participant. Like in most drug trials we rely on the

fact that the volunteer participation motivates honest answers. But yes, we – and others - cannot be sure.

Authors Henning Bundgaard and Kasper Iversen's response to Hans Gaines

Thank you for your comments. Our study investigated the "effectiveness of adding a mask recommendation to other public health measures to prevent SARS-CoV-2 infection". We a participants might have been infected at home from asymptomatic members of their ho The participants were only asked to wear masks when outside the home. We consider that this reflects the generally used recommendations as it is hard to imaging a recommendation to wear masks at home.

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Authors Henning Bundgaard and Kasper Iversen's response to Eemil Zhang

Thank you for your input. The Lammers, Crusuis, Gast 2020 paper you refer to discuss that the perception of the spread – whether linear or exponentially biased – will affect the way people act on the recommendations. However, the SARS-CoV-2 infection rate was not growing exponentially in Denmark during the study period. Moreover, if the question is whether people perceive it as exponentially growth - and thus would change their behavior thereafter - this perception would be expected to be similar between the groups.

Authors Henning Bundgaard and Kasper Iversen's response to Brendan Moran

Thanks for your comments. We agree, the "lag" relating to infection late during the trial and time to seroconversion was to some extent captured by the PCR. In our sample size calculation, we applied a power of 80% with an assumed infection rate of 2% in the control group. The power was ensured as the infection rate was 2.1% in the control group, and the number of participants who finalized the study was as little higher as compared to the number needed to include according to the sample size calculation.

Carl Llor • Primary care physician and senior researcher. University Institute in Primary Care Research Jordi Gol, Via Roma Health Centre, Barcelona. • 6 December 2020

External validity of these results to hard-hit areas.

Dear Editor,

Bundgaard et al. showed in their randomized controlled trial [1] that face mask use supplementing other public health strategies did not significantly reduce SARS-CoV2 infection in people wearing the mask. Apart from the limitations of the study mentioned by the authors themselves, mainly the low face mask wear adherence and the lack of assessment of whether masks could decrease disease transmission from mask wearers to others, there are other variables that can make generalization of these results difficult. The randomized controlled trial design is irrefutably the best method in clinical research addressing interventions and we have to applaud the authors for conducting such a great trial in a short period of time, but this trial was conducted in a co with a low-moderate incidence of COVID-19 and during lockdown (April and May 2020).

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People in many areas of the world are less likely to avoid public places and stay home than residents of Denmark. Social distancing could qualify as an oxymoron in Southern Europe, South America, the United States and citizens of many other crowded parts of the world, where walking arm-in-arm with friends, eating out in crowded restaurants and terraces, or kissing relatives, neighbors and friends are part of their cultures. There is now solid evidence that individuals in poor health are more susceptible to serious illnesses [2]. In Southern Europe, for example, low-paid employees are less likely to do their jobs from home and taking public transport to crowded workplaces might lead to more contagions, as are families pushed into housing with insufficient space.

The “real life conditions” in many areas in the world are quite different from Denmark. We should ask if this modest protection of face mask wearers from infection with SARS-Cov-2 in this country would have been the same if this trial had been conducted in crowded areas with no curfew. We agree with the authors that more well-conducted studies are needed before drawing a conclusion like this.

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Suliman Ahmad, Zoe Gan • Faculty of Life Sciences & Medicine, King's College London, London, UK • 6 December 2020

Comment on: Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers

To The Editor,

The authors are to be commended for their contributions regarding the efficacy of face masks in mitigating the risk of transmission of SARS-CoV-2 infection (1). However, these findings should be interpreted with caution due to a number of confounding variables that were not accounted for in the study design.

Firstly, the instruction guide provided on how to wear a mask were extremely brief. It was advised that participants “place the mask over the nose and under the chin” and to “remember hand hygiene when using the mask” but no guidance was offered regarding appropriate use of the mask while it was worn, nor safe disposal of the mask when it was no longer needed. Self-contamination by touching the mask with contaminated hands after it has been donned, face masks with others and reusing masks is recognised as a potential risk of SARS-CoV-2 transmission (2). Detailed and explicit instructions should have therefore been given on safe and appropriate usage of medical masks.

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Furthermore, it was recommended that masks should be changed every eight hours. This eight-hourly time frame was based on World Health Organisation (WHO) guidance at the time of the trial (April-May 2020) according to the authors. However, to our knowledge, WHO recommendations at this time were that a medical mask should be replaced every six hours, or when damp or soiled (2,3). Therefore it would have been prudent to issue guidance to participants on replacing a mask within this time frame or when wet, soiled or damaged, as extended use of a mask may risk contamination with the SARS-CoV-2 virus.

In addition, adherence to mask-wearing was not only poor but poorly assessed. Only 46% of participants wore the mask as recommended, as measured through a single question (“are you using the mask according to our recommendation?”) on a weekly survey. The subjective nature of such an approach lends itself to self-reporting bias due to differences between individuals in perceiving how well they followed recommendations (4). This could have been mitigated through further questioning on the survey to more objectively estimate compliance, such as enquiring about the duration and frequency of use (5).

In summary, we believe that the conclusions drawn by this study are weak due to omissions in the study design and the potential benefits of mask-wearing as protection against SARS-CoV-2 may therefore have been missed.

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Conflict of interest: None to declare

Greg Taylor • Avrea Radiologist • 6 December 2020

Mask effect with low prevalence

Perhaps your article can be interpreted as saying that at a time with low prevalence, especially compared with the current daily rates, mask wearing confers at best minimal benefit. Here in South Dakota, other than factory transmission by a symptomatic worker, we had virtually no spread of Covid this spring and summer, I saw a few abnormal Covid chest xrays per month. Now we are at the breaking point, I see several abnormal Covid chest xrays per day.

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Help

Dr. SJM • ACP • 9 December 2020

No future trials are needed!

I respectfully disagree with Dr. Bundgaard that additional trials are needed to help answer the question of protective benefit masks in COVID-19. We had 12 RCTs (1) from influenza and other respiratory viruses that showed us there was no added benefit from mask use. Despite this compelling evidence, we believed that the situation was different with SARS-2 in the presymptomatic phase. With the DANMASK 19, powered with 6000 individuals, it is consistent with all previous trials of mask benefit that the effects are negligible. We need to show integrity in mandating masks when the evidence CLEARLY does not support such a measure. Neither has there been any additional benefit in countries that have been more adherent to masks. The only evidence based conclusions we can recommend to the public are to avoid crowds and to enhance hand hygiene. Nothing more!

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Alberto Donzelli • Scientific Committee of Foundation “Allineare Sanità e Salute” – Milan - Italy. • 14 December 2020

The effectiveness of mask recommendation (mainly outdoors) is questionable, for overlooked reasons

The DANMASK-19 (1) conclude: “The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers… The difference was not statistically significant, the 95% CIs are compatible with a 46% reduction to a 23% increase in infection.”

Two editorialists (2) state: “Across all analyses odds ratios were approximately 0.8, consistent with a 20% reduction in incident SARS-CoV-2 infection if masks are recommended. The sample size was insufficient to determine the statistical significance of a 20% reduction”. However, 52 participants in the mask group and 39 control participants reported COVID-19 in their household, that might be considered as randomized clusters. Assuming the same (or proportional) numbers of Covid-19 and

similar households' denominators, summing the Sars-CoV-2 infections of each group with the COVID-19 of its households, the mask group plus households experienced more infections/diseases than the control group plus households. Moreover, 40% of face mask group reduced physical activity (1).

The criticism that "the antibody-positive results in both intervention and control groups could have been false positives" (2), biasing the findings towards the null, does not apply to the reported households' COVID-19.

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Help

The criticism that "only 46% of those in the intervention group reported adherence" (2) ex instructed, weakens the editorialists' thesis indeed, because infection, the primary outcome, occurred in 2.0% of "adherents", further approaching the control group's 2.1%.

The editorialists point that the intervention group females had less infections (odds ratio, 0.65; 0.38-1.12 [please note: males 1.12; 0.59-2.12]), because women "may be more likely to adhere" (2). Inconsistently, their citation (3) shows that women indeed are more compliant than men with each of ten restraining measures, and significantly so in three, including handwashing and distancing, but *not* with wearing face masks.

The mechanistic evidence that masks reduce wearer exposure and block his/her respiratory droplets implies specularly that microorganisms eventually multiplying in the infected persons' airways are in turn blocked at each exhalation and partially re-inhaled, increasing the cumulative viral load and the infection, and contagiousness (4). This overlooked mechanism works in the opposite direction to the protective one: only well-designed trials can establish which net effect prevails at the community level. In the Hajj pilgrims trial (5) the net effect outdoors shifted towards an excess of respiratory infections in mask wearers (and perhaps in pilgrims sharing tents with others in the mask group). Wearing masks long and everywhere is not evidence-based.

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Disclosures:

There are no conflicts of interest to disclose.

Magnus Glindvad Ahlström, Frederik Boëtius Hertz, and Kristian Schønning • Department of Clinical Microbiology 9301, Rigshospitalet, Henrik Harpestrengs Vej 4A, Copenhagen, Denmark • 15 Decembe

PDF

Help

To mask or not – diagnostics matter.

Bundgaard *et al*. present data from a randomized controlled trial (DANMASK-19) to assess whether face mask use outside home reduces risk for SARS-CoV-2 infection (1). Infection was assessed by antibody testing, PCR testing, and healthcare diagnosis. Infection occurred in 42 participants recommended mask wearing (1.8%), and 53 control participants (2.1%). 75/95 (79%) infections were diagnosed by seroconversion. Participants tested themselves for antibodies at baseline and end of intervention using a lateral flow assay.

Antibodies to SARS-CoV-2 develop in symptomatic individuals in the second week after symptom onset and occur later in less severe infections (2, 3). The incubation period is 4-6 days (4). The purpose of mask intervention is to limit exposure to SARS-CoV-2. Yet, seroconversions in the two first weeks of the intervention period may be attributed to SARS-CoV-2 exposures before intervention. The study was conducted in a period of lockdown in Denmark. In the week preceding the first intervention period, 1504 SARS-CoV-2+ cases were identified in 13,940 PCR tests (positive rate: 10.8%); in the last week of the second intervention period 306 cases were identified in 67,773 PCR tests (positive rate: 0.5%). Therefore, a burn-in intervention period before baseline serological testing would have been appropriate.

Seroconversion occurred in 1.5% (75/4862) of participants. Seroconversions were rare and warranted confirmation by secondary testing. The authors validated the test used and found a specificity of 99.5% (CI: 98.7-99.9). This validation was done by skilled laboratory personnel using plasma samples laboratory personnel (5). In DANMASK-19, testing was done by the participants themselves using whole blood specimens. If test specificity is the same under these conditions is doubtful.

Twenty incident SARS-CoV-2 infections were diagnosed by PCR testing in a healthcare setting (n=15) or at the end of the intervention (n=5). PCR tests are specific and often use multiple SARS-CoV-2 targets (1; Part 6 of the Supplement) simulating confirmatory testing. Lag time between infectious exposure and positive PCR is only 4-5 days, which reduces need for a burn-in period. There were 5 cases in the intervention group and 15 cases in the control group diagnosed by PCR (OR: 0.34; 95%CI: 0.10-0.99). If analysis is restricted to securely ascertained infections, the effect of face masks was both clinically and statistically significant. In the prespecified analysis reported in

the study, this effect may be obscured by virus exposures occurring before intervention and inappropriateness of the serological diagnostic strategy applied.

Diagnostics matter also in randomized clinical trials.

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1. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al. Effectiveness of addi recommendation to other public health measures to prevent SARS-CoV-2 infectio Danish mask wearers. Ann Intern Med. 2020; 18:M20-6817. [PMID: 33205991] doi: 10.7326/M20-6817
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PDF

Help

Max Longin • Mathematician in Denmark • 15 December 2020

This study design would not even proof that a 100% protection has a protective effect

Imagine a 100% perfect protection against COVID-19 (a hermetic room), what outcome should be expected for this by-definition safe group using this study design?

Here is the math only for estimating

- the false-positive antibody-tests

- positive test due to before-baseline infections

But as the study design grants protection at average only 4.5 hours/day infections outside the room should be added to the calculated expectations (in the study false-classified as noneffective

protection).

The study reports antibody testing has an estimated 99,2% specificity. For about 2400 tests this leads to an expectation of 2400*0.008=19 false-positive tests in each antibody test group.

IgG-antibodies form very delayed. So in non-increasing rate of new infections (as the case in 05/2020 in Denmark) about 80% of all true-positive IgG tests at study-end show infections before study-baseline. So the expectation of positive tests due to before-baseline infections in th… group is 10.4 (80% of 13 (=32-19) „true-positive“ IgG tests)

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The mentioned false-detection arises solely to from a test-property (specificity) and befor… baseline events, so the expectations for the control group for false-positive test (19) and for true-positive tests due to before-baseline infections (10.4) equals the expectations for the safe group, adding up to: expectation(IgG-SafeGroup)=29.4

IgM responds from >2-6 weeks after infection. So about 50% of the IgM true positive tests are likely due to before-baseline infections. Analogue to above 19 false positive and 9 positive IgM tests (50% of 18 (=37-19) „true-positive“ IgM tests) due to before-baseline infections sum up to: expectation(IgM-SafeGroup)=29

PCR-tests hardly suffer from specifity and time lags in the study, so no positive PCR-tests should be expected in the safe group: expectation(PCR-SafeGroup)=0

A temporally evenly distributed health care diagnosis during study will again suffer from the delay from infection to diagnosis (first 9 days (=30% of 30 days) diagnosis will likely show before-baseline infections). So 0,3*10=3 cases are likely due to before-baseline infections and have to be expected for the safe group as well: expectation(HealthCare-SafeGroup)=3

Even without additional expected infections at home, friends etc. - falsely assigned as inside the hermetic room the expected outcome in the by-definition safe group is already about 75% of the control outcome (or 90% of the face-mask-group).

Altogether this study design expects for a by-definition 100%-protection:

- measure an Odd Ratio of ≥0.75 (≤25% protection),

- include OR=1 (i.e. no-protection-at-all) in the 95%-Confidence Interval and

- exclude OR≤0.4 (≥60% protection) from 95%-CI

Jun Xu • **none** • **25 December 2020**

Masks Work

Dear Editor,

I agree with the DANMASK-19 findings that common masks provide small protection for the wearers. But how much protection for the people around the wearers?

To get a full picture of the masks' protective effect, an ideal trial should separate the mask group from the non-mask group. **If a trial mixes two groups together, their infection rates wi… distorted.** In other words, the non-mask group's infection rate will be underestimated be… non-maskers are benefitting from the mask group's source control, while the mask group's will be overestimated because the maskers are suffering from the non-mask group's spreads.

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A German study [1] estimates that the effects of mandating face mask use in public would reduce the growth rates of infections by 40% to 60%. This is a clear picture of the impact of a face mask mandate on infections because the mask and non-mask groups in the study didn't affect each other.

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1. Mitze T., Kosfeld R., Rode J., Wälde K. Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Method Approach. IZA – Institute of Labor Economics (Germany);2020.ISSN: 2365-9793, DP No. 13319.

Magnus Glindvad Ahlström, Frederik Boëtius Hertz, and Kristian Schønning • Department of Clinical Microbiology 9301, Rigshospitalet, Henrik Harpestrengs Vej 4A, Copenhagen, Denmark • 15 December 2020

To mask or not – diagnostics matter.

Bundgaard *et al.* present data from a randomized controlled trial (DANMASK-19) to assess whether face mask use outside home reduces risk for SARS-CoV-2 infection (1). Infection was assessed by antibody testing, PCR testing, and healthcare diagnosis. Infection occurred in 42 participants recommended mask wearing (1.8%), and 53 control participants (2.1%). 75/95 (79%) infections were diagnosed by seroconversion. Participants tested themselves for antibodies at baseline and end of intervention using a lateral flow assay.

Antibodies to SARS-CoV-2 develop in symptomatic individuals in the second week after symptom onset and occur later in less severe infections (2, 3). The incubation period is 4-6 days (4). The purpose of mask intervention is to limit exposure to SARS-CoV-2. Yet, seroconversions in the two first weeks of the intervention period may be attributed to SARS-CoV-2 exposures before intervention. The study was conducted in a period of lockdown in Denmark. In the week preceding the first intervention period, 1504 SARS-CoV-2+ cases were identified in 13,940 PCR tests (positive rate: 10.8%); in the last week of the second intervention period 306 cases were identified in 67,773

PCR tests (positive rate: 0.5%). Therefore, a burn-in intervention period before baseline serological testing would have been appropriate.

Seroconversion occurred in 1.5% (75/4862) of participants. Seroconversions were rare and warranted confirmation by secondary testing. The authors validated the test used and found a specificity of 99.5% (CI: 98.7-99.9). This validation was done by skilled laboratory personnel using plasma samples laboratory personnel (5). In DANMASK-19, testing was done by the participants themselves using whole blood specimens. If test specificity is the same under these conditions is doubtful.

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Diagnostics matter also in randomized clinical trials.

References

1. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al. Effectiveness of adding a mask recommendation to other public health measures to prevent SARS-CoV-2 infection in Danish mask wearers. Ann Intern Med. 2020; 18:M20-6817. [PMID: 33205991] doi: 10.7326/M20-6817
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Jiahe Chen, MS, PhDc, Hanke Zhang, MS, PhDc, Nadine K. Zawadzki, MPH, PhDc, Joel W. Hay, PhD, Cynthia L. Gong, PharmD, PhD • Schaeffer Center for Health Economics and Policy; Fetal & Neonatal Institute, Division of Neonatology, Children's Hospital Los Angeles, University of Southern California, Los Angeles, CA • 17 December 2020

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Universal mask mandates are not supported by the evidence

The COVID-19 pandemic has led to near-universal adoption of non-pharmaceutical interv policies in the United States, including masking in public places. Recently, Bundgaard et al [1] reported they did not find a significant protective effect of wearing surgical face masks in their randomized control trial (RCT). This result is consistent with our review of Chu et al's meta-analysis [2] reviewing the ability of masking to reduce coronavirus transmission, in which the included studies were mostly limited by their quasi-experimental study designs and narrow healthcare-based settings.

E-values can be used to quantify the extent to which unmeasured confounding can nullify the observed results.[3] We calculated E-values for the outcomes in Bundgaard et al's study, finding an E-value (confidence limit) of 1.74 (1) for the primary composite end point of antibodies against SARS-CoV-2 (OR=0.82, 95% CI 0.54-1.23). For presence of IgM (OR=0.87, 95% CI = 0.54-1.41) and IgG (OR=1.07, 95% CI = 0.66-1.75), the E-value (confidence limit) was 1.56 (1) and 1.34 (1) respectively. Finally, the outcome of healthcare-diagnosed SARS-CoV-2 (OR=0.52, 95% CI = 0.18-1.53) had an E-value (confidence limit) of 3.25 (1). These low E-values indicate that unobserved activities like vigilant handwashing could easily explain the findings in this study.

Although Bundgaard et al acknowledge their study's limitations including missing data, variable adherence and absence of blinding, it is more applicable to real-world settings during the pandemic than the observational studies in Chu et al's meta-analysis, considering Bundgaard et al used an RCT study design and focused specifically on reducing COVID-19 transmission under non-healthcare community settings. In fact, that only 7% of mask-wearers reported non-adherence appears low, considering that 100% adherence was defined as properly covering the nose and mouth and changing the mask if worn for >8 hours. In addition, participants received three-layer disposable surgical face masks, which is inconsistent with policies mandating that any cloth covering should be used. At best, the Bundgaard et al's findings provide negative or insignificant support for public mask-wearing policies. Nonetheless, the authors should be commended for their efforts to conduct a real-world RCT on a politically charged topic.

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Danish mask wearers: a randomized controlled trial. Ann Intern Med. 2020 Nov 18. doi: 10.7326/M20-6817.

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Help

Henning Bundgaard, Anna K Ringgaard, Daniel Emil Tadeusz Raaschou-Pedersen, Johan Skov Bundga

Kasper K Iversen • University of Copenhagen • 9 June 2021

Authors' Response to Moran, Spinelli, Gains, Llor, Rand.

We thank readers for the many interesting comments and address some of them here. We agree with **Brendan Moran**, that the “lag” relating to infection late during the trial and time to seroconversion was to some extent captured by PCR tests. In our sample size calculation, we applied a power of 80% with an assumed infection rate of 2% in the control group. The power was ensured as the infection rate was 2.1% in the control group, and the number of participants who finalized the study was as little higher as compared to the number needed to include according to the sample size calculation. We agree with the interesting point made by **Matthew A. Spinelli, David V. Glidden, Efstathios D. Gennatas, George W. Rutherford and Monica Gandhi** that cluster randomization might be a good alternative to our randomization approach. However, in practical terms it might be difficult to perform such cluster randomization; will all – or just most – citizens in the towns randomized to wear masks accept to do so? – will all – or just most – citizens in the town randomized not the wear a mask accept to do so? – there are several ethical concerns. Furthermore, as SARS-CoV-2 spreads in clusters, and the number of randomized clusters should therefore be very large to ensure a nonbiased result – making such a study logistically difficult to implement. We instructed the participants in correct use of the masks, we provided high quality masks, delivered at home, free of charge and we assessed compliance through the email surveys 4 times during the study, and the worst reported compliance was accounted for in analyses. Our take is that compliance was very high – and most likely higher than what is seen during every-day use of face masks.

Hans Gaines may be right that participants might have been infected at home from asymptomatic, i.e. un-diagnosed members of their household. The participants were only asked to wear masks when outside the home consistent with public health recommendations on use of masks -- as it is hard to imagine a recommendation to wear masks at home. We also agree with **Carl Llor** that the circumstances have changed since April-May when we conducted our study. We do not believe that the cultural and social behavior in Denmark is so different from other countries, but we agree that habits like kissing and hugging relatives, neighbors and friends are different in different cultures – and such habits might represent a risk for SARS-CoV-2 transmission. We agree that the question of the effectiveness of masks in crowded places and when in proximity to others

is important – and was not addressed in our study. We tested the effect of adding the masks to the general recommendations including the recommendation to keep a social distance of 1-2 meters - even in crowded places. However, we agree – we need more studies to assess the efficacy of masking in different settings. We would like to highlight in response the comment by **Janet Rand** that our study demonstrated that "the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use" and that "the findings, however, should not be used to co… that a recommendation for everyone to wear masks in the community would not be effe… reducing SARS-CoV-2 infections, because the trial did not test the role of masks in source control of SARS-CoV-2 infection." Despite these statements in our paper, some have misinterpreted our results and unfortunately, made conclusions to questions that were not addressed by our study.

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ong valcot • Retired • 12 September 2021

Infection rate mored than order of magnitude too high

When the study was conducted in 30 day period in Denmark about 4,300 people got infected which is about 0.07% of population but the study registerd about 2% infection rate in the 30 day period. The discrepancy by factor of 28 is way too high. Denmark could not have 28 higher infection prevalence than the offcial rate. The multiplier of 28x would imply that by the end of 2020 all adults in Denmark would be infected.

Since the majority of infections in the study were determined by the self-administered antibody tests one must conclude that there was much higher rate of false positives than what the manufacturer of tests claimed.

For this reason the study has a fatal flaw and its conclusiosn should be dismissed. The study does not have anything interesting or valid to tell us about the efficacy of masks.

Brian P Hanley • Butterfly Sciences, Scientist • 4 February 2022

Other confounding factors

1. PPE problems occur among MS-PhD-DVM's that may handle select agents which occasionally kill, getting investigators into MMWR. Hence, we have regular safety training and officers (RO's) tasked to ensure PPE is properly fitted and worn. (In practice, cookies are involved to ease the pain of staff attendance.) Observing public mask use notes partial compliance styles invisible in one 46% number. A. Wide gaps mask. B. Under-nose mask. C. Chin mask. D. Not a mask.

2. Tyranny of R_0 encourages incorrect infectious disease thinking. Reality is not that someone sick transmits to 1, 2, maybe 3 people. Super-spreaders drive pandemics, infecting tens or hundreds of people (Lloyd-Smith 2005). From whom should we expect masking conformance? Not superspreaders, who, in or out of the treatment arm, will drive outsize effects from low non-compliance levels.
3. My physician reports indicate ~50% of 2020 ER SARS-CoV-2 cases arrived for other reasons with CXR Dx pneumonia. O2<90% (lowest conscious patient <50%) is a basic triage diagnostic for SARS-CoV-2. What does this mean for masking? The O2 compromis tachypneic do not tolerate masks well. Thus, we should expect those shedding vir least likely to tolerate a mask – ergo, they will be in that 54% non-compliance. This catch-22 of the SARS-CoV-2 pandemic should be addressed directly in our discussions of control.
4. Degree of morbidity, and ultimately death rate, matters for populations. Masks lower the infecting dose, which should affect death rate. Obviously, 10 infected cells^20th generation is less than 1000^20thor 10,000^20th. Capturing the effect of masking on morbidity and mortality would take a very large study. However, we should be clear that “Who dies?” is the bottom line. Thus, is rapid test diagnostic a proper surrogate endpoint? Further, is an infecting dose study possible?
5. I attempted to address the economic/pandemic intertwined issues with a joint editorial in 2020 calling for immediate rollout of killed, component, and nucleotide vaccines, monitored as occurs in stage 4 (Hanley 2020). My observation is that the USA working class’ incomes were often devastated while the white-collar (computer-work) class was not. The working class took masking as a symbol and vaccines ended up in that same tent. More discussion of inequality exacerbation is warranted.
6. Given a 46% compliance rate not based on direct monitoring, clinical trials tell us compliance is lower. Thus, pharma prefers subjects stay in their facility for complete monitoring. People forget, confabulate, etc.

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Hanley BP, Keen S, Church G. A Call for a Three-Tiered Pandemic Public Health Strategy in Context of SARS-CoV-2. Rejuvenation Res. 2020 Aug;23(4):281-283. doi: 10.1089/rej.2020.2363. Epub 2020 Jun 24. PMID: 32539623; PMCID: PMC7462018.

IT sokuhou kara kita • IT sokuhou Research Lab • 27 August 2022

This post is amazing

This is a great research. Great respect to the author.

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Morbidity and Mortality Weekly Report (*MMWR*)

Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates — United States, March 1–December 31, 2020

Weekly / March 12, 2021 / 70(10);350–354
On March 5, 2021, this report was posted online as an MMWR *Early Release.*

Summary

What is already known about this topic?

Universal masking and avoiding nonessential indoor spaces are recommended to mitigate the spread of COVID-19.

What is added by this report?

Mandating masks was associated with a decrease in daily COVID-19 case and death growth rates within 20 days of implementation. Allowing on-premises restaurant dining was associated with an increase in daily COVID-19 case growth rates 41–100 days after implementation and an increase in daily death growth rates 61–100 days after implementation.

What are the implications for public health practice?

Mask mandates and restricting any on-premises dining at restaurants can help limit community transmission of COVID-19 and reduce case and death growth rates. These findings can inform public policies to reduce community spread of COVID-19.

Related Materials

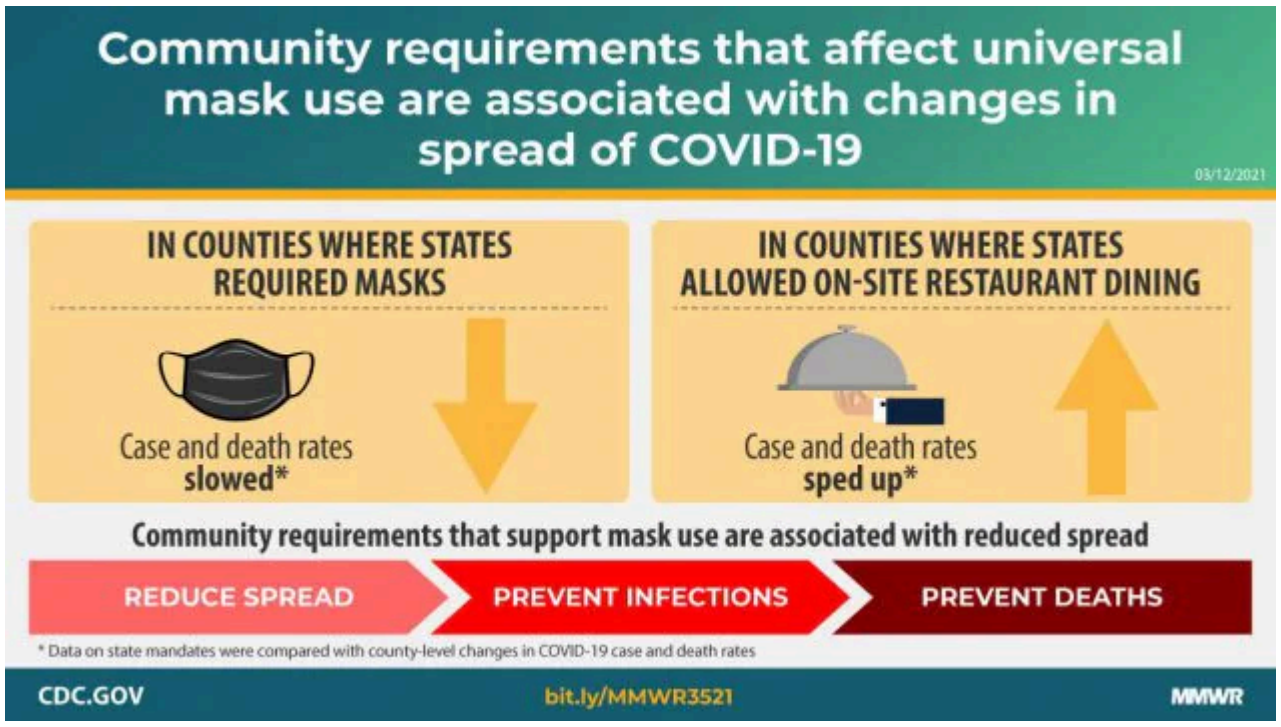
Mask mandates, on-premises dining, and COVID-19

MMWR Article PDF

Please note: This report has been corrected. An erratum has been published.

Gery P. Guy Jr., PhD[1]; Florence C. Lee, MPH[1]; Gregory Sunshine, JD[1]; Russell McCord, JD[1]; Mara Howard-Williams, JD[2]; Lyudmyla Kompaniyets, PhD[1]; Christopher Dunphy, PhD[1]; Maxim Gakh, JD[3]; Regen Weber[1]; Erin Sauber-Schatz, PhD[1]; John D. Omura, MD[1]; Greta M. Massetti, PhD[1]; CDC COVID-19 Response Team, Mitigation Policy Analysis Unit; CDC Public Health Law Program (VIEW AUTHOR AFFILIATIONS)

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CDC recommends a combination of evidence-based strategies to reduce transmission of SARS-CoV-2, the virus that causes COVID-19 (*1*). Because the virus is transmitted predominantly by inhaling respiratory droplets from infected persons, universal mask use can help reduce transmission (*1*). Starting in April, 38 states and the District of Columbia (DC) issued mask mandates in 2020. Reducing person-to-person interactions by avoiding nonessential shared spaces, such as restaurants, where interactions are typically unmasked and physical distancing (≥6 ft) is difficult to maintain, can also decrease transmission (*2*). In March and April 2020, 49 states and DC prohibited any on-premises dining at restaurants, but by mid-June, all states and DC had lifted these restrictions. To examine the association of state-issued mask mandates and allowing on-premises restaurant dining with COVID-19 cases and deaths during March 1–December 31, 2020, county-level data on mask mandates and restaurant reopenings were compared with county-level changes in COVID-19 case and death growth rates relative to the mandate implementation and reopening dates. Mask mandates were associated with decreases in daily COVID-19 case and death growth rates 1–20, 21–40, 41–60, 61–80, and 81–100 days after implementation. Allowing any on-premises dining at restaurants was associated with increases in daily COVID-19 case growth rates 41–60, 61–80, and 81–100 days after reopening, and increases in daily COVID-19 death growth rates 61–80 and 81–100 days after reopening. Implementing mask mandates was associated with reduced SARS-CoV-2 transmission, whereas reopening restaurants for on-premises dining was associated with increased transmission. Policies that require universal mask use and restrict any on-premises restaurant dining are important components of a comprehensive strategy to reduce exposure to and transmission of SARS-CoV-2 (*1*). Such efforts are increasingly important given the emergence of highly transmissible SARS-CoV-2 variants in the United States (*3*,*4*).

County-level data on state-issued mask mandates and restaurant closures were obtained from executive and administrative orders identified on state government websites. Orders were analyzed and coded to extract mitigation policy variables for mask mandates and restaurant closures, their effective dates and expiration dates, and the counties to which they applied. State-issued mask mandates were defined as requirements for persons to wear a mask 1) anywhere outside their home or 2) in retail businesses and in restaurants or food establishments. State-issued restaurant closures were defined as prohibitions on restaurants operating or limiting service to takeout, curbside pickup, or delivery. Allowing restaurants to provide indoor or outdoor on-premises dining was defined as the state lifting a state-issued restaurant closure.* All coding underwent secondary review and quality assurance checks by two or more raters; upon agreement among all raters, coding and analyses were published in freely available data sets.[†,§]

Two outcomes were examined: the daily percentage point growth rate of county-level COVID-19 cases and county-level COVID-19 deaths. The daily growth rate was defined as the difference between the natural log of cumulative cases or deaths on a given day and the natural log of cumulative cases or deaths on the previous day, multiplied by 100. Data on cumulative county-level COVID-19 cases and deaths were collected from state and local health department websites and accessed through U.S. Department of Health and Human Services Protect.[¶]

Associations between the policies and COVID-19 outcomes were measured using a reference period (1–20 days before implementation) compared with seven mutually exclusive time ranges relative to implementation (i.e., the effective date of the mask mandate or the date restaurants were permitted to allow on-premises dining). The association was examined over two preimplementation periods (60–41 and 40–21 days before implementation) and five postimplementation periods (1–20, 21–40, 41–60, 61–80, and 81–100 days after implementation).

Weighted least-squares regression with county and day fixed effects was used to compare COVID-19 case and death growth rates before and after 1) implementing mask mandates and 2) allowing on-premises dining at restaurants. Because state-issued policies often applied to specific counties, particularly when states began allowing on-premises dining, all analyses were conducted at the county level. Four regression models were used to assess the association between each policy and each COVID-19 outcome. The regression models controlled for several covariates: restaurant closures in the mask mandate models and mask mandates in the restaurant reopening models, as well as bar closures,** stay-at-home orders,†† bans on gatherings of ≥10 persons,§§ daily COVID-19 tests per 100,000 persons, county, and time (day). P-values <0.05 were considered statistically significant. All analyses were weighted by county population with standard errors robust to heteroscedasticity and clustered by state. Analyses were performed using Stata software (version 14.2; StataCorp). This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.¶¶

During March 1–December 31, 2020, state-issued mask mandates applied in 2,313 (73.6%) of the 3,142 U.S. counties. Mask mandates were associated with a 0.5 percentage point decrease (p = 0.02) in daily COVID-19 case growth rates 1–20 days after implementation and decreases of 1.1, 1.5, 1.7, and 1.8 percentage points 21–40, 41–60, 61–80, and 81–100 days, respectively, after implementation (p<0.01 for all) (Table 1) (Figure). Mask mandates were associated with a 0.7 percentage point decrease (p = 0.03) in daily COVID-19 death growth rates 1–20 days after implementation and decreases of 1.0, 1.4, 1.6, and 1.9 percentage points 21–40, 41–60, 61–80, and 81–100 days, respectively, after implementation (p<0.01 for all). Daily case and death growth rates before implementation of mask mandates were not statistically different from the reference period.

During the study period, states allowed restaurants to reopen for on-premises dining in 3,076 (97.9%) U.S. counties. Changes in daily COVID-19 case and death growth rates were not statistically significant 1–20 and 21–40 days after restrictions were lifted. Allowing on-premises dining at restaurants was associated with 0.9 (p = 0.02), 1.2 (p<0.01), and 1.1 (p = 0.04) percentage point increases in the case growth rate 41–60, 61–80, and 81–100 days, respectively, after restrictions were lifted (Table 2) (Figure). Allowing on-premises dining at restaurants was associated with 2.2 and 3.0 percentage point increases in the death growth rate 61–80 and 81–100 days, respectively, after restrictions were lifted (p<0.01 for both). Daily death growth rates before restrictions were lifted were not statistically different from those during the reference period, whereas significant differences in daily case growth rates were observed 41–60 days before restrictions were lifted.

Top

Discussion

Mask mandates were associated with statistically significant decreases in county-level daily COVID-19 case and death growth rates within 20 days of implementation. Allowing on-premises restaurant dining was associated with increases in county-level case and death growth rates within 41–80 days after reopening. State mask mandates and prohibiting on-premises dining at restaurants help limit potential exposure to SARS-CoV-2, reducing community transmission of COVID-19.

Studies have confirmed the effectiveness of community mitigation measures in reducing the prevalence of COVID-19 (*5*–*8*). Mask mandates are associated with reductions in COVID-19 case and hospitalization growth rates (*6*,*7*), whereas reopening on-premises dining at restaurants, a known risk factor associated with SARS-CoV-2 infection (*2*), is associated with increased COVID-19 cases and deaths, particularly in the absence of mask mandates (*8*). The current study builds upon this evidence by accounting for county-level variation in state-issued mitigation measures and highlights the importance of a comprehensive strategy to decrease exposure to and transmission of SARS-CoV-2. Prohibiting on-premises restaurant dining might assist in limiting potential exposure to SARS-CoV-2; however, such orders might disrupt daily life and have an adverse impact on the economy and the food services industry (*9*). If on-premises restaurant dining options are not prohibited, CDC offers considerations for operators and customers which can reduce the risk of spreading COVID-19 in restaurant settings.*** COVID-19 case and death growth rates might also have increased because of persons engaging in close contact activities other than or in addition to on-premises restaurant dining in response to perceived reduced risk as a result of states allowing restaurants to reopen. Further studies are needed to assess the effect of a multicomponent community mitigation strategy on economic activity.

Increases in COVID-19 case and death growth rates were significantly associated with on-premises dining at restaurants after indoor or outdoor on-premises dining was allowed by the state for >40 days. Several factors might explain this observation. Even though prohibition of on-premises restaurant dining was lifted, restaurants were not required to open and might have delayed reopening. In addition, potential restaurant patrons might have been more cautious when restaurants initially reopened for on-premises dining but might have been more likely to dine at restaurants as time passed. Further analyses are necessary to evaluate the delayed increase in case and death growth rates.

The findings in this report are subject to at least three limitations. First, although models controlled for mask mandates, restaurant and bar closures, stay-at-home orders, and gathering bans, the models did not control for other policies that might affect case and death rates, including other types of business closures, physical distancing recommendations, policies issued by localities, and variances granted by states to certain counties if variances were not made publicly available. Second, compliance with and enforcement of policies were not measured. Finally, the analysis did not differentiate between indoor and outdoor dining, adequacy of ventilation, and adherence to physical distancing and occupancy requirements.

Community mitigation measures can help reduce the transmission of SARS-CoV-2. In this study, mask mandates were associated with reductions in COVID-19 case and death growth rates within 20 days, whereas allowing on-premises dining at restaurants was associated with increases in COVID-19 case and death growth rates after 40 days. With the emergence of more transmissible COVID-19 variants, community mitigation measures are increasingly important as part of a larger strategy to decrease exposure to and reduce transmission of SARS-CoV-2 (*3*,*4*). Community mitigation policies, such as state-issued mask mandates and prohibition of on-premises restaurant dining, have the potential to slow the spread of COVID-19, especially if implemented with other public health strategies (*1*,*10*).

Top

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Top

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Top

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Top

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Top

* For the purposes of this analysis, no distinction was made based on whether reopened restaurants were subject to state requirements to implement safety measures, such as limit dining to outdoor service, reduce capacity, enhance sanitation, or physically distance, or if no mandatory restrictions applied. When states differentiated between bars that serve food and bars that do not serve food, restrictions for bars that serve food were coded as restaurants and restrictions for bars that do not serve food were coded as bars.

† https://ephtracking.cdc.gov/DataExplorer/?c=33&i=165 (accessed February 24, 2021)

§ https://ephtracking.cdc.gov/DataExplorer/?c=33&i=162 (accessed February 24, 2021)

¶ https://protect-public.hhs.gov (accessed February 3, 2021)

** https://data.cdc.gov/Policy-Surveillance/U-S-State-and-Territorial-Orders-Closing-and-Reope/9kjw-3miq (accessed February 24, 2021)

†† https://data.cdc.gov/Policy-Surveillance/U-S-State-and-Territorial-Stay-At-Home-Orders-Marc/y2iy-8irm (accessed February 24, 2021)

§§ https://data.cdc.gov/Policy-Surveillance/U-S-State-and-Territorial-Gathering-Bans-March-11-/7xvh-y5vh (accessed February 24, 2021)

¶¶ 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

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Top

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Top

TABLE 1. Association between state-issued mask mandates* and changes in COVID-19 case and death growth rates† — United States, March 1–December 31, 2020

Return

Time relative to day state mask mandate was implemented	Case growth rates		Death growth rates	
	Percentage point change (95% CI)	p-value§	Percentage point change (95% CI)	p-value§
41–60 days before	0.0 (–0.7 to 0.7)	0.98	–0.8 (–1.8 to 0.1)	0.07
21–40 days before	0.5 (–0.8 to 1.8)	0.49	0.3 (–0.8 to 1.5)	0.56
1–20 days before	Referent	—	Referent	—
1–20 days after	–0.5 (–0.8 to –0.1)	0.02	–0.7 (–1.4 to –0.1)	0.03
21–40 days after	–1.1 (–1.6 to –0.6)	<0.01	–1.0 (–1.7 to –0.3)	<0.01
41–60 days after	–1.5 (–2.1 to –0.8)	<0.01	–1.4 (–2.2 to –0.6)	<0.01
61–80 days after	–1.7 (–2.6 to –0.9)	<0.01	–1.6 (–2.4 to –0.7)	<0.01
81–100 days after	–1.8 (–2.8 to –0.7)	<0.01	–1.9 (–3.0 to –0.8)	<0.01

Abbreviation: CI = confidence interval.

* A state-issued mask mandate was defined as the requirement that persons operating in a personal capacity (i.e., not limited to specific professions or employees) wear a mask 1) anywhere outside their home or 2) in retail businesses and in restaurants or food establishments.

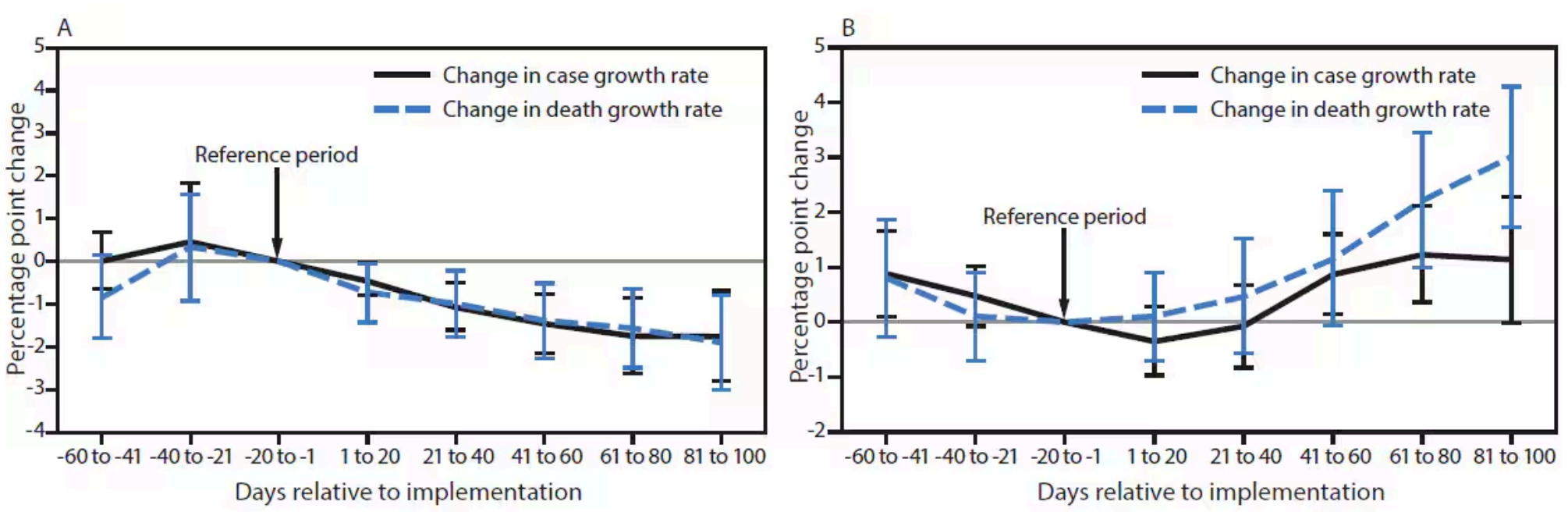
† Percentage points are coefficients from the weighted least-squares regression models. Reported numbers are from regression models, which controlled for county, time (day), COVID-19 tests per 100,000 persons, closure of restaurants for any on-premises dining, closure of bars for any on-premises dining, and the presence of gathering bans and stay-at-home orders.

§ P-values <0.05 were considered statistically significant.

Top

FIGURE. Association between changes in COVID-19 case and death growth rates* and implementation of state mask mandates† (A) and states allowing any on-premises restaurant dining§ (B) — United States, March 1–December 31, 2020

Return



* With 95% confidence intervals indicated with error bars.

† A state-issued mask mandate was defined as the requirement that persons operating in a personal capacity (i.e., not limited to specific professions or employees) wear a mask 1) anywhere outside their home or 2) in retail businesses and in restaurants or food establishments.

§ The effective date of the state order allowing restaurants to conduct any on-premises dining or the date a state-issued restaurant closure expired.

Top

TABLE 2. Association between states allowing any on-premises restaurant dining* and changes in COVID-19 case and death growth rates† — United States, March 1–December 31, 2020

Return

Time relative to day states allowed on-premises dining	Case growth rates		Death growth rates	
	Percentage point change (95% CI)	p-value§	Percentage point change (95% CI)	p-value§
41–60 days before	0.9 (0.1 to 1.6)	0.02	0.8 (–0.2 to 1.8)	0.13
21–40 days before	0.5 (–0.1 to 1.0)	0.08	0.1 (–0.7 to 0.9)	0.78
1–20 days before	Referent	—	Referent	—
1–20 days after	–0.4 (–0.9 to 0.2)	0.22	0.1 (–0.7 to 0.9)	0.78
21–40 days after	–0.1 (–0.8 to 0.6)	0.83	0.5 (–0.5 to 1.5)	0.36
41–60 days after	0.9 (0.2 to 1.6)	0.02	1.1 (–0.1 to 2.3)	0.06
61–80 days after	1.2 (0.4 to 2.1)	<0.01	2.2 (1.0 to 3.4)	<0.01
81–100 days after	1.1 (0.0 to 2.2)	0.04	3.0 (1.8 to 4.3)	<0.01

Abbreviation: CI = confidence interval.

* The effective date of the state order allowing restaurants to conduct any on-premises dining or the date a state-issued restaurant closure expired.

† Percentage points are coefficients from the weighted least-squares regression models. Reported numbers are from regression models, which controlled for county, time (day), COVID-19 tests per 100,000 persons, mask mandates, closure of bars for any on-premises dining, and the presence of gathering bans and stay-at-home orders.

§ P-values <0.05 were considered statistically significant.

Top

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Mask mandate and use efficacy for COVID-19 containment in US States

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Abstract

Background: COVID-19 pandemic mitigation requires evidence-based strategies. Because COVID-19 can spread via respired droplets, most US states mandated mask use in public settings. Randomized control trials have not clearly demonstrated mask efficacy against respiratory viruses, and observational studies conflict on whether mask use predicts lower infection rates. We hypothesized that statewide mask mandates and mask use were associated with lower COVID-19 case growth rates in the United States.

Methods: We calculated total COVID-19 case growth and mask use for the continental United States with data from the Centers for Disease Control and Prevention and Institute for Health Metrics and Evaluation. We estimated post-mask mandate case growth in non-mandate states using median issuance dates of neighboring states with mandates.

Results: Earlier mask mandates were not associated with lower total cases or lower maximum growth rates. Earlier mandates were weakly associated with lower minimum COVID-19 growth rates. Mask use predicted lower minimum but not lower maximum growth rates. Growth rates and total growth were comparable between US states in the first and last mask use quintiles during the Fall-Winter wave. These observations persisted for both natural logarithmic and fold growth models and when adjusting for differences in US state population density.

Conclusions: We did not observe association between mask mandates or use and reduced COVID-19 spread in US states. COVID-19 mitigation requires further research and use of existing efficacious strategies, most notably vaccination.

Keywords: COVID-19, SARS-CoV-2, face covering, medical mask, mask mandate, nonpharmaceutical intervention

Introduction

The COVID-19 pandemic has increased mortality and induced socioeconomic upheaval worldwide (1). Evidence-based containment strategies are warranted, given that age, obesity, cardiovascular disease, and diabetes are common comorbidities associated with severe COVID-19 symptoms (e.g., pneumonia, blood clots, cytokine storm), hospitalization, and death (2, 3). Respired droplets and aerosols containing SARS-CoV-2 are intuitive modes of community transmission (4). To reduce viral spread, governments have issued mandates to wear medical masks or cloth face coverings in public settings. From April to December 2020, 40 States of the United States issued mask mandates. Mask mandates have limited precedent, making efficacy unclear. Our first objective was to evaluate the efficacy of mask mandates in attenuating COVID-19 growth in US states.

Prior studies have conflicted on whether masks reduce COVID-19 spread. For USS Theodore Roosevelt crew, mask use was lower among COVID-19 cases compared with non-infected (56% vs. 81%) (5). There were no infections for 48% of universally masked patrons exposed to COVID-19 positive hair stylists (6), but PCR tests were not obtained for the other 52% of patrons (6), and first wave COVID-19 hospitalizations were no higher in public schools (high density with minimal masking) than elsewhere in Sweden (7). A randomized controlled trial (RCT) of Danish volunteers found no protective benefit of medical masks against COVID-19 infection (8). In RCTs before COVID-19, viral infections were not lower in Vietnamese clinicians who wore cloth or medical masks than in the control arm (9), and N-95 respirators (but not medical masks) protected Beijing clinicians from bacterial and viral diseases compared to no masks (10). Mask compliance in RCTs is not always clear (11). Mask use was 10% and 33% for Beijing households with and without intrahousehold COVID-19 case growth, respectively (12). This suggests greater mask use may reduce COVID-19 spread. Our second objective was to assess if mask use predicts lower COVID-19 case growth.

We assessed if mask mandates and compliance in US States predict statewide COVID-19 growth during the second and third infection waves (1 June 2020-1 March 2021). Controlling for infection wave timing with logarithmic and linear relative growth models, we found limited association between COVID-19 case growth and mask mandates or mask use before 1 October 2020, and no association during the subsequent and largest third wave. These findings do not support the hypothesis that statewide mandates and enhanced mask use slow COVID-19 spread. Pharmaceutical interventions (including recently available COVID-19 vaccines) provide alternative, evidence-based strategies to minimize COVID-19 related morbidity and mortality.

Materials and methods

Data Sources and Terms

We obtained total (confirmed and probable) COVID-19 cases up to 6 March 2021 for the 49 continental US states, normalized per 100,000 residents, from the Centers for Disease Control and Prevention (CDC) (13). To reduce reporting lag effects, we used 7-day simple moving means (e.g., the 7-day simple moving mean of cases on 31 March is the mean of daily cases between 28 March and 3 April). Hawaii was excluded because COVID-19 growth patterns deviated from those of continental US states. Confirmed and probable cases are defined by the Council of State and Territorial Epidemiologists. Confirmed cases require PCR amplification of SARS-CoV-2 RNA from patient specimens. Probable cases require one of the following: clinical and epidemiologic evidence, clinical or epidemiologic evidence supported by SARS-CoV-2 antigen detection in respiratory specimens, or vital records listing COVID-19 as contributing to death. Total PCR tests for each state were obtained from Worldometers on 25 May 2021 (14).

Mask mandates are statewide emergency executive public health orders requiring nose and mouth coverings in public settings in more than 50% of counties within a state (15, 16). We assigned US states to one of five quintiles based on when mandates went into effect (effective dates): 18 April-16 May 2020

(Q1), 29 May-3 July 2020 (Q2), 8 July-27 July 2020 (Q3), 1 Aug-9 Dec 2020 (Q4), or no statewide mandate as of 6 March 2021 (Q5). Effective dates were obtained from US state executive and health departments and press releases (available upon request).

We assessed mask use with the University of Washington Institute for Health Metrics and Evaluation (IHME) COVID-19 model site (17), which estimates daily compliance from Premise, the Facebook Global Symptom Survey (University of Maryland), the Kaiser Family Foundation, and the YouGov Behavior Tracker Survey. Mask use is the percentage of people who always wear masks in public settings. We assigned US states to mask quintiles based on the mean percent mask use from 1 Jun-1 Oct 2020 (Summer) or from 1 Oct 2020-1 Mar 2021 (Fall-Winter).

To assess geographic differences, we assigned each US state to one of five regions: Northeast (Connecticut, Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont); Midwest (Illinois, Indiana, Iowa, Kentucky, Kansas, Michigan, Minnesota, Missouri, Ohio, West Virginia, Wisconsin); Mountains-Plains (Colorado, Idaho, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Utah, Wyoming); South (Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia); and Pacific (Alaska, Arizona, California, Nevada, Oregon, Washington).

Growth Rate Calculation

COVID-19 growth has been modeled logarithmically (15, 18, 19) and linearly (19, 20). Therefore, we calculated COVID-19 case growth for each US state by measuring percent natural logarithmic (Ln Growth) and percent linear (Fold Growth) relative growth rates:

$$\text{Ln Growth:} = 100 * ln\frac{C_t}{C_{t-1}}$$

$$\text{Fold Growth:} = 100 * \left(-1 + \frac{C_t}{C_{t-20}}\right)$$

Where C_t, C_{t-1}, and C_{t-20} are total normalized cases on a day, the prior day, and 20 days prior, respectively. We determined adjusted population density by calculating the weighted mean of each state's urban (U) and rural (R) population density using the following formulas:

$$\text{Urban Density (U)} = u1p1 + u2p2 + u3p3$$

$$\text{Mean Rural Density (R)} = \frac{State\ Population * (1-F)}{State\ Area - a1+a2+a3}$$

For the three most populous urban regions in each US state, we obtained urban population density (*u*; people/square mile in an urban area), urban land area (*a*; size of urban area in square miles), and population proportion (*p*; fraction of combined urban population) via 2010 US Census Bureau estimates (21). For some states, two rather than three urban regions were used. The proportion of urban (F) and rural (1-F) population of each state was similarly obtained (21). We thus calculated adjusted population density of each state as:

$$\text{Adjusted Population Density (APD)} = UF + R(1-F)$$

To assess association between population density and growth rates, we multiplied Fold Growth by the inverse of normalized APD:

$$\text{Adj. Fold Growth} = \text{Fold Growth} * \left(\frac{Mean\ APD\ of\ all\ US\ States}{State\ APD}\right)$$

We defined minima and maxima (extrema) as the lowest and highest growth rates between the end of the Summer wave and the height of the Fall-Winter wave. Ln Growth extrema comprised 20-day windows when Ln Growth rates were lowest or highest:

$$\text{Ln Growth extremum} = \max/\min_{\substack{20\ Jul\ 2020 \\ \leq t \leq 1\ Mar\ 2021}} \frac{\sum_{t=1}^{t=20} Ln\ Growth\ on\ Day\ t}{20}$$

Fold Growth extrema similarly comprise the lowest and highest Fold Growth:

$$\text{Fold Growth extremum} = \max/\min_{\substack{20\ Jul\ 2020 \\ \leq t \leq 1\ Mar\ 2021}} Fold\ Growth\ (\text{t-20, t})$$

For each state, surges are differences between maxima and minima (relative growth rate increase), masks at extrema are the 20-day mean mask use at minima and maxima, and ΔMasks is the percent change in mask use between maxima and minima.

To assess association between mandates and growth rates in the 48 contiguous states (excluding Alaska and Hawaii), we determined Ln, Fold, and Adj. Fold Growth between 1 March 2021 (C_{301}) and the mandate effective date (C_M) for US states in mandate quintiles 1-3:

$$\text{Post-Mandate Ln Growth} = 100 * \ln\frac{C_{301}}{C_M}$$

$$\text{Post-Mandate Fold Growth} = 100 * (-1 + \frac{C_{301}}{C_M})$$

For states in quintiles 4-5, *modeled effective dates* are medians of actual dates among bordering states of mandate quintiles 1-3. For example, the modeled effective date of Tennessee (10 July) is the median of effective dates of Arkansas (20 July), Alabama (16 July), Kentucky (10 July), North Carolina (26 June), and Virginia (29 May).

For each state, Summer 2020 (1 June-1 Oct) and Fall-Winter 2020-21 (1 Oct-1 Mar) mask use is mean mask use between these dates. Cases on 1 June or 1 Oct were the 20-day mean total normalized cases on these two dates. We likewise defined Summer and Fall-Winter case growth using Ln and Fold Growth formulas:

$$\text{Summer Ln Growth} = \ln\frac{C_{1001}}{C_{601}} \qquad \text{Summer Fold Growth} = 100 * (-1 + \frac{C_{1001}}{C_{601}})$$

$$\text{Fall-Winter Ln Growth} = \ln\frac{C_{301}}{C_{1001}} \qquad \text{Fall-Winter Fold Growth} = 100 * (-1 + \frac{C_{301}}{C_{1001}})$$

Where c_{601}, c_{1001}, and c_{301} are total normalized cases on 1 June 2020, 1 October 2020, and 1 March 2021, respectively.

Statistics

We used Prism 9.2 (GraphPad; San Diego, CA) to construct figures and perform null hypothesis significance tests, for which the significance threshold was $p < \alpha = 0.05$ (**Worksheet D in S1 Table**). Error bars denote standard deviations, 95% confidence intervals, or interquartile ranges as indicated in figure legends. We performed D'Agostino-Pearson tests to assess normality of residuals.

To evaluate mask mandate and use efficacy among categories (mandate effective date or mask use quintiles), we performed ordinary one-way ANOVA with Tukey posttests. For non-normal data, we performed Kruskal-Wallis with Dunn posttests. For two sample comparisons (e.g., **Fig. 3G, J**), we conducted two-tailed t tests or Mann-Whitney tests for normal and non-normal data, respectively. This decision tree conforms with recommended practices for datasets of $N > 5$ (22).

For interval variable associations, we performed ordinary least squares (OLS)-simple linear regression with null hypotheses of zero slope. Infectious disease research has employed OLS previously (23, 24), with linear and ln-linear models reported in recent COVID-19 studies (25, 26). For the Summer wave, Northeast states were excluded because they deviated from other states with respect to total cases and growth covariation. We used weighted least squares (WLS) for heteroscedastic data, as determined by the GraphPad Prism Test for Homoscedasticity. Regardless of statistical significance, R^2 values denote coefficients of determination for lines of best fit with unconstrained slopes.

Results

COVID-19 growth rates vary with time

With the aim of reducing COVID-19 case growth, 40 US states enacted mask mandates in 2020. We wondered if mask mandate timing affected COVID-19 growth patterns. To identify patterns of COVID-19 growth, we graphed natural logarithmic (Ln) Growth of COVID-19 in US states as a function of time (**Worksheet A in S1 Table**). We observed six phases of COVID-19 growth up to 6 March 2021: first wave (before May 2020), Spring minimum (May-June 2020), Summer wave maximum (June-August 2020), post-Summer minimum (August-October 2020), Fall-Winter wave maximum (October-January 2020), and third minimum (March 2021) (**Fig. 1A and S1 Fig**). Hawaii growth patterns deviated from those of continental US states and was thus excluded from further analysis. Regardless of mask mandate effective date quintile, Ln growth patterns were comparable for all continental US states, and there was no association between normalized total cases and PCR tests (**S1 Fig**).

Earlier mask mandates are not consistently associated with COVID-19 growth rates in US states

A recent study reported time-enhanced negative association between mask mandates and Ln Growth of COVID-19 (15), but simple Fold-Growth (an alternative COVID-19 metric (19, 20)) may be preferred for post-exponential, linear pandemic spread. PCR testing for COVID-19 was limited before Summer 2020 (27). Thus, to determine if US states with earlier mask mandates exhibited less COVID-19 spread, we examined both Ln Growth and Fold Growth at the post-Summer wave minimum and the Fall-Winter wave maximum (**Fig 1A-B**)—periods of low and high transmission, respectively. We assigned US states to one of five quintiles (MQ1-5), with MQ1 including states with the earliest mandates, MQ4 the latest mandates, and MQ5 states without mandates. Ln minima ($p=0.07$; **Fig. 1C**) and Fold minima ($p=0.047$; **Fig. 1D**) trended lower for earlier mandates. Fold minima was 3-fold higher in MQ4 than MQ1 after adjusting for population density ($p=0.04$), but all other pairwise comparisons were not significant (**Fig. 1E**). This suggested that mask mandate duration was a weak predictor of lower minimum growth. Ln maxima ($p=0.23$; **Fig. 1F**) and Fold maxima ($p=0.19$; **Fig. 1G**) did not differ among quintiles. Adjusting for population density, Fold maxima were 2.8-fold higher in MQ4 than MQ2 ($p=0.01$), but MQ1, 3, and 5 were indistinguishable (**Fig. 1H**), suggesting mask mandate duration was not associated with lower maximum growth. Likewise, surges (growth rate increases from minima to maxima) were MQ-independent for Ln ($p=0.08$) and Fold ($p=0.13$) models, and only MQ2 and MQ4 exhibited significantly different Fold surges with population density adjustment ($p=0.03$; **S2 Fig**). Most MQ4 states exhibited lower initial and Summer 2020 infection waves than Q1-2 (**S1 Fig**), suggesting high MQ4 growth rates could be an artifact of lower total cases. While there was strong positive association between earlier mandates and Fall-Winter mask use ($p<0.001$; **Fig. 1I**), total cases on 1 March 2021 were MQ-independent ($p<0.07$; **Fig. 1J**). Direct MQ1 vs. MQ5 comparison by t test uncovered a small (1.2-fold) and non-significant ($p=0.078$) difference in total cases. Taken together, these findings suggest that US state mask mandates were not associated with slower spread of COVID-19.

Early mask mandates do not predict lower post-mandate COVID-19 growth in contiguous US states

Most US states enacted mandates during infection waves, which confounds assessment of effectiveness. To assess association between mandate effective date and post-mandate case growth, we compared growth after actual MQ1-3 mandates with growth after modeled MQ4-5 mandates up to 1 March 2021. For a MQ4-5 state, the modeled date was the effective date median of contiguous, common-border MQ1-3 states (**Fig. 2A**). Post-mandate growth in total cases was MQ-independent by Ln (p=0.43), Fold (p=41), and population density-adjusted Fold (p=0.15) models (**Fig. 2B**). Direct MQ1 vs. MQ5 comparison by Mann-Whitney test uncovered a small (1.3-fold) and non-significant (p=0.86) difference in adjusted fold-growth. Overall, we did not obtain an association between mandates and lower COVID-19 growth.

Mask use is not associated with most state COVID-19 case growth

We speculated that statewide mask use, rather than mask mandates per se, may predict lower COVID-19 growth rates. The Institute of Health Metrics and Evaluation (IHME) provides robust estimates for mask use (defined as the percentage of people who always wear masks in public settings) (17). By simple linear regression, mask use was associated with lower Ln, Fold, and adjusted Fold minima ($p<0.0001$; **Fig 3A-B** and **S3A Fig**). To better understand this trend, we assigned US states to one of five mask use quintiles (UQ1-5), with UQ1 including states with the highest mask use and UQ5 states with the lowest mask use. UQ5 exhibited a 3.4-fold greater adjusted Fold minimum than UQ1 (p=0.002; **Fig 3C**), suggesting potential association between mask use and COVID-19 spread at minima. By contrast, mask use was not associated with Ln (p=0.071), Fold (p=0.058), or adjusted Fold (p=0.076) maxima (**Fig 3D-E** and **S3D Fig**). Adjusted Fold maxima were also UQ-independent (p=0.56; **Fig 3F**), with direct UQ1 vs. UQ5 comparison by Mann-Whitney test uncovering a modest (1.5-fold) and non-significant (p=0.16) difference in maxima. This suggests that mask use is not associated with COVID-19 spread at maxima.

We wondered why mask use was associated with lower minimum but not lower maximum growth rates. Mask use was not associated with total cases at Ln minima (p=0.54) or maxima (p=0.086; **S3C-D Fig**),

indicating potential confounders in the mask-minimum growth relationship. Excluding Northeast states, which exhibited the largest first waves and July 2020 seroprevalence (13, 28), total cases predicted lower Ln minima (p=0.001; **S3E Fig**). This suggested that the link between mask use and lower minima may be an artifact of the tendency for faster case growth to occur at lower case prevalence. In support of this, for 1 June – 1 Oct. 2020 mask use quintiles, normalized cases grew from 400 to 1350 at similar rates for UQ1 (which includes eight Northeast states) and UQ5 (p=0.22; **Fig. 3G**). UQ5 exhibited exponential growth and reached these case totals ~50 days after UQ1 (**Fig 3H-I**), further implying that higher growth rates may reflect lower total cases in low mask use states before minima. 0-80 days after Ln maxima, when total case differences were smaller among states, UQ1 and UQ5 exhibited indistinguishable growth rates (p=0.78; **Fig 3J**; 1 Oct. 2020 – 1 March 2021 mask use quintiles). Growth was post-exponential for both UQ1 and UQ5 during this period (**Fig 3K-L**), and total cases predicted lower Ln maxima in all continental US states (p<0.0001; **S3F Fig**). Together, these data suggest that mask use is an unreliable predictor of COVID-19 growth in US states.

Mask use does not predict Summer or Fall-Winter COVID-19 cumulative growth in US states.

As expected, total cases were negatively associated with Ln growth in non-Northeast states for 1 June-1 Oct. 2020 and all continental US states for 1 Oct. 2020 – 1 March 2021 (p<0.0001; **S4A-B Fig**). We reasoned that even if mask use could not predict growth rate, mask use may be negatively associated with cumulative case growth. 1 June-1 Oct. 2020 (Summer) 1 Oct. 2020 – 1 March 2021 (Fall-Winter) represent two distinct COVID-19 growth waves (**Fig 4A-B**). Excluding Northeast states, masks were not associated with lower Summer growth using Ln (p=0.11; **Fig 4C**) or Fold (p=0.18; **S4C Fig**) models. Mask use trended with lower adjusted Fold Summer growth (p=0.05; **S4D Fig**). While adjusted Fold Summer growth was 3-fold higher in UQ4 than UQ1 (p=0.009), all other pairwise comparisons were not significant (**Fig. 4D**). Likewise, mask use was not associated with lower Fall-Winter growth using Ln (p=0.94; **Fig 4E**), Fold (p=0.91; **S4E Fig**), or adjusted Fold (p=0.71; **S4F Fig**) models, and adjusted Fold Fall-Winter growth was not significantly different among mask use quintiles (p=0.38; **Fig. 4F**). These

data suggest that mask use is not consistently associated with Summer wave growth and not associated with Fall-Winter wave growth in US states. Furthermore, low Summer growth did not protect Northeast states from subsequent Fall-Winter growth. In summary, statewide SARS-CoV-2 transmission waves appear independent of reported mask use (17).

Discussion

Our main finding is that mask mandates and use likely did not affect COVID-19 case growth. Mask mandates were associated with greater mask use but ultimately did not influence total normalized cases or post-mandate case growth. Higher mask use (rather than mandates per se) has been argued to decrease COVID-19 growth rates (11). While compliance varies by location and time, IHME estimates are derived from multiple sources and densely sampled. Even when accounting for population density, higher mask use was not associated with lower Ln or fold maximum growth rates or lower Fall-Winter case growth among continental US states. By contrast, mask use-growth rate association was highly significant at minima. This antinomy warrants consideration. Mask use did not predict normalized cases at growth minima or maxima, whereas there were more cases in the highest than the lowest mask use quintile before minima. Northeast states exhibited the highest seroprevalence by July 2020 (28) and comprised 80% of the highest mask use quintile, suggesting that mask use may be a lagging indicator of case growth. At maxima, when case prevalence was similar among states, COVID-19 growth rates were also similar for the highest and lowest mask use quintiles. Thus, initial association between masks and lower COVID-19 growth rates that dissipated during the Fall-Winter 2020-21 wave is likely an artifact of fewer normalized cases begetting faster growth in states with coincidental low mask use.

There is inferential but not demonstrable evidence that masks reduce SARS-CoV-2 transmission. Animal models (29), small case studies (6), and growth curves for mandate-only states (16) suggest that mask efficacy increases with mask use (11). However, we did not observe lower growth rates over a range of

compliance at maximum Fall-Winter growth (45-83% between South Dakota and Massachusetts during maxima) (17) when growth rates were high. This complements a Danish RCT from 3 April to 2 June 2020, when growth rates were low, which found no association between mask use and lower COVID-19 rates either for all participants in the masked arm (47% strong compliance) or for strongly compliant participants only (8). While N-95 respirators offer some protection against respiratory viruses (10), there is limited evidence for cloth and medical masks. Higher self-reported mask use protected against SARS-CoV-1 in Beijing residents (30), but RCTs found no differences in PCR confirmed influenza among Hong Kong households assigned to hand hygiene with or without masks (mask use 31% and 49%, respectively) (31). Medical and cloth masks did not reduce viral respiratory infections among clinicians in Vietnam (9) or China (10), and rhinovirus transmission increased among universally masked Hong Kong students and teachers in 2020 compared with prior years (32). These findings are consistent with a 2020 CDC meta-analysis (33) and a 2020 Cochrane review update (34).

Our study has implications for respiratory virus mitigation. Public health measures should ethically promote behaviors that prevent communicable diseases. The sudden onset of COVID-19 compelled adoption of mask mandates before efficacy could be evaluated. Our findings do not support the hypothesis that greater public mask use decreases COVID-19 spread. As masks have been required in many settings, it is prudent to weigh potential benefits with harms. Masks may promote social cohesion during a pandemic (35), but risk compensation can also occur (36). By obscuring nonverbal communication, masks interfere with social learning in children (37). Likewise, masks can distort verbal speech and remove visual cues to the detriment of individuals with hearing loss; clear face-shields improve visual integration, but there is a corresponding loss of sound quality (38, 39). Prolonged mask use (>4 hours per day) promotes facial alkalinization and inadvertently encourages dehydration, which in turn can enhance barrier breakdown and bacterial infection risk (40). British clinicians have reported masks to increase headaches and sweating and decrease cognitive precision (41). Survey bias notwithstanding, these sequelae are associated with medical errors (42). Future research is necessary to

assess risks of long-term daily mask use (34). As COVID-19 remains a public health threat, it is also appropriate to emphasize interventions with demonstrated efficacy against COVID-19, most notably vaccination (43) and vitamin D repletion (44).

In conclusion, we found mask mandates and use to be poor predictors of COVID-19 spread in US states. Strengths of our study include assessing COVID-19 association with both mandates and reported use; evaluating both Ln and Fold growth models; accounting for population density differences; and measuring case growth after modeled mandate effective dates in states with late or no mandates. Our study also has key limitations. We did not assess counties or localities, which may trend independently of state averages. While dense sampling promotes convergence, IHME masking estimates are subject to survey bias. We only assessed one biological quantity (confirmed and probable COVID-19), but the ongoing pandemic warrants assessment of other factors such as hospitalizations and mortality. Importantly, our study does not disprove the efficacy of all masks in limited and controlled circumstances, such as properly worn N95 respirators. A recent study found that at typical respiratory fluence rates, medical masks decrease airway deposition of 10-20μm SARS-CoV-2 particles but not 1-5μm SARS-CoV-2 aerosols (45). Aerosol expulsion increases with COVID-19 disease severity in non-human primates, as well as with age and BMI in humans without COVID-19 (46). Together with enhanced vaccination rates, aerosol treatment with improved ventilation and air purification could help reduce the size of COVID-19 outbreaks.

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Figure Legends

Fig 1. Earlier mask mandates are not consistently associated with lower COVID-19 growth rates in continental US States. A-B. Natural logarithmic (A) and Fold (B) COVID-19 growth in continental US states. Red horizontal lines denote growth rate minima (Min) and maxima (Max) between Summer and Fall-Winter waves. Surge: growth rate increase between Min and Max. C. Ln minima were not associated with the time quintile of a state's mandate effective date (MQ). D. Fold minima trended lower in MQ1 than MQs 3 and 5. E. Adjusted Fold minima were lower in MQ1 than MQ4 and indistinguishable for all other pairwise comparisons. F-G. Ln (F) and Fold (G) maxima were not associated with mandate effective date time quintiles. H. Adjusted Fold maxima were lower in MQ2 than MQ4 and indistinguishable for all other pairwise comparisons. I. States with earlier mask mandates exhibited greater mask use between Oct. 2020 and March 2021. J. Cases per 100,000 by 1 March 2021 were not associated with mandate effective date time quintiles. Different letters denote $p<0.05$ by Tukey tests after one-way ANOVA (C, F, G) or all pairwise comparison Dunn tests after Kruskal-Wallis (D, E, H-J). *: $p<0.05$ by Kruskal-Wallis. n.s.: not significant. Error bars: 95% confidence intervals (A-B), standard deviations (C, F, G), and interquartile ranges (D, E, H-J).

Fig 2. Earlier mask mandates are not associated with lower post-mandate COVID-19 growth rates in contiguous US states. A. Effective and modeled effective (***bold, italicized***) dates in 2020 for mask mandates in contiguous US states. State colors denote effective date time quintiles. Modeled dates of MQ4-5 states (late or no actual mandates) are medians of effective dates among bordering states of MQ1-3 (earlier mandates). Dashed lines denote MQ1-3 states that border a given MQ4-5 state. B-D. Between actual or modeled mandate effective dates and 1 March 2021, Ln Growth (B), Fold Growth (C), and population density-adjusted Fold Growth (D) were not associated with mandate effective date time quintiles. n.s.: not significant by one-way ANOVA (B) or Kruskal-Wallis (C-D). Error bars: standard deviations (B) and interquartile ranges (C-D).

Fig 3. Mask use does not consistently predict COVID-19 case growth in continental US states. A-C. At minima, mask use was associated with lower ln (A), fold (B), and population density-adjusted fold (C) growth rates. D-F. At maxima, mask use was not associated with ln (D), fold (E), or population density-adjusted fold (F) growth rates. G. States in June-Oct. 2020 mask use quintiles (UQ) 1 and 5 grew from 400 to 1350 normalized cases at indistinguishable rates before minima. H-I. Ln cases (H) and cases (I) vs. time for UQ1 and UQ5. J. States in Oct. 2020-March 2021 mask use UQ1 and UQ5 exhibited indistinguishable Fold Growth 80 days after maxima. K-L. Ln cases (K) and cases (L) vs. time for UQ1 and UQ5. Simple linear regression used weighted (A-B) or ordinary (D-E) least squares. R^2 values refer to unconstrained lines of best fit. Different letters denote $p<0.05$ by all pairwise comparison Dunn tests after Kruskal-Wallis (C, F). n.s.: not significant. Error bars: Interquartile ranges (C, F, J, K) and 95% confidence intervals (G-H).

Fig 4. Mask use does not predict lower COVID-19 growth during the Summer or Fall-Winter waves. A-B. Ln Growth rate (A) and total COVID-19 cases (B) for continental US states from 20 April 2020 to 6 March 2021. Red vertical lines denote Summer (Jun-Oct 2020) and Fall-Winter (Oct 2020-Mar 2021) waves. C. Mask use does not predict Summer Ln Growth in non-Northeast states. D. In the Summer wave, population-adjusted Fold Growth was lower in Summer mask use UQ1 than UQ4 and indistinguishable among UQ2-5. E. Mask use does not predict Fall-Winter Ln Growth in continental US states. F. In the Fall-Winter wave, population-adjusted Fold Growth was indistinguishable among Fall-Winter mask use quintiles. Simple linear regression used ordinary least squares (C, E). R^2 values refer to unconstrained lines of best fit. Different letters denote $p<0.05$ by all pairwise comparison Dunn tests after Kruskal-Wallis (D, F). n.s.: not significant. Error bars: 95% confidence intervals (A-B) and interquartile ranges (D, F). Solid circles (●): All continental US states. Hollow circles (○): Excluded Northeast states.

Supporting Information Legends

S1 Fig. A. Natural logarithmic COVID-19 growth rates in continental US states by mask mandate time quintile. Y-axis values are differences between natural logarithms of total cases on a day and natural logarithms of total cases on the prior day. States are listed by time quintiles at which mask mandates became effective statewide. Thin black and wide gray denote mean and 95% confidence intervals, respectively. Red vertical lines denote dates of mask mandate issuance. Red horizontal lines indicate growth rate minima (phase 4) and maxima (phase 5) between the Summer and Fall-Winter waves. B. There is no association between cases and COVID-19 PCR tests among US states (case and test totals as of 25 May 2021).

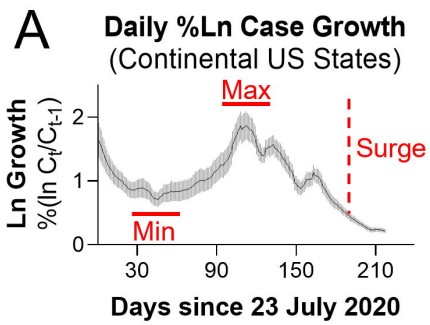
S2 Fig. Earlier mask mandates are not consistently associated with lower COVID-19 growth surges in continental US States. Ln (A) and Fold (B) surges were not associated with the time quintile of a state's mandate effective date. C. Adjusted Fold maxima were lower in MQ2 than MQ4 and indistinguishable for all other pairwise comparisons. Different letters denote $p<0.05$ by all pairwise comparison Dunn tests after Kruskal-Wallis (C). n.s.: not significant by one-way ANOVA. Error bars: standard deviations (A, B) and interquartile ranges (C).

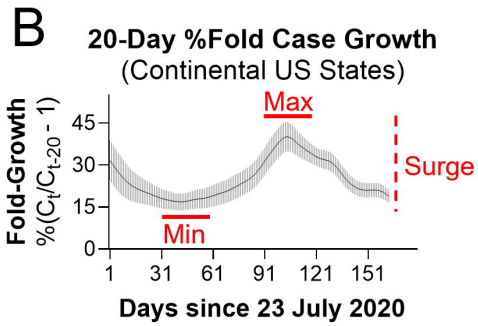
S3 Fig. **Inverse association between normalized cases and COVID-19 growth rates in continental US states**. A. At minima, mask use predicts lower population density-adjusted Fold Growth. B. At maxima, mask use does not predict population density-adjusted Fold Growth. C. Normalized cases do not predict mask use at minima. D. Normalized cases do not predict mask use at maxima. E. At minima, greater total cases predict lower growth rates in non-Northeast continental US states. F. At maxima, greater total cases predict lower growth rates in continental US states at maxima. Black circles (●): All continental US states. Hollow blue circles (○): Excluded Northeast states. Solid blue circles (●): Included Northeast states. Red squares (■): Midwest states. Green triangles (▲): Mountain-Plains States. Grey

triangles (▼): South states. Gold diamonds (♦): Pacific states. Simple linear regression used ordinary (A-D, F) or weighted (E) least squares and included all continental states except E (which excluded Northeast states). ε: Non-normal residuals by D'Agostino-Pearson test. R^2 values refer to unconstrained lines of best fit.

S4 Fig. **Limited association between mask use and COVID-19 case growth during Summer and Fall-Winter waves**. A. Mask use does not predict Summer Fold Growth in non-Northeast states. B. Mask use is marginally associated with lower population-adjusted Fold Growth in non-Northeast states. C-D. Normalized cases were associated with lower Ln Growth during Summer (C) and Fall-Winter (D) waves in non-Northeast states (C) and all continental US states (D), respectively. E-F. Mask use does not predict Fall-Winter Fold Growth (E) or population-adjusted Fold Growth (F) in continental US states. Simple linear regression used ordinary least squares and excluded Northeast states (A, C, D) or included all continental US states (B, E, F). ε: Non-normal residuals by D'Agostino-Pearson test. R^2 values refer to unconstrained lines of best fit.

S1 Table. **Supplemental Data Tables**. Worksheet A. 7-day rolling mean of total normalized cases (cases per 100,000 residents of each US state from CDC), 31 March 2020 - 1 March 2021. Worksheet B. Natural logarithmic daily case growth, 1 April 2020 – 1 March 2021. 20-day minima and maxima are denoted in red and gold, respectively. Mask mandate effective dates and modeled effective dates are provided for each state. Worksheet C. Population density calculations. See Materials and Methods for explanation of formulas. Worksheet D. 20-day Fold Growth, 12 August 2020 – 1 March 2021. Minima and maxima are denoted in red and gold, respectively. Population density-adjusted Fold Growth data are provided for each state. Worksheet E. Mask use for each US state at Ln and Fold extrema and during the Summer and Fall-Winter waves. Date range mask use values are simple arithmetic means of daily mask use over the specified date range. Numeric daily mask use (obtained from IHME) are provided.

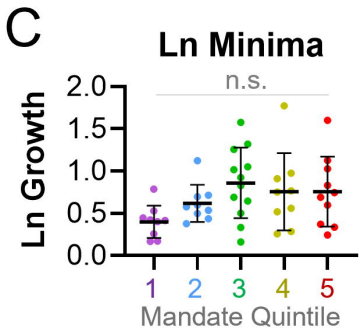


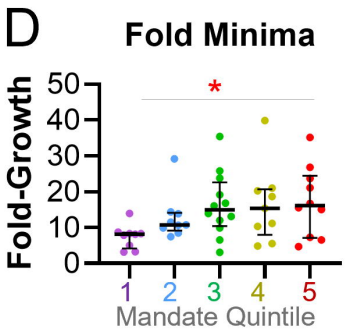


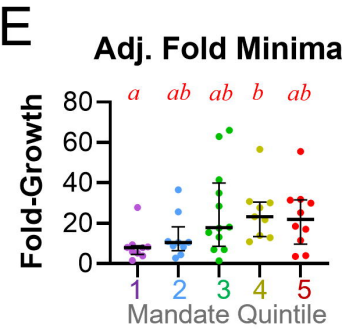
Mandates Issued by US States (Mandate Quintiles)

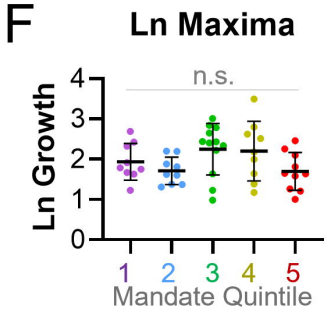
MQ1	MQ2	MQ3	MQ4	MQ5
Earliest			Latest	

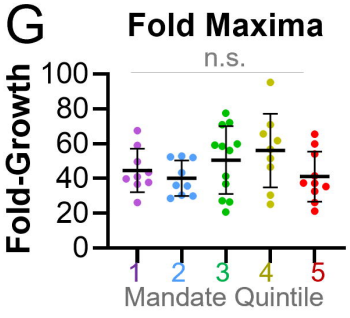
Quintile	Mandate Effective Date	Median Cases/100k
1	18 April - 16 May 2020	8841
2	29 May - 3 July 2020	8216
3	8 July - 27 July 2020	9001
4	1 Aug. - 9 Dec. 2020	10077
5	No Statewide Mandate	10005

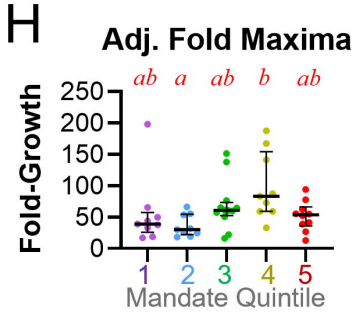


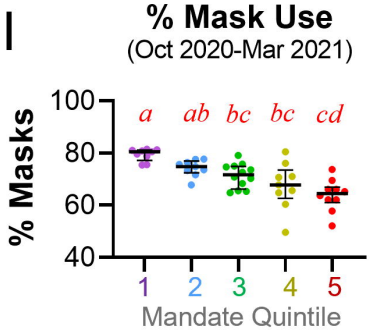


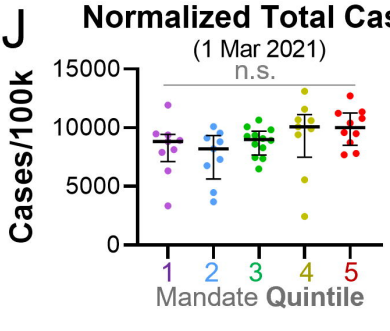


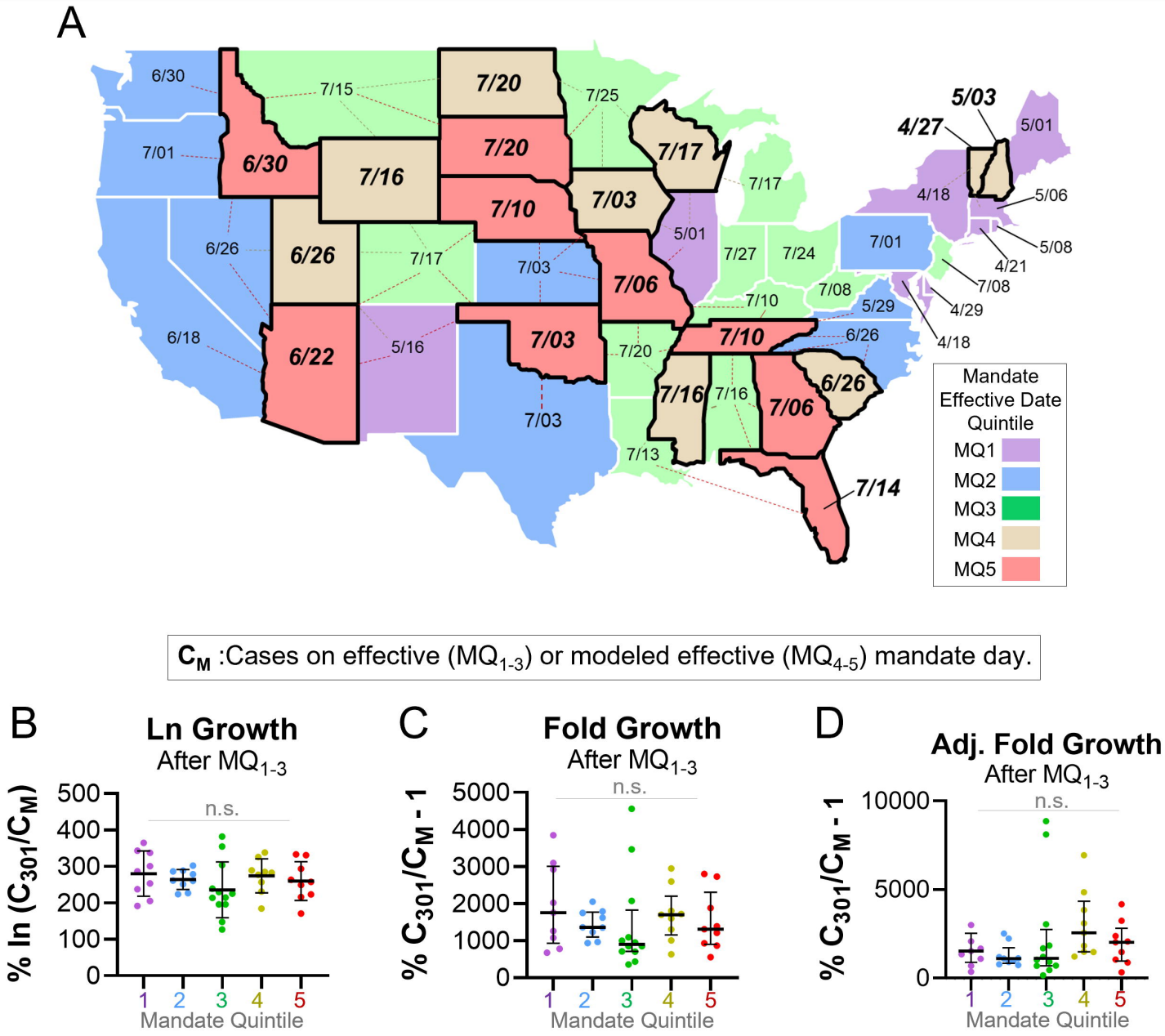










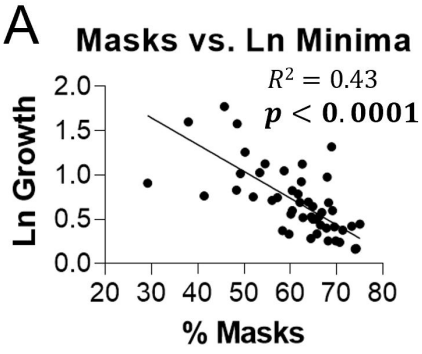

A
6/30
7/15
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7/01
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7/17
5/01
6/26
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6/26
7/03
7/13
7/14
5/03
4/27
5/01
4/18
5/06
5/08
4/21
7/08
4/29
4/18
Mandate Effective Date Quintile
MQ1
MQ2
MQ3
MQ4
MQ5
C_M :Cases on effective (MQ_{1-3}) or modeled effective (MQ_{4-5}) mandate day.
B
Ln Growth
After MQ_{1-3}
% ln (C_{301}/C_M)
n.s.
500
400
300
200
100
0
1
2
3
4
5
Mandate Quintile
C
Fold Growth
After MQ_{1-3}
% C_{301}/C_M - 1
n.s.
5000
4000
3000
2000
1000
0
1
2
3
4
5
Mandate Quintile
D
Adj. Fold Growth
After MQ_{1-3}
% C_{301}/C_M - 1
n.s.
10000
5000
0
1
2
3
4
5
Mandate Quintile

Mask Use Among US States (Use Quintiles)

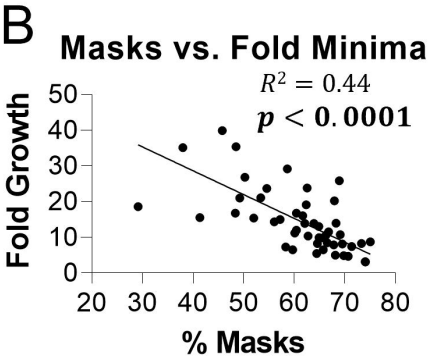
UQ1	UQ2	UQ3	UQ4	UQ5

Highest — Lowest

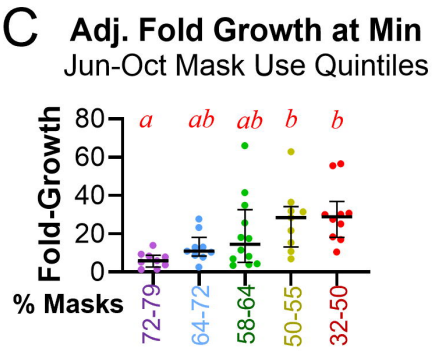
A



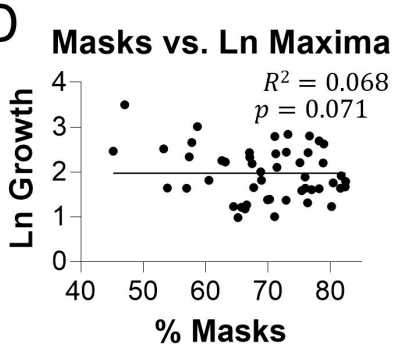
B



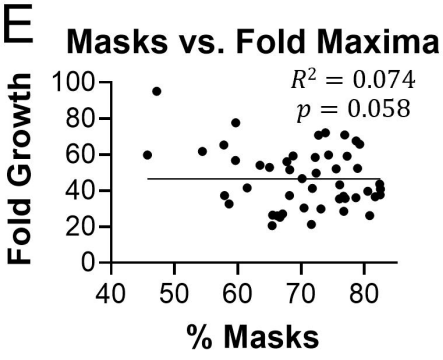
C



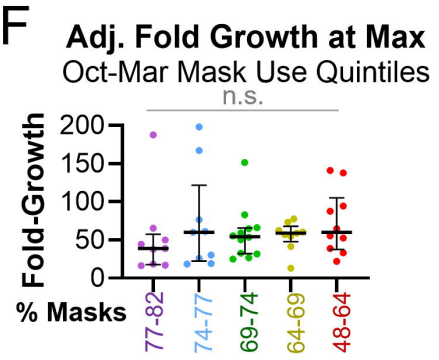
D



E



F

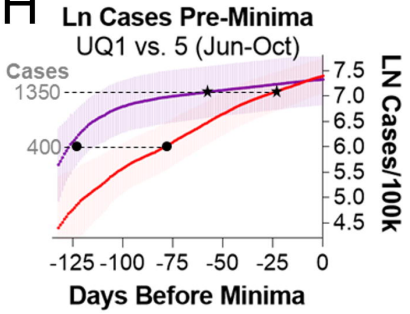


G

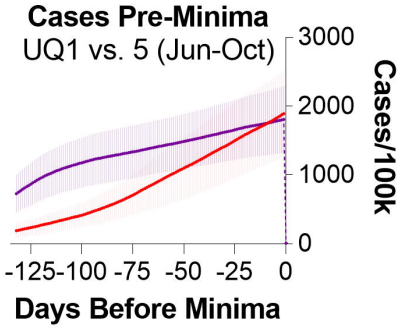
Mean ± 95% CI

	400-1350/100k in __ Days	% Masks Jun-Oct
UQ1	58.7 ±20.8	74 ±1.8
UQ5	73.8 ±17.4	43 ±4.2
p	0.22 (t test)	<0.001 (t test)

H



I

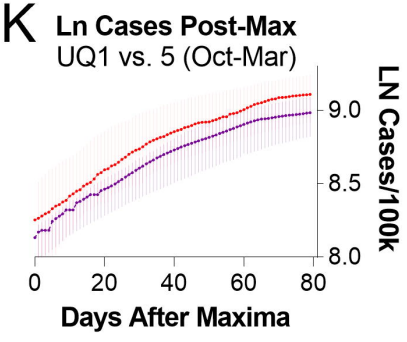


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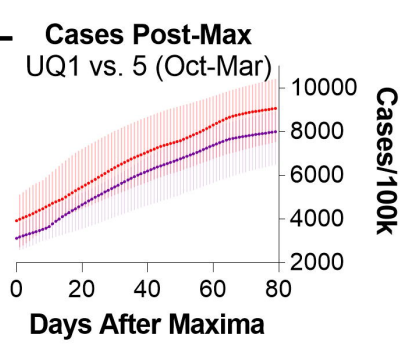
Median (InterQuartile Range)

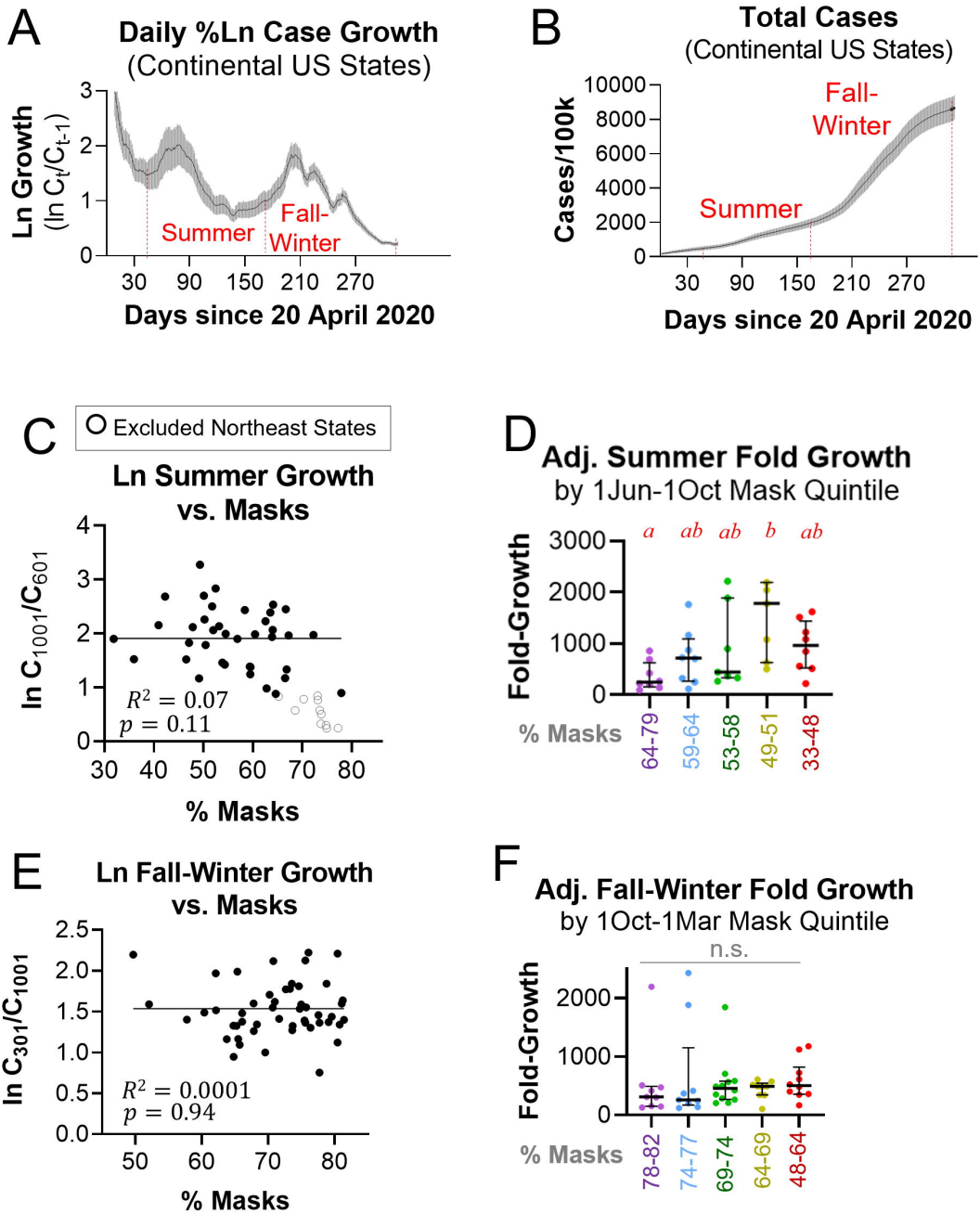
	Fold Growth 80 Days Post Max	% Masks Oct-Mar
UQ1	1.45 (1.3-2.0)	80 (78-81)
UQ5	1.31 (1.1-2.2)	61 (55-64)
p	0.78 (Mann-Whitney)	<0.001 (M-W)

K



L




A
Daily %Ln Case Growth
(Continental US States)
Ln Growth
(ln C_t/C_{t-1})
Summer
Fall-
Winter
Days since 20 April 2020
B
Total Cases
(Continental US States)
Cases/100k
Fall-
Winter
Summer
Days since 20 April 2020
C
Excluded Northeast States
Ln Summer Growth
vs. Masks
ln C_{1001}/C_{601}
$R^2 = 0.07$
$p = 0.11$
% Masks
D
Adj. Summer Fold Growth
by 1Jun-1Oct Mask Quintile
Fold-Growth
a ab ab b ab
% Masks
64-79
59-64
53-58
49-51
33-48
E
Ln Fall-Winter Growth
vs. Masks
ln C_{301}/C_{1001}
$R^2 = 0.0001$
$p = 0.94$
% Masks
F
Adj. Fall-Winter Fold Growth
by 1Oct-1Mar Mask Quintile
n.s.
Fold-Growth
% Masks
78-82
74-77
69-74
64-69
48-64

Physics of Fluids

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Note: This paper is part of the special topic, Flow and the Virus.
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ABSTRACT

The ongoing COVID-19 pandemic has highlighted the importance of aerosol dispersion in disease transmission in indoor environments. The present study experimentally investigates the dispersion and build-up of an exhaled aerosol modeled with polydisperse microscopic particles (approximately 1 μm mean diameter) by a seated manikin in a relatively large indoor environment. The aims are to offer quantitative insight into the effect of common face masks and ventilation/air purification, and to provide relevant experimental metrics for modeling and risk assessment. Measurements demonstrate that all tested masks provide protection in the immediate vicinity of the host primarily through the redirection and reduction of expiratory momentum. However, leakages are observed to result in notable decreases in mask efficiency relative to the ideal filtration efficiency of the mask material, even in the case of high-efficiency masks, such as the R95 or KN95. Tests conducted in the far field (2 m distance from the subject) capture significant aerosol build-up in the indoor space over a long duration (10 h). A quantitative measure of apparent exhalation filtration efficiency is provided based on experimental data assimilation to a simplified model. The results demonstrate that the apparent exhalation filtration efficiency is significantly lower than the ideal filtration efficiency of the mask material. Nevertheless, high-efficiency masks, such as the KN95, still offer substantially higher apparent filtration efficiencies (60% and 46% for R95 and KN95 masks, respectively) than the more commonly used cloth (10%) and surgical masks (12%), and therefore are still the recommended choice in mitigating airborne disease transmission indoors. The results also suggest that, while higher ventilation capacities are required to fully mitigate aerosol build-up, even relatively low air-change rates ($2\,h^{-1}$) lead to lower aerosol build-up compared to the best performing mask in an unventilated space.

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I. INTRODUCTION

Expiratory events, such as breathing, speaking, sneezing, or coughing, produce droplets, ranging in micrometers to millimeters in size, that serve as the primary pathway for the transmission of many infectious diseases, including coronavirus disease 2019 (COVID-19).[1–6] The ongoing COVID-19 pandemic underscored glaring gaps in our understanding of pathogen transmission required to effectively contain and prevent outbreaks, including, but not limited to, the development of reliable guidelines for safe social distancing,[1,2] usage of personal protective equipment (PPE),[7,8] and indoor ventilation.[1,9] The initial guidelines released in early 2020 by the World Health Organization and many national health agencies assumed that COVID-19 spreads primarily through large droplets that settle on surfaces within 1 to 2 m from the infected individuals. Although an intense scientific debate on the main transmission pathways of COVID-19 continues,[10,11] the mounting data on local outbreaks and relevant research[9,12,13] have prompted significant modifications to official guidelines, which now attribute the spread of COVID-19 to a wide range of droplet sizes, including both larger respiratory droplets and microscopic aerosols, produced during various expiratory events.[14–16]

Recent research has shown that smaller droplets and droplet nuclei containing significant viral load can travel up to 8 m during expiratory events,[3] substantially exceeding the present social distancing limits. Furthermore, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been shown to retain infectivity in aerosol form for a minimum of three hours past expiration from an infected person,[5] making it possible for the pathogens to be transported over extended distances due to ambient flows in indoor

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environments.[6,11,17–20] The critical importance of safety considerations at indoor workplaces has been recently highlighted by the analysis of various COVID-19 superspreader events,[13] the vast majority of which took place indoors. This underscores the importance of understanding the spread and accumulation of human-borne aerosols in indoor environments through the lens of social distancing, mask usage, occupancy, exposure duration limits, and ventilation.

Another contentious issue brought to the forefront of scientific debates by the COVID-19 pandemic is the efficacy of face masks.[7,8] Although some clinical evidence of respirator mask efficiency existed prior to the COVID-19 pandemic,[21] there is mounting evidence that continuous usage of appropriate face masks can reduce the rate of virus transmission;[7,8] however, the efficacy of different mask types for both the reduction of viral emissions and prevention of individual inhalation of pathogens requires further quantitative analysis.[1,2] This is of particular importance for indoor settings, where PPE can significantly affect the accumulation of the pathogens and their transmission through filtration and reduction/redirection of momentum during expiratory events.

Recent observational studies and meta-analyses of mask effectiveness have estimated that mask usage reduces the risk of respiratory virus spread by 70% to 80%.[22] Efficacy of home-made masks at preventing spread of influenza showed that surgical masks are three times more effective at blocking micro-organism transmission than home-made masks[23–25] although none of these studies include randomized control trials.[26] There is, however, evidence that communities in which masks were in widespread use exhibited significantly reduced community spread.[24,25]

The higher risk of infectious disease transmission in indoor environments, particularly with poor ventilation, has been recognized in the scientific community well before the onset of the COVID-19 pandemic[27] and prompted a number of studies on transmission and aerosol transport indoors.[28–31] The ongoing COVID-19 pandemic has re-invigorated the research efforts in this area due to the growing association between local outbreaks and various indoor settings. For example, Qian *et al.*[13] reported that all except one of the 318 analyzed COVID-19 outbreaks were associated with indoor spaces. Bhagat *et al.*[32] provided an overview of potential effects of ventilation on the indoor spread of COVID-19, and general guidelines for minimizing airborne transmission are detailed in Morawska *et al.*[11] Mittal, Meneveau, and Wu[33] proposed a framework for estimating the risk of airborne transmission of COVID-19 based on probabilistic factors and highlighted the critical need for reliable quantification of key model parameters for future modeling and validation.

The airborne transmission of pathogens in indoor environment is directly related to the dynamics of virus-laden aerosols.[28] The associated transmission risk models are based on either simplified analytical formulations[34–36] or computational fluid dynamics (CFD) tools.[17,33,37] The former typically employ a well-mixed room assumption, where pathogen carrying aerosols are assumed to be instantaneously and uniformly distributed in a given room, such as in the classical Wells–Riley equation.[34] Such simplified modeling has also been employed for COVID-19 risk assessment.[36,38] On the other hand, at the expense of notably higher computational costs and model complexity, CFD-based modeling can provide added insight into spatial evolution of aerosols produced by various expiratory events in realistic indoor environments. Along these lines, a number of studies have modeled airborne spread of COVID-19;[17,39] however, all models rely on quantitative results from experimental studies for an array of input parameters, such as the initial number and size distribution of aerosol particles and initial velocities and duration of expiratory events. Further, the use of PPE, including face masks, needs to be incorporated into computational models, which either significantly complicates the modeling[40] or requires experimental data.[33] Thus, there is a need to incorporate the progress made in a number of recent qualitative and quantitative studies focused on PPE performance into larger-scale investigations focused on aerosol dispersion in indoor environments. This will provide a more comprehensive outlook on workplace health and safety, where the use of PPE is not only often mandated by local legislature, but also can help mitigate the limitation of available ventilation options.

The present study is aimed at bridging the gap between studies focused on face mask efficacy assessment and indoor dispersion of aerosols by experimentally evaluating the aerosol accumulation in a controlled indoor environment, with various types of face masks and ventilation settings considered. Typical nasal breathing is modeled in the present work using a high-fidelity physical model. While this type of expiration is known to produce the lowest aerosol counts per event, this type of breathing is the most common type of expiration and thus accounts for the majority of aerosol production during continuous occupancy at work and public places.[41] A combination of flow visualization, velocity and concentration measurements, and modeling is used to provide a quantitative outlook on the effect of different face masks on aerosol build-up over extended time periods in a generic indoor setting. The result provides critical estimates of apparent filtration efficiency essential for producing adaptive health and safety guidelines for workplaces during pandemic and epidemic events as well as for the development of advanced modeling tools.

II. METHODOLOGY

Experiments were conducted in the Fluid Mechanics Research Laboratory at the University of Waterloo. An overview of the setup is provided in Fig. 1(a). All tests were performed in a $7.8 \times 5.7 \times 2.7$ m room with an air volume of approximately 120 m^3 that was vacated except for the test model and essential equipment. To study the dispersion of exhaled aerosols in an unventilated space, the room was sealed from all surroundings, which included shutting off the ventilation system and sealing all air passageways through the room envelope.

The test model was a Prestan adult CPR manikin (model PP-AM-100-DS), placed upright in a seated position on a chair in the center of the room [Figs. 1(a) and 2(a)]. Breathing with aerosol-laden exhalation was provided by a custom breathing apparatus, the details of which are provided in Fig. 1(b). The positive and negative air pressure cycle was provided by a mechanical ventilator (developed and donated to the project by Crystal Fountains, Inc.), which operated through the repeated compression and decompression of an adult size med-rescuer bag-valve-mask (BVM) (1500 mL bag volume) by a pneumatic piston. Physiological parameters representative of typical adult nasal breathing[42] were set in terms of respiratory period/rate, exhalation time, and breath volume through adjustment of the piston plunging depth, forward and backward stroke speeds, and contact time with the BVM, resulting in the breathing parameters reported in Table I. These parameters were monitored and logged during operation of the ventilator via forward and backward stroke limit switches

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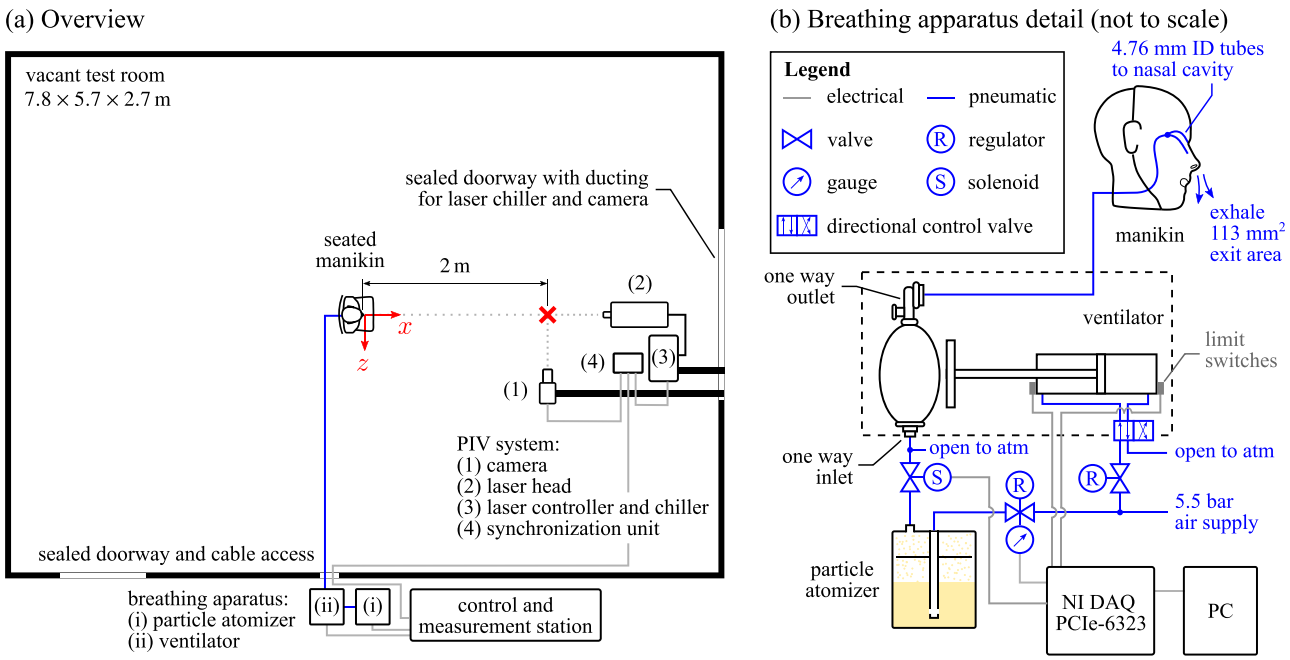


FIG. 1. (a) Overview of the experimental setup and (b) details of the breathing apparatus.

on the piston, with signal sampling performed using National Instruments' LabVIEW software and a PCIe-6323 DAQ.

Aerosols were produced by atomizing olive oil into particles with a mean diameter of about 1 μm (volume-weighted) using a Laskin nozzle style atomizer based on the designs of Kahler, Sammler, and Kompenhans.[43] Controlled injection of particles into the breathing stream was achieved using a normally closed solenoid valve located downstream of the atomizer, the opening of which was synchronized with the breathing cycle through LabVIEW. The solenoid was opened at the start of inhalation (i.e., at the forward stroke limit) and was held open for 2.0 s as this matched the re-inflation time of the BVM without particle injection. The particle production rate was controlled by a pressure regulating valve upstream of the atomizer, the pressure of which was logged in LabVIEW and remained within 0.172 bar ± 0.5 % throughout operation. This pressure level was verified to be below the minimum pressure needed to open the BVM outlet valve, therefore ensuring exhaust from the BVM during the exhalation (compression) portion of the cycle only. Olive oil was selected for the aerosol liquid

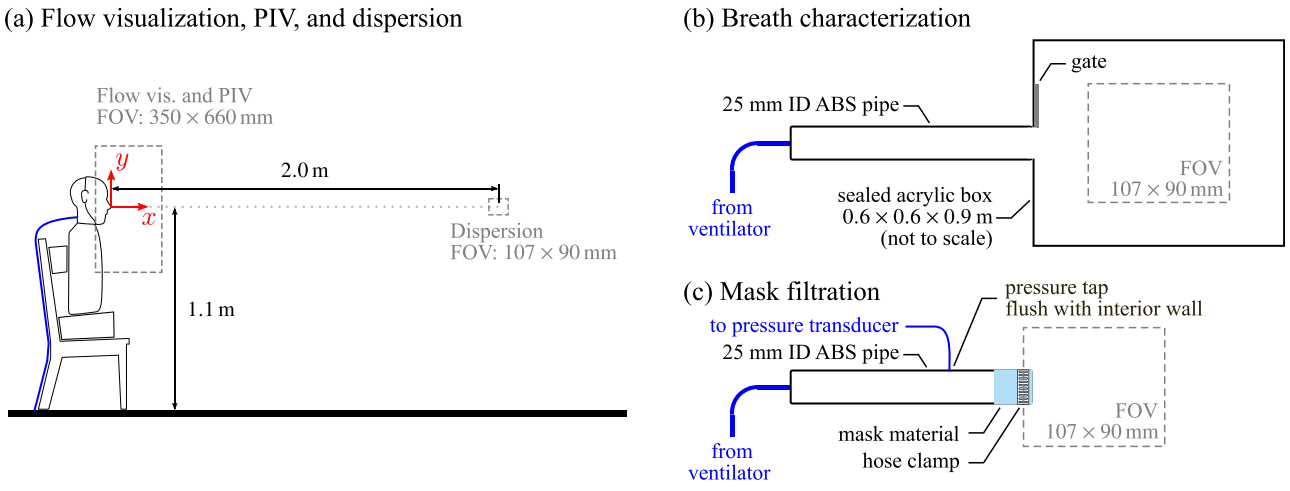


FIG. 2. Profile view of experimental setups for (a) flow visualization, PIV, and dispersion tests, (b) breath characterization, and (c) mask filtration tests.

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TABLE I. Breathing and aerosol production parameters (95% confidence).

Parameter	Value	Unit
Exhalation time	1.75±2%	s
Respiratory period	4.32±2%	s
Respiratory rate	13.9±2%	breath/min
Breath volume	690±3.5%	mL
Avg. exhalation flow rate[a]	0.40±4%	$L\,s^{-1}$
Particles injected	$2.75 \times 10^8 \pm 7.5\%$	particles/breath
Breath particle concentration	$3.98 \times 10^8 \pm 8\%$	particles/l

[a]Flow rate computed over exhalation time.

component as its use in an atomizer of this design is known to give a polydisperse distribution of particle sizes with a mean diameter of approximately 1 μm,[43] matching the smaller scale of aerosols expelled during typical human respiration,[41,44,45] and the nuclei formed after larger droplets evaporate.[46] Furthermore, oil-based aerosols offer good light scattering properties for optical detection, are charge-neutral,[47] and have a residence time on the order of several hours, in comparison to several minutes for water-based alternatives, which is critical given the approximate one hour viability half-life of the SARS-CoV-2 virus[5] and that virion containing droplet nuclei may remain suspended in air for hours.[2] It should be noted that higher exhalation aerosol concentrations than those typical for normal breathing[44,48,49] was employed (Table I) to reduce measurement uncertainty in experimental aerosol concentration estimates. For consistent data comparison, all concentration measurements are normalized by the initial breath particle concentration, which was maintained constant throughout the study.

The breathing apparatus and measurement control station were located outside of the test room [Fig. 1(a)], with all connections to the interior passed through a sealed cable access. This allowed for tests to be controlled from outside the room, thereby removing any unintended effects the presence of the breathing apparatus, control and measurement equipment, and/or test operators may have had on the results. The output of the ventilator was connected to the manikin using a 12.7 mm inner diameter flexible tube, which was split into two 4.76 mm inner diameter tubes that exhaust into the manikin's nasal cavity. The total nostril exit area was 113 mm^{-1}, which is within the expected range for male adults.[50] The limitations of this experimental setup are the absence of a thermal plume typically present around a human being[32] and that the inhalation does not occur at the manikin, but rather at the inlet of the BVM [Fig. 1(b)].

Qualitative and quantitative measures of aerosol dispersion from the test model were performed using simultaneous illumination and imaging of particles with a laser and digital camera, respectively [Fig. 1(a)]. The methodology constitutes planar particle image velocimetry (PIV) measurements,[51] with the specific equipment employed including an EverGreen 70 mJ/pulse Nd:YAG laser, PCO sCMOS cameras (5.5 MP, 6.5 μm pixel pitch) fitted with 105 mm focal length macro lenses, and a LaVision PTUx timing unit. This equipment was located in the test room, with the air needed for camera and laser cooling supplied through dedicated ventilation ducting connected to a nearby sealed doorway, ensuring no air exchange with the test environment. Control and data acquisition were performed from the exterior measurement station using LaVision's DaVis 10.0 software. The ventilator limit switch signals were passed into the PIV timing unit, allowing for measurement synchronization with the breathing cycle.

Measurements involving the manikin were performed in two locations, both depicted in Fig. 2(a), with the measurement planes located at the mid-span of the test model (within the x-y plane). The first measurement field of view (FOV) measured 350 × 650 mm, covering the area of exhaled breath for both masked and unmasked cases, and was imaged using two cameras, each at a magnification factor of 0.04. Here, flow visualization and PIV images were acquired at 15 Hz, with the latter requiring aerosol seeding of both the breathing stream and ambient environment. Double-frame PIV images were acquired using frame separation times between 15 and 20 ms, resulting in particle displacement below approximately 20 pixel. The particle images were then processed in DaVis 10 using sliding background subtraction and intensity normalization, followed by an iterative, multi-pass cross correlation algorithm with a final window size of 32 × 32 pixel (50% overlap) to determine local flow velocities at a spatial resolution of 2.98 mm.

At the second measurement location, a single camera was used to image a 107 × 90 mm FOV centered at the height of the exhalation point (1.1 m from the floor) but at a 2 m distance [Fig. 2(a)]. Here, single images were acquired at a rate of 0.25 Hz for up to 10 h in order to track the dispersion of exhaled aerosols from the test subject. In order to minimize the gradients of light intensity within the image, the laser sheet was expanded substantially larger than the dimensions of the field of view (approximately 200% more), such that the core region of the laser beam covered the entire field of view. The directivity of dispersion was investigated by rotating the manikin about the y-axis while keeping the measurement location fixed, with orientation angles of 0°, 90°, and 180° considered. For each case, imaged particles (2–3 pixel in the imaging plane) were detected and counted using a particle detection algorithm in DaVis 10.1 software, providing the measure of local particle concentration based on the average over the local measurement volume. The particle detection algorithm measures particle counts by scanning the image for peaks in local intensities after the image is pre-processed using a sliding minimum subtraction and low-pass Gaussian filter to enhance the individual intensity peaks. A threshold for the background noise is employed and kept constant between all the cases for consistency.

A total of seven PPE configurations were considered, with the manikin fitted with (i) no mask, (ii) an unvalved KN95 mask, (iii) a typical three-ply blue pseudo-surgical mask, (iv) a three-ply cotton cloth non-medical mask, (v) a 3M R95 particulate respirator (equivalent to N95 for human borne aerosols), (vi) an unvalved KN95 mask with 3 mm gaps around cheeks and nose, and (vii) a KN95 mask with a single one-way valve on the left side. The parameters presented in Table I were kept constant across all cases. To adjust for a higher average rigidity of the manikin face and have repeatable mask fits, straps typically worn around the ears were tightened by anchoring them to a single peg located inline with the top of the ears and at the center of the back of the head. Note that this was not the case for the R95 respirator, which has straps that circumnavigate the head and neck. Tests with the KN95 mask with artificial gaps [case (vi)] were performed by first ensuring the same baseline fit as that of the unvalved KN95 mask [case (ii)], with the gaps created by 3 mm thick pieces of vinyl foam placed on the cheeks and cheekbones of the manikin, which produced consistent leakage sites similar to the approach employed by Weber

11 July 2024 19:12:39

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et al.[52] The length of the foam pieces was minimized to reduce blockage while ensuring consistent gap dimensions between multiple runs.

Tests characterizing breath particle concentration, breath volume, and ideal mask filtration efficiency were also performed, with the setups used presented in Figs. 2(b) and 2(c). These tests utilized the same breathing apparatus, breathing parameters, and imaging setup as the dispersion tests, with the outlet of the ventilator fed to a 25 mm inner diameter rigid pipe. For characterization of the breath particle concentration, the outlet of the pipe was fed into an acrylic box (dimensions $0.6 \times 0.6 \times 0.9$ m) which was sealed off after a single breath and images were acquired at 1 Hz for 0.5 h. A uniform particle distribution was reached after approximately 15 min, after which the number of particles was measured. From this, and the FOV area and laser sheet thickness (2.0 mm), the total number of particles contained in the volume and therefore injected by the breath was estimated, resulting in the value reported in Table I. The provided uncertainty range is based on the variance found across ten runs of repeatability.

For breath volume, ideal mask filtration efficiency, and mask pressure drop characterizations, the outlet of the pipe was exhausted to open air and the measurement field of view was moved to the exit of the pipe, as shown in Fig. 2(c). Mask material was sealed around the pipe outlet using a 3 mm thick o-ring and hose clamp. PIV double-frame measurements with a frame separation times of 666 μs were acquired at 15 Hz for the duration of the exhalation over 50 cycles. Image processing was performed in DaVis 10 using sliding background subtraction and intensity normalization, followed by vector calculation using iterative, multi-pass cross correlation with a final window size of 24×24 pixel (75% overlap), yielding a spatial resolution of 0.25 mm. The resulting velocity field data were integrated to give phase average volumetric flow rate, yielding the total breath volume reported in Table I. A pressure tap flush with the interior of the pipe wall was installed two diameters upstream of the pipe exit and was connected to a Setra pressure transducer (Model 264), providing static pressure measurements relative to the local atmospheric pressure. For ideal mask filtration efficiency, the total number of particles exhausted over an exhalation cycle was counted. The result was then compared to the case with no mask, with 50 breath cycles used to establish a confidence interval.

III. RESULTS AND DISCUSSION

This section first discusses the ideal filtration characteristics of various masks used in the present study. Thereafter, the near-field flow visualization and velocity measurements around the face of the test subject are discussed. Finally, the results corresponding to particle dispersion in the test room are presented along with the supporting model results.

A. Baseline mask characteristics

Significant variability in essential mask characteristics has been reported in previous studies, which tends to be more significant for non-certified mask types. Thus, baseline parameters for each mask type considered in the present study have been established experimentally and ensured to be consistent for the same mask types tested here. The baseline ideal filtration characteristics of the studied masks are established for the breathing parameters (Table I) and aerosol employed in the study. An estimate of ideal filtration efficiency, and the associated pressure drop across the mask, is established through tests where the mask is sealed at the point of exhaust [Fig. 2(c), as described in Sec. II], thereby removing the dependency on mask fit to the test model. The results are presented in Fig. 3(a), showing the particle concentration during exhalation, with results averaged over 50 cycles and normalized by the peak concentrations reached in the unfiltered case (no mask).

In Fig. 3(a), for the no-mask case, exhalation begins at approximately 0.5 s, with particle counts downstream of the outlet increasing rapidly after the initiation of the exhalation, followed by an extended period of stabilization at the peak value, and a subsequent decrease in the particle concentration toward the end of the exhalation cycle. A

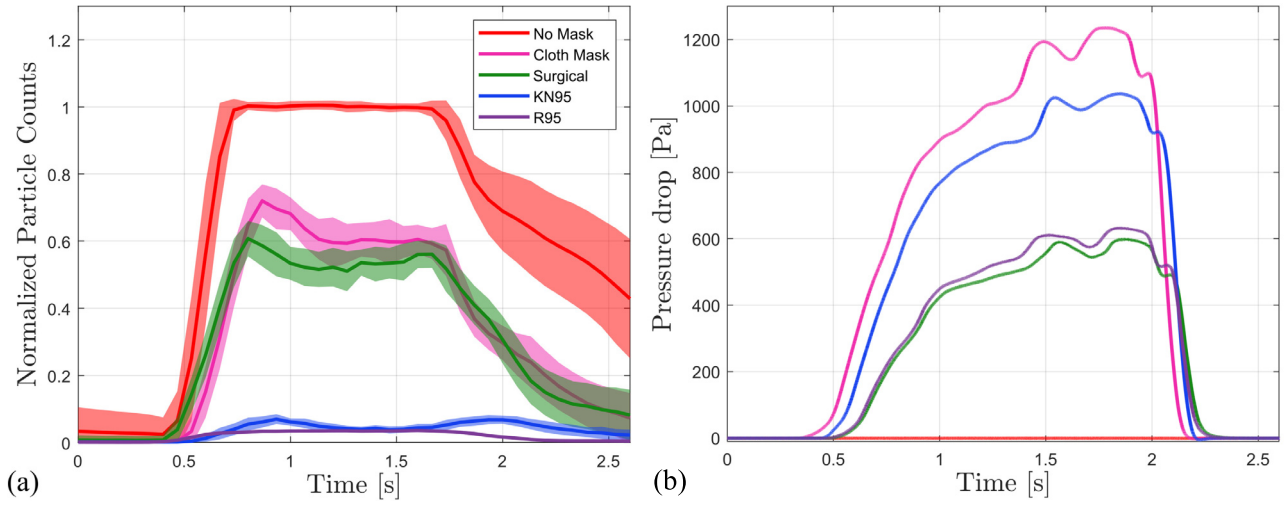


FIG. 3. (a) Particle counts after aerosol particles are passed through various masks and normalized by the particle counts at the plateau in the no-mask case, and (b) associated pressure drop across the mask at a flow rate of 0.4 L s^{-1}. Results are from the setup shown in Fig. 2(c) and are averaged over 50 exhalation cycles. Shaded areas correspond to ± 1 standard deviation. The standard deviations for pressure drop measurements are negligible, and thus, not visible.

11 July 2024 19:12:39

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similar trend is observed for the tested mask cases, with lower plateau values reached as a result of filtration. The ideal filtration efficiency for a mask is estimated by computing the change in the average particle concentration within the time interval of 1 and 1.5 s, i.e., the plateau value, relative to the no-mask case, with obtained results summarized in Table II. The efficiency of the KN95 and R95 masks is the highest at approximately 95% and 96%, respectively, which agrees well with the rated efficiencies for these masks in the absence of leakage. Such high efficiencies are attributed to the electrostatic filters embedded in these masks, which have been shown to effectively filter both charged and neutrally charged particles.[53,54] Filtration efficiencies for the blue surgical mask and cloth masks are significantly lower at 47% and 40%, respectively, meaning that more than half of the aerosol particles pass through these masks. The present results are in reasonable agreement with Jung *et al.*,[55] who compared filtration efficiencies of a number of medical and non-medical masks. Note that a relatively wide variation of filtration efficiencies has been reported for these types of PPE in previous studies,[56–58] largely attributed to the lack of stringent filtration performance standards.

Pressure drop across a mask and the corresponding flow resistance coefficient ($\Delta P/Q$, where Q is the peak flow rate) are important considerations since both provide measures of mask breathability and, consequently, comfort when worn by an individual, with a lower pressure drop and resistance coefficient indicating higher comfort. The results in Fig. 3(b), along with the parameters summarized in Table II, show that the KN95 and cloth masks have the highest pressure drops and resistance coefficients, indicating relatively poor breathability. In comparison, the pressure drop across the R95 mask is approximately 40% lower than that of the KN95 mask, which is significant given a similar level of filtration efficiency. Pressure drop across the surgical mask is comparable to that of the R95, indicating a similar level of breathability and comfort; however, this comes at the cost of significantly reduced filtration efficiency. It should be noted that substantial variability in measured pressure drop can occur even for the same mask types from different manufacturers;[26,56,57,59,60] however, the trends observed in the present measurements fall within the range of values reported previously. Therefore, these results can serve as a qualitative guide toward the balance between ideal filtration performance and breathability for common face masks.

B. Exhalation flow characterization

With baseline filtration characteristics of the masks established, their effect on the evolution of exhaled breath through the nose of the test model is now considered in the vicinity of the face using particle flow visualization and velocimetry techniques. Results for the KN95 and surgical mask are seen to qualitatively represent a high-efficiency mask and common cloth/non-medical masks, respectively. Thus, these two configurations are used here as representative face mask groups, and the results are contrasted with the no-mask case. Figure 4 illustrates nasal exhalation through an instantaneous flow visualization image at the vertical mid-plane of the face and at a phase angle of 180° within the breathing cycle (exhalation begins at 0°). Multimedia views included for each case depict the flow development over a few breathing cycles. The exhaled flow in the case of no mask [Fig. 4(a) (Multimedia view)] is typical of a transient turbulent jet, with the expelled aerosols directed downwards and the jet front reaching a distance from the nose of approximately 300 mm within approximately 1 s. The turbulent nature of the jet is apparent, with small scale eddies, visualized by particle clouds, present throughout the jet core, with the darker patches around the jet perimeter showing fluid entrained into the jet by turbulent mixing. In fitting the manikin with a mask, both the KN95 and surgical masks [Figs. 4(b) (Multimedia view) and 4(c) (Multimedia view), respectively] are successful in arresting nearly all forward momentum of the exhaled jet. As noted across the literature,[61–63] this is the primary protective mechanism of a mask for direct exposure to aerosols as it serves to reduce and redirect the forward momentum of the exhaled breath, which, as will be shown in Sec. III C, has a significant effect on the dispersion of exhaled aerosols away from the subject over time.

It is important to note that, while masks [Figs. 4(b) (Multimedia view) and 4(c) (Multimedia view)] decrease the forward momentum of the respiratory jet, a significant fraction of aerosol escapes the masks, particularly at the bridge of the nose. Further, aerosols can also be seen in front of the surgical mask due to the lower material filtration efficiency (Table II). These leakages are more readily apparent in the multimedia views. Recent studies employing similar visualization techniques for other types of expiratory events, such as sneezing, coughing, laughing, and speaking,[32,61,64] show similar leakage through surgical and common cloth masks. In those studies, higher pressure differences were imposed and therefore particles passing through the mask may have been expected, while the present results highlight that the pressure difference created by normal breathing is sufficient to cause aerosols to pass through the fabric of a surgical mask. In contrast, such leakage is negligible in the KN95 case [Fig. 4(b) (Multimedia view)], which is representative of high quality, certified masks.

As previously noted, a significant quantity of aerosol escapes at the bridge of the nose in Figs. 4(b) (Multimedia view) and 4(c) (Multimedia view), which highlights the importance of the fit of the mask to the face. Here, the fit of each mask is typical of appropriate usage, with the straps tightened (as outlined in Sec. II) and the built-in wire shaped to the bridge of nose. Nonetheless, aerosols escape at the perimeter of the mask due to inevitable imperfections in the mask fit, with the most significant quantity of particles escaping at the bridge of the nose. Other leakage sites include the interface of the mask edges with the cheeks and lower jaw [not captured in Figs. 4(b) (Multimedia view) and 4(c) (Multimedia view) due to laser sheet positioning]; however, these results and other supplementary measurements (not shown for brevity) confirm that leakage at the bridge of the nose far exceeds all other leakage points. At the bridge of the nose, the particle clouds that escape the masks are relatively dense in comparison to the exhaled

TABLE II. Filtration characteristics of various masks at an integrated flow rate of 0.4 L s^{-1}. ΔP and P_{dyn} indicate the peak pressure drop and the peak dynamic pressure, respectively, obtained at the peak flow rate ($Q = 0.61$ L s^{-1}). The 95% confidence intervals on the mean filtration efficiencies and peak pressure drop are within ±1.5% and ±0.25%, respectively, for all the cases.

Mask material	Filtration efficiency (%)	ΔP (Pa)	$\Delta P/P_{dyn}$	$\Delta P/Q$ (Pa s/m^3 × 10^{-5})
Cloth	40	1196	1356	19.67
Surgical	47	573	650	9.42
KN95	95	1014	1150	16.68
R95	96	606	687	9.97

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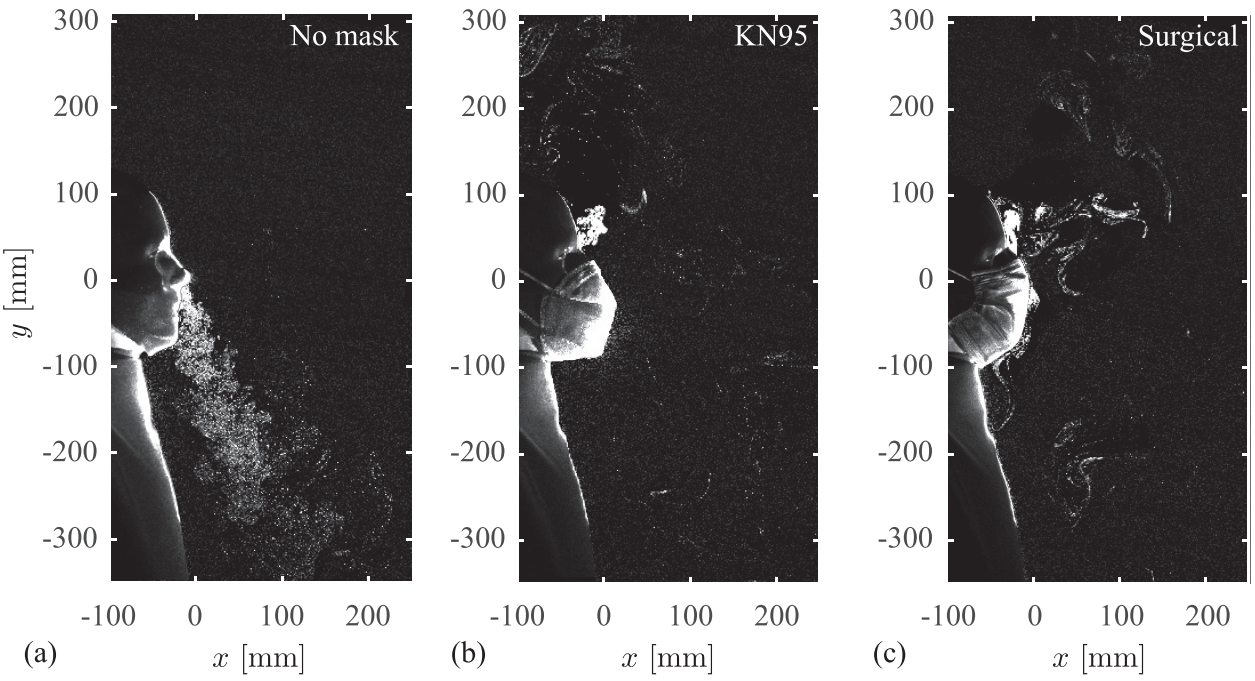


FIG. 4. Instantaneous flow visualizations at 180° within the breathing cycle for the (a) no mask, (b) KN95, and (c) surgical mask cases. Multimedia views: https://doi.org/10.1063/5.0057100.1; https://doi.org/10.1063/5.0057100.2; https://doi.org/10.1063/5.0057100.3

jet in the no-mask case, which is attributed to the significant redirection of momentum needed to force particles out at the top of the mask, resulting in much lower exit velocities and hence reduced turbulent diffusion. The observed particle concentrations just outside the mask qualitatively agree with the results of Sickbert-Bennett *et al.*[65,66] who obtained fitted filtration efficiency (FFE) estimates of more than 95% for inhalation with N95 type masks. However, their FFE estimates are based on the particle concentration entering the mask from the ambient air and are not directly indicative of the mask efficiency when considering the exhalation of aerosols. The results in Fig. 4 illustrate that a notable amount of particles leak out at the perimeter of all masks, which is expected to result in notably lower effective filtration efficiency, compared to ideal filtration efficiency, when exhalation is considered.

Figure 5 presents phase-averaged velocity fields, again at a phase angle of 180° within the breathing cycle, matching Fig. 4. Multimedia views are also provided for each case, showing phase-averaged velocity field development over the full exhalation cycle. Note that these measurements were performed at the mid-plane of the manikin face, not at the center of a given nostril. For the case with no mask [Fig. 5(a) (Multimedia view)], typical turbulent jet characteristics are noted, with jet propagation and spreading rate typical of accelerating jet flows.[67] Within the measurement plane, peak velocities range from 0.10 to 0.12 $\mathrm{m\,s^{-1}}$ in the core of the jet, which is within the range of velocities investigated in previous studies for normal breathing.[53,56,68–71] The results confirm that the forward momentum is decreased dramatically when the subject is fitted with a mask [Figs. 5(b) (Multimedia view) and 5(c) (Multimedia view)], as was seen in the flow visualizations (Fig. 4). For these cases, the expelled flow is directed primarily upward and backward by the mask and remains attached to the forehead due to the Coanda effect, with peak velocities reduced to less than 0.10 $\mathrm{m\,s^{-1}}$. For the surgical mask, the flow that penetrates through the front of the mask is of relatively low forward momentum and, consequently, much lower penetration depth, as seen in Fig. 4(c) (Multimedia view). Together, the flow visualization and PIV results (Figs. 4 and 5, respectively) highlight important safety aspects when considering aerosols dispersed by an individual's breathing. When not fitted with a mask, exhalation from the nose produces a relatively strong turbulent jet containing well mixed particles that will disperse relatively quickly away from the subject. While in the case of equipping a mask, the jet momentum is significantly reduced and redirected, leading to leakages of aerosols at any point where the mask does not maintain a tight seal to the face. Based on the results obtained here, the leakages are most significant at the bridge of the nose, leading to dense aerosol clouds exiting near and remaining close to the fore and top of the head.

C. Aerosol dispersion in an indoor environment

Noting the significance of both the ideal filtration characteristics (Sec. III A) and fit of a mask (Sec. III B), it is apparent that both effects must be taken into account in order to provide an accurate measure of the effectiveness of a mask in reducing the dispersion of an aerosol exhaled by an individual. This is investigated through the measurement of aerosol dispersion from the test model in a vacant indoor space over a period of 10 h, with the particle concentration measured at a 2 m distance from the subject [Fig. 2(a)], aligned with the widely accepted social distancing recommendations.

In an enclosed space with negligible convective effects, such as the room in which the tests are conducted, the concentration of

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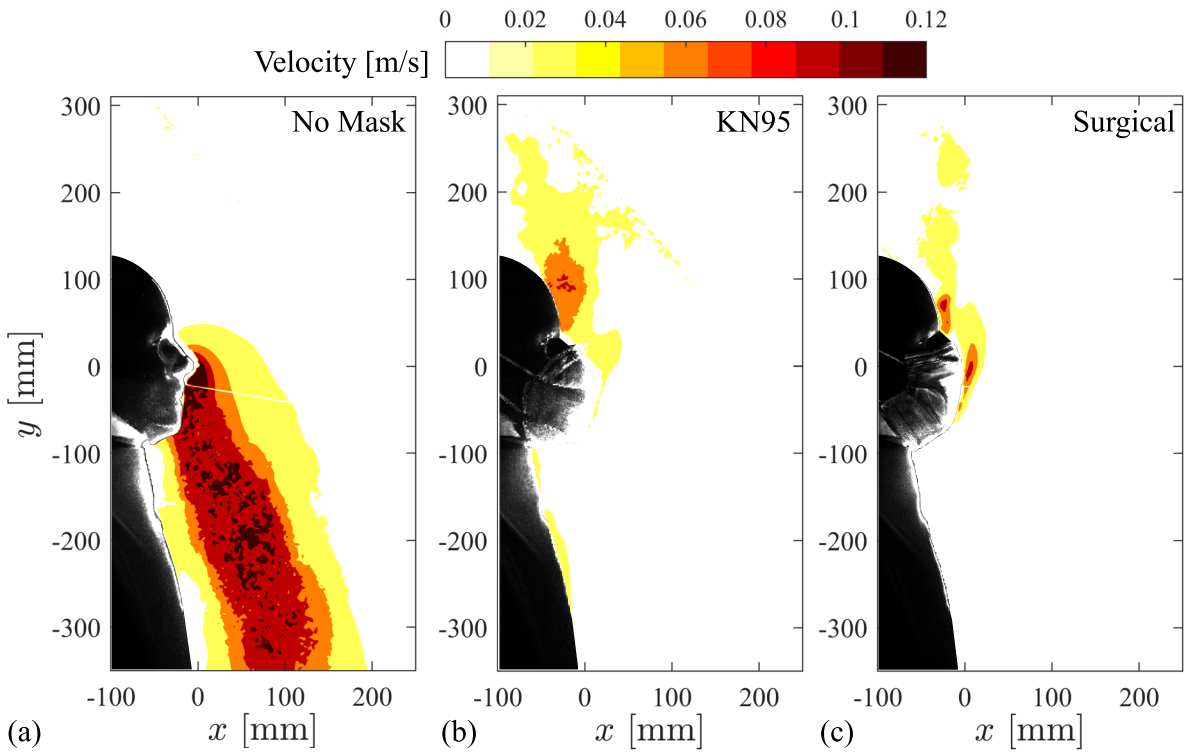


FIG. 5. Phase-averaged velocity fields at 180° within the breathing cycle for the (a) no mask, (b) KN95, and (c) surgical mask cases. Multimedia views: https://doi.org/10.1063/5.0057100.4; https://doi.org/10.1063/5.0057100.5; https://doi.org/10.1063/5.0057100.6

dispersed aerosols away from the source is governed by the unsteady diffusion equation

$$\frac{dc}{dt} = \nabla \cdot (K \nabla c) + R - \lambda c, \tag{1}$$

where c is the concentration of aerosol particles (particles m^{-3}), t is time, K is the diffusion coefficient (m^2 s^{-1}), R is the particle injection rate (particles m^{-3} s^{-1}), and the sink term containing the decay rate λ (s^{-1}) which takes into account particle decay.[35]

While Eq. (1) has been used for modeling in a number of previous studies,[17,32,35,72] the model outcomes are predicated on appropriate estimation of the injection rate, decay, and diffusion terms, with the commonly employed coarse estimates only providing qualitative understanding of the spatial and temporal evolution of particle concentration for various room and source configurations. In practice, it is extremely challenging to obtain reasonable estimates for these values,[32] while computational results remain extremely sensitive to these parameters.

A significant simplification to Eq. (1) is commonly employed by assuming instantaneous distribution of produced aerosols in the room as in the following equation:

$$\frac{dc}{dt} = R - \lambda c. \tag{2}$$

The solution to Eq. (2), subject to the initial condition $c^*(t = 0) = 0$, is given by

$$c^*(t) = \frac{R^*}{\lambda^*}(1 - e^{-\lambda^* t}). \tag{3}$$

For the purposes of practical data assimilation considered in the present study, the underlying simplification absorbs the effect of diffusion into the sink and source terms. This makes the solution dependent on the spatial location, and the relevant parameters are marked with an asterisk (c^*, R^*, λ^*). Equation (3) models the temporal evolution of concentration in a typical first-order fashion with a saturation concentration of $c^*_{sat} = R^*/\lambda^*$. Although previous studies have noted significant deviations of diffusion-based computational results from the well-mixed model,[72–74] the simplified model will be shown to fit well with the experimental data and thus provides a suitable comparison basis for saturation conditions. The latter allows for relative source strength comparisons between different test cases, which is of particular importance for the evaluation of the apparent mask filtration efficiency.

Experimental results from the aerosol dispersion tests are presented in Fig. 6, with results normalized by the average particle concentration of a single breath (Table I) and smoothed using a 10 min moving average. For clarity, the variability between repeated measurements is illustrated by the shaded regions only in the no-mask and KN95 cases, which are representative of the typical variability observed in all the tested cases. In Fig. 6(b), the results are also plotted on a logarithmic scale and are fitted based on the typical first-order behavior described by Eq. (3). The obtained least squares fit parameters are presented in Table III, with the corresponding confidence intervals determined based on repeated tests.

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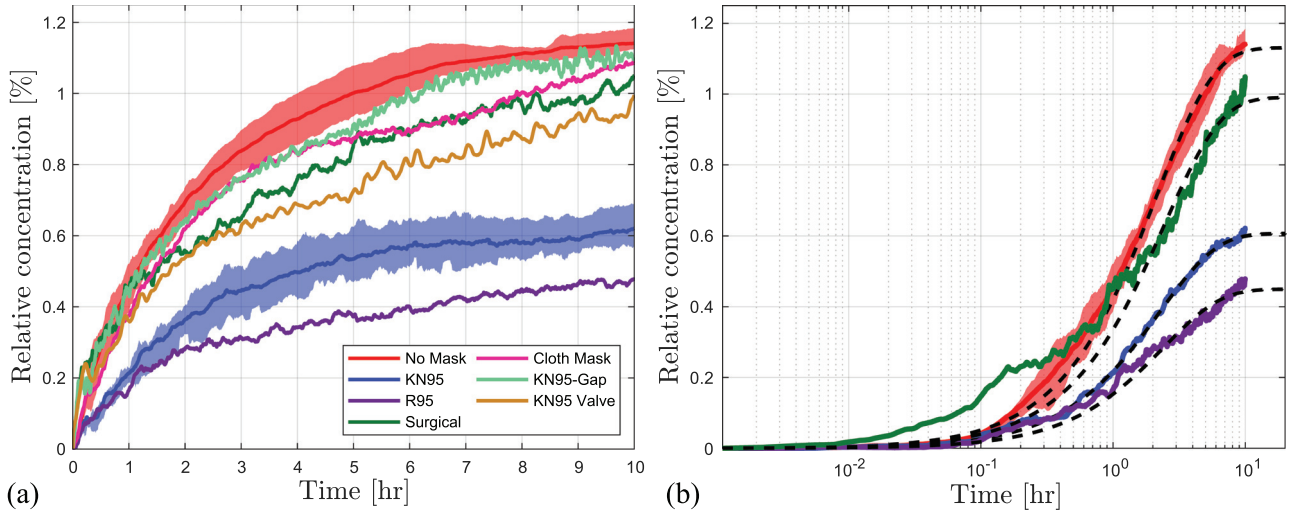


FIG. 6. Effect of various masks on the dispersion of aerosols measured at 2 m in front of the manikin. (a) Results are smoothed using a 10 min moving average. (b) Moving average particle concentration on semi-logarithmic scale for selected cases with a black dashed line showing model fits. Shaded areas show variability within repeated runs.

It can be seen that the simplified model captures the essential concentration trends well. The average relative concentration in the no-mask case is seen to asymptotically tend to the local steady state value of 1.13% of the breath particle concentration after a period of 10 h. Upon fitting various masks to the manikin, the relative concentrations are lowered in comparison to the no-mask case, indicating a reduction in the source strength due to filtration. The same is also captured in the reduction of the relative particle injection rate. However, the relative changes in the injection rate are significantly lower than those expected purely based on the ideal filtration efficiency of the mask material (Table II), which is attributed to the substantial aerosol leakage seen in Fig. 4.

Given close adherence of the experimental data to Eq. (3), the estimated saturated, i.e., steady state, concentration levels can be used to deduce the apparent filtration efficiency of the masks,

$$\eta_{\mathrm{AFE}} = 100 \times \left(\frac{c^*_{\mathrm{sat}_{\mathrm{NoMask}}} - c^*_{\mathrm{sat}}}{c^*_{\mathrm{sat}_{\mathrm{NoMask}}}} \right). \tag{4}$$

TABLE III. Apparent filtration characteristics of various masks based on particle dispersion tests over 10 h. R^* ((%/h) of the breath particle concentration) and λ^* (h^{-1}) are fit parameters estimated using a multi-variable least squares fit of Eq. (3) to the experimental data in Fig. 6. Values for the parameters are shown with a 95% confidence interval based on the t-statistic. Confidence interval on η_{AFE} incorporates the variation in the no-mask case.

Material	R^* (%h)	λ^* (h^{-1})	$c^*_{\mathrm{sat}} = R^*/\lambda^*$ (%)	η_{AFE} (%)
No mask	0.53 ± 0.11	0.46 ± 0.11	1.13 ± 0.057	...
Cloth	0.45 ± 0.27	0.44 ± 0.31	1.02 ± 0.11	9.8 ± 9.7
Surgical	0.41 ± 0.36	0.41 ± 0.39	0.99 ± 0.11	12.4 ± 9.7
KN95	0.27 ± 0.10	0.45 ± 0.12	0.61 ± 0.095	46.3 ± 9.4
R95	0.19 ± 0.09	0.42 ± 0.11	0.45 ± 0.09	60.2 ± 9.0
KN95-gap	0.46 ± 0.16	0.42 ± 0.21	1.09 ± 0.09	3.4 ± 8.9
KN95-valve	0.37 ± 0.12	0.41 ± 0.14	0.90 ± 0.09	20.3 ± 8.9

The resulting estimates for the apparent filtration efficiency (η_{AFE}) are reported in Table III, which confirms that η_{AFE} for all the masks is significantly lower than the filtration efficiencies for their respective materials presented in Table II. The R95 mask has the highest η_{AFE} of 60.2%, which is attributed to the tighter fit of the mask obtained by the overhead straps, a relatively stiff fabric, and the built-in soft sealing layer at the nose bridge of the mask. For KN95 mask, the gaps along the cheeks and the nose bridge are found to be comparatively larger, which leads to a lower η_{AFE} despite a similar filtration efficiency of the material. The cloth and surgical masks perform relatively poorly with efficiencies of only 9.8% and 12.4%, respectively, due to both low material filtration efficiency and significantly higher amounts of leakages around the cheeks and bridge of the nose. Further, due to the higher flexibility of the cloth and surgical mask material, they easily deform during exhalation, causing an increase in the size of the preexisting gaps, allowing more aerosols to escape.

In order to further evaluate the effect of leakage through the gaps around the cheeks and the nose, a separate case with the KN95 mask was considered with 3 mm gaps created artificially, as described in Sec. II. The 3 mm gaps are representative of the typical gaps observed for the surgical and cloth masks and provide a "loose-fitting" KN95 case. Results for the KN95-gap case in Fig. 6 and Table III show a significant reduction in the filtration efficiency compared to the baseline KN95 mask, with η_{AFE} decreasing from 46.3% to a paltry 3.4%. This offers a holistic perspective on the implications of loose fitting masks and aerosol build-up, in contrast with the results of Sickbert-Bennet *et al.*[65] whose single-point measurement directly behind the mask shows an efficiency (FFE) of more than 90% with a sub-optimally fit N95 mask. An additional point of comparison is provided in the present study by an appropriately fitted KN95 mask equipped with a one-way valve, which has an apparent efficiency of approximately 20%. This illustrates that controlled discharge through a valve on a high-efficiency mask may lead to a better overall exhale filtration compared to either a lower-grade mask (cloth or surgical) or a loosely fitted high-efficiency mask.

11 July 2024 19:12:39

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An important aspect of mask usage that is not apparent in Fig. 6 due to temporal smoothing and averaging over repeated runs is illustrated in Fig. 7, which presents raw particle concentrations for a selected subset of test cases. The instantaneous particle concentrations measured within the field of view in Fig. 7(a) show large temporal variations in local concentrations when masks are used, which consistently exceed those seen for the no-mask case. The instantaneous magnitudes of particle concentrations reach up to 1.6% of the single breath concentration in the case of blue surgical mask, roughly 40% above the saturation concentration reached in the no-mask case. These maximum excursions in the cases of the KN95 and R95 masks are lower; however, the instantaneous spikes in concentration surpass the average no-mask concentration in the first hour of the test. These excursions in the local particle concentrations are attributed to the presence of dense particle clouds that frequently pass through the field of view, as illustrated in Fig. 7(b). The figure shows representative concentration maps of the particle clouds in the blue surgical and the KN95 mask cases. Peak concentrations reach up to 3% of the particle breath concentrations in the blue surgical mask case, which are localized within the core regions of the clouds and indicate a much higher threat than that perceived based on the averaged results in Fig. 6. Although these particle clouds were present in every tested case with a mask, their frequency and sizes decreased for masks with better fits and higher apparent filtration efficiencies (η_{AFE}), as illustrated by representative realizations for KN95 and R95 masks in Fig. 7(b). The implication for disease mitigation is a significant temporal variability in the exposure risk associated with masks in an unventilated indoor environment. Recent studies[72,73] have noted similar concentration excursions attributed to the local flows, exceeding the predictions based on the well-mixed and diffusion based models.

It is of practical interest to investigate the directivity of the exhaled particles for social distancing purposes in indoor environments with poor ventilation. Directivity of the particle dispersion at the 2 m distance from the source was investigated in the no-mask and KN95 cases, and the results are presented in Fig. 8. The results for the no-mask case in Fig. 8(a) show that the average concentrations reached at 90° and 180° decrease in comparison to those at 0°, but the effect of the orientation is less than 10%. In the case of KN95 mask [Fig. 8(b)], the particle concentrations at the non-zero orientations are only slightly higher than those at 0°. While the general trend highlighted by these results is in accordance with the expectations based on the flow visualization results (Fig. 4), the differences with orientation are relatively minor which indicates that the anticipated effect of directivity due to advection is primarily confined to the near vicinity of the source. In the absence of ventilation effects, turbulent diffusion appears to largely equalize the concentration along the circumferential direction at and beyond the 2 m radial distance surrounding the source. This is in accordance with the typical deposition mechanisms observed in the case of suspended particles.[75] However, the observed effect may be limited to relatively large room sizes, such as those used in the current experiment, where the advection effects near the source become negligible well inside the boundaries of the room. The current results are in qualitative agreement with the results from diffusion based models[35] in a poor ventilation scenario.

Finally, the effect of room ventilation and/or air cleaning is investigated on the aerosol dispersion 2 m in front of the manikin. Measurements are conducted at three different settings of a mobile air purifier installed in the corner of the room (left top corner in Fig. 1). Due to a high efficiency particle air (HEPA) filtration (>99% efficiency), the unit allows a controlled modeling of ventilation settings, with effective air-change rates (ACH) of 1.7, 2.45, and 3.2 h^{-1} considered in the present investigation. The results presented in Figs. 9(a) and 9(b) show a notable reduction in local concentration in front of the manikin even with relatively low effective air-change rates, as also noted by previous studies[35,73]) The measured concentrations are seen to decrease with increasing ACH, and the steady-state (c^*_{sat}) is achieved

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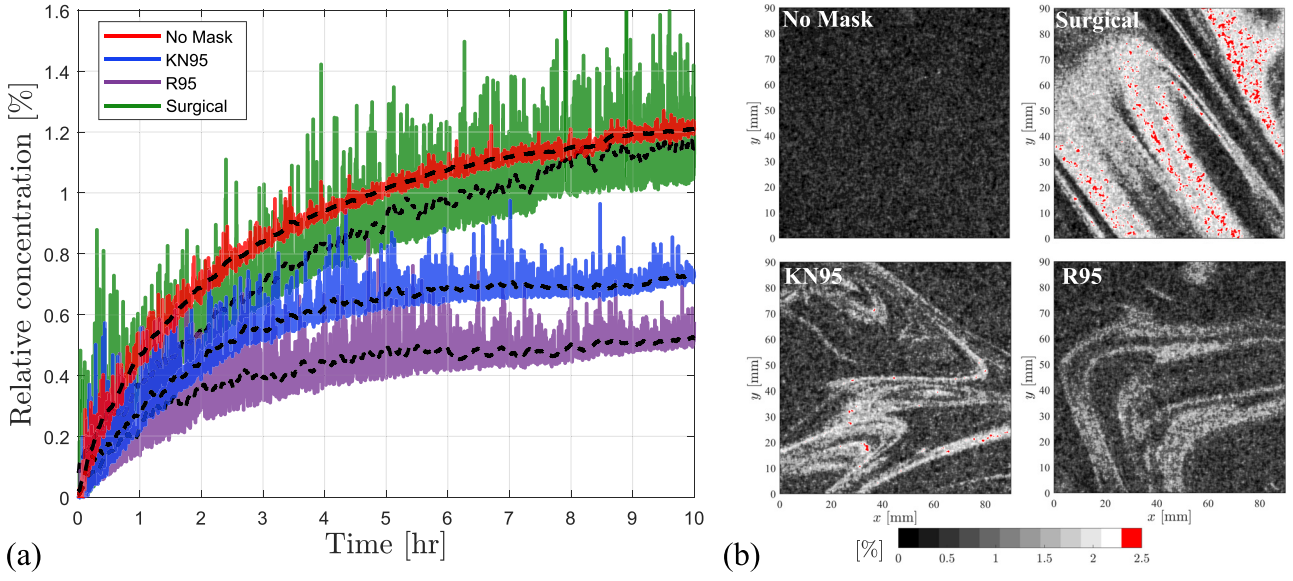


FIG. 7. (a) Raw particle concentration for representative test cases considered in Fig. 6 with moving average shown with black dashed lines. (b) Instantaneous relative particle concentration fields for the selected cases. Relative concentrations are represented as a fraction of the breath particle concentration.

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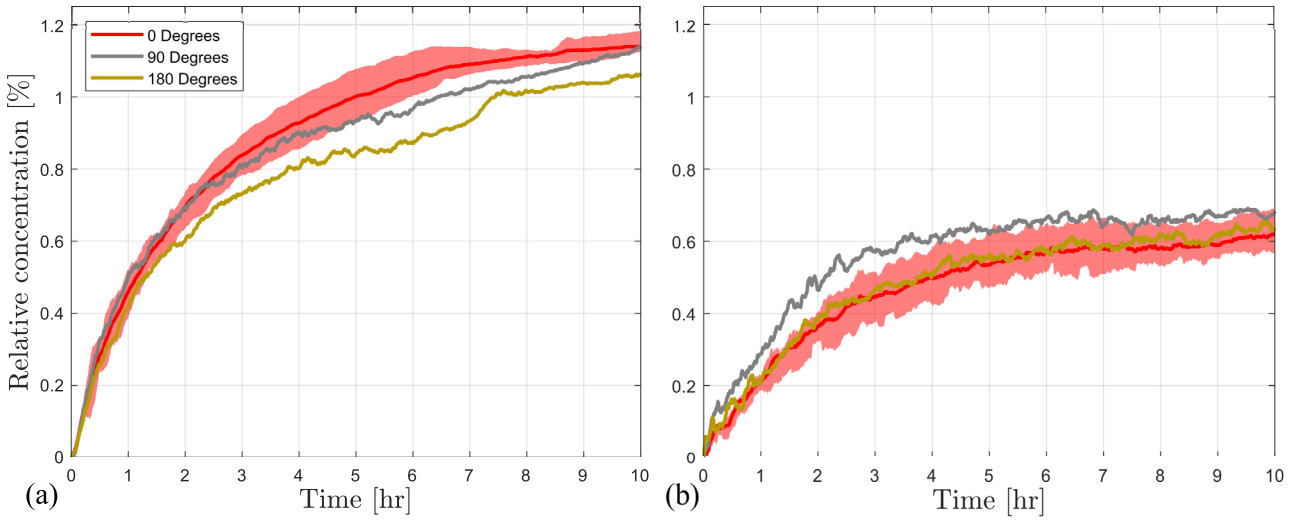


FIG. 8. Dispersion characteristics of the aerosols measured at a radius of 2 m from the manikin for (a) no mask and (b) KN95 mask.

within less than 4 h in all the air-cleaning cases. The results are fitted to the simplified model [Eq. (3)] in Fig. 9(b), and the fits are seen to approximate the data well. The corresponding fit parameters are summarized in Table IV. As expected, the increase in ACH results in a notable increase in the decay rate (λ^*), which is reflected in the earlier saturation of the local concentration. This is also in accordance with the increased diffusion coefficient in mixing ventilation scenarios as shown by Foat *et al.*[72] and Cheng *et al.*[76] at comparable ACH. The steady-state values are used to estimate an apparent filtration efficiency (η_{AFE}) of the system in order to draw meaningful comparisons with the results from the mask cases in an unventilated scenario. In this case, the apparent filtration efficiency (η_{AFE}) is obtained by the relative change in the steady-state concentration (c^*_{sat}) between the ventilated and unventilated cases. The results in Table IV show that the steady-state concentrations are decreased in the range 69%–84% for the considered cases and correspond to a much higher η_{AFE} compared with the best performing mask in an unventilated scenario (Table III). However, this also suggests that relatively low ventilation rates (ACH $< 3.2\,\mathrm{h}^{-1}$) may not be sufficient to reduce exposure to within acceptable levels at the typical social distancing guideline of 2 m, which supports the findings from previous studies.[73,77]

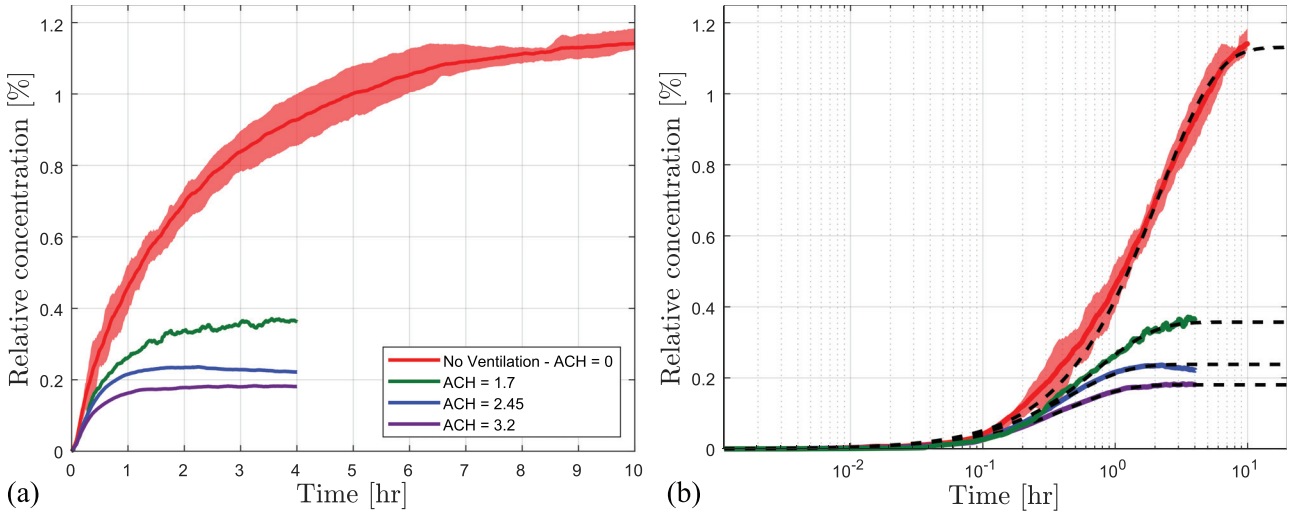


FIG. 9. Effect of ventilation on the dispersion characteristics of the aerosols measured at 2 m in front of the manikin without a mask on a (a) linear, and (b) logarithmic scale in time. Black dashed line indicates model fits to the moving average data.

11 July 2024 19:12:39

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TABLE IV. Apparent filtration efficiencies for various air-change rates (ACH) based on particle dispersion tests with no-mask. R^* ((%/h) of the breath particle concentration) and λ^* (h^{-1}) are fit parameters estimated using a multi-variable least squares fit of Eq. (3) to the experimental data in Fig. 9.

ACH	R^* (%/h)	λ^* (h^{-1})	$c^*_{sat} = R^*/\lambda^*$ (%)	η_{AFE} (%)
0	0.53	0.46	1.13	...
1.7	0.48	1.36	0.35	69
2.45	0.52	2.19	0.24	79
3.2	0.41	2.27	0.18	84

IV. CONCLUSIONS

The present study experimentally investigates the dispersion and accumulation of aerosol particles in indoor environments in the context of the guidelines proposed by national health agencies to control the transmission of COVID-19. Experiments were conducted in a controlled laboratory environment with a test manikin in a seated position mimicking relaxed exhalation through the nose, typical of an average adult. The manikin was equipped with five different commercially available masks that have seen widespread use throughout the course of the COVID-19 pandemic. Both near-field flow visualizations and far-field particle concentration measurements allow for a holistic investigation of the effect of masks and ventilation in the test room, and provide a quantitative measure relative to aerosol concentrations and mask efficiencies of interest for transmission risk assessment, model development, and implementation of adaptive health and safety practices at workplace. The results highlight that (i) considerable relative aerosol concentration levels can be reached at a 2 m distance from the subject in an unventilated space, and even when the subject is equipped with a mask, the relative concentrations are notably higher than those expected based on the ideal/rated efficiency of the masks; (ii) fit of the mask to the face, in terms of limiting leakage around the mask perimeter, is critical for limiting aerosol dispersion in an unventilated space, especially for high efficiency masks (e.g., N95/KN95); and (iii) increased ventilation/air-cleaning capacity significantly reduces the transmission risk in an indoor environment, surpassing the apparent mask filtration efficacy even at relatively low air-change rates (~2 room volumes per hour).

The baseline filtration characteristics for the various masks tested in this study indicate that more than 50% of aerosols (polydisperse, 1 μm mean diameter) can pass through the material of commercially available cloth and surgical masks in ideal conditions (zero leakage due to fit), whereas ideal filtration efficiency is 95% (or higher) in the case of KN95 and R95 masks. Flow visualizations and velocity measurements in the near-field (immediate vicinity of the face) indicate that none of the tested masks is performing at their ideal filtration efficiencies due to leakages through gaps in the fit of the mask. This occurs around the cheeks, below the jaw, and at the bridge of the nose, with the latter being the most significant for all masks. Aerosols are seen to escape through these leakage sites in the form of concentrated particle clouds that do not mix quickly with the ambient air on account of relatively low flow velocities and hence low levels of turbulent mixing. The degree of leakage varies between masks, with high-efficiency masks, such as the KN95, performing better. Factors affecting leakage at the mask perimeter include mask geometry, strap style and elasticity, and whether or not the mask is equipped with a deformable nose piece that can be tightly shaped to the nose. Furthermore, although the present study does not characterize the effectiveness of masks during inhalation, the aforementioned loss of filtration efficiency due to perimeter leakage is also expected to be present during inhalation, although it is to a lesser extent due to the improved sealing effect produced by the negative pressure difference relation to the ambient.

The near-field velocity measurements indicate that the forward momentum of breath exhaled through the nose is reduced significantly and redirected when the subject is equipped with a mask. Furthermore, this attenuation of the forward momentum increases with the filtration efficiency of the mask material when a proper fit is ensured. Thus, the present results endorse the use of high-efficiency, unvalved masks with a proper fit when the recommended social distancing guidelines cannot be maintained between individuals.

Measurements of aerosol concentration at a 2 m distance from the subject show a characteristic increase in average particle concentration with time in the absence of ventilation, following the first order response based on the well-mixed room model. Across all cases, relative particle concentrations saturate at elevated levels, indicating accumulation of aerosol particles within the room. When the subject is not fitted with a mask, the saturation concentration is the highest among all the cases tested. A decrease in saturation concentration is seen for all mask types; however, the effective filtration is notably lower than the ideal filtration efficiency of the material due to leakages in accordance with a mask's ability to decrease the number of particles released into the room per breath. Thus, the apparent filtration efficiency of a mask (η_{AFE}) is estimated based on the relative difference in saturation concentration at the measurement location between cases with and without a mask. This metric provides a more representative measure of mask efficiency and is of particular interest for future modeling studies and continuous occupancy risk assessment.

The results show that a standard surgical and three-ply cloth masks, which see current widespread use, filter at apparent efficiencies of only 12.4% and 9.8%, respectively. Apparent efficiencies of 46.3% and 60.2% are found for KN95 and R95 masks, respectively, which are still notably lower than the verified 95% rated ideal efficiencies. Furthermore, the efficiencies of a loose-fitting KN95 and a KN95 mask equipped with a one-way valve were evaluated, showing that a one-way valve reduces the mask's apparent efficiency by more than half (down to 20.3%), while a loose-fitting KN95 provides a negligible apparent filtration efficiency (3.4%). The present results provide an important practical contrast to many other previous experimental and numerical investigations, which do not consider the effect of mask fit when locally evaluating mask efficiency or incorporating mask usage in a numerical model. Nevertheless, if worn correctly, high-efficiency masks still offer significantly improved filtration efficiencies (apparent and ideal) over the more commonly used surgical and cloth masks, and hence are the recommended choice in mitigating the transmission risks of COVID-19.

The directivity of aerosol dispersion was assessed through concentration measurements at a 2 m distance and at locations in front of (0°), to the side of (90°), and behind (180°) the subject with a surgical and KN95 masks. For all the cases, the effect of orientation was less than about 10% of the local particle concentration and indicated a relatively minor directivity effect at a distance of 2 m. It is conjectured

11 July 2024 19:12:39

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based on the flow measurements in the vicinity of the manikin face that significant directivity effects are confined to the relatively close proximity of the host.

The effect of ventilation/air-cleaning was consider using a HEPA air purifier at the recommended pre-pandemic air-change rates (ACH = 1.7–3.2 h^{-1}). The results show that ventilation air-exchange or purification is effective in decreasing both the final saturation concentration and the time required to reach the saturation state. Based on the apparent filtration efficiency, tests performed with no mask at an air-change rate of 1.7 h^{-1} (and higher) outperform cases with high-efficiency masks (KN95 and R95) and no room ventilation. However, at these low ventilation rates, a notable particle concentration is still present at a 2 m distance, which is indicative of higher ventilation rates needed to ensure negligible aerosol build-up over prolonged occupancy.

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DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review

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Abstract

The use of cloth facemasks in community settings has become an accepted public policy response to decrease disease transmission during the COVID-19 pandemic. Yet evidence of facemask efficacy is based primarily on observational studies that are subject to confounding and on mechanistic studies that rely on surrogate endpoints (such as droplet dispersion) as proxies for disease transmission. The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle. Although weak evidence should not preclude precautionary actions in the face of unprecedented events such as the COVID-19 pandemic, ethical principles require that the strength of the evidence and best estimates of amount of benefit be truthfully communicated to the public.

Keywords: facemasks, health policy, COVID-19, infectious disease, epidemiology, bioethics

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Introduction

Until April 2020, World Health Organization COVID-19 guidelines stated that "[c]loth (e.g. cotton or gauze) masks are not recommended under any circumstance,"[1] which were updated in June 2020 to state that "the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence."[2] In the surgical theater context, a Cochrane review found "no statistically significant difference in infection rates between the masked and unmasked group in any of the trials."[3] Another Cochrane review, of influenza-like-illness, found "low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18)."[4]

These observations may come as a surprise to those in countries, such as the United States, where government leaders, news media, and even public health officials have repeatedly asserted that the widespread use of masks will help to prevent transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. By September 2020, the U.S. federal government had distributed 600 million face masks for use by the public as part of the response to the pandemic.[5,6] At the local level, 32 states and numerous

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[4] Tom Jefferson et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses (Review)*, 11 COCHRANE DATABASE SYS. REV. 1, 2 (2020).

[5] Helen Branswell et al., *The Trump Administration Haphazardly Gave Away Millions of Covid-19 Masks — To Schools, Broadcasters, and Large Corporations*, STAT NEWS, Aug. 13, 2020, https://www.statnews.com/2020/08/13/the-trump-administration-haphazardly-gave-away-millions-of-masks-to-schools-broadcasters-and-fortune-500-companies/.

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municipalities implemented mask mandates,[7,8] and calls for a nationwide mask mandate garnered significant attention.[9] At the height of the pandemic, New York City instituted a $1000 fine for those who refuse to wear face masks in public,[10] and prominent national leaders stated that "[w]earing masks is not a political statement, it is a scientific imperative."[11] Over 40% of the global population lives in countries that mandate mask-wearing in public areas.[12] As COVID-19 persists, community masking policies continue to be the subject of public health and public attention.

These public statements, official policies, and mask requirements have become politically divisive.[13] Non-partisan, evidence-based decision-making is essential to increasing public confidence in appropriate public health interventions. We review the evidence for aerosol transmission of SARS-CoV-2, the mechanistic evidence of how masks may interrupt transmission of respiratory infections and in particular SARS-CoV-2, and the available clinical evidence of the impact of cloth facemask use in community settings on respiratory infection rates, including by SARS-CoV-2.

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I. Evidence of aerosol transmission of SARS-CoV-2

Airborne diseases can be transmitted from person to person when respiratory secretions containing infectious particles from one person come into contact with the mucosal membranes of another, such as the eyes, nose, or mouth.[14] Such secretions are emitted into the surrounding air when infected individuals cough[15] or sneeze,[16] or even during the events of daily living irrespective of health status,[17] such as breathing,[18] talking,[19,20] or singing.[21]

These activities result in the emission of secretions of all sizes.[22] Larger particles greater than a "critical size" behave ballistically,[23] falling to nearby surfaces within a 1- to 2-meter radius[24,25] (although air currents can allow particles to travel beyond this distance[26,27]), while smaller particles evaporate before falling to the ground.[28] There is no universally accepted threshold delineating these two categories, but by convention droplets are those particles greater

[14] Eunice Y. C. Shiu et al., *Controversy Around Airborne Versus Droplet Transmission of Respiratory Viruses: Implication for Infection Prevention*, 32 CURRENT OPINION INFECTIOUS DISEASES 372, 373 (2019).
[15] Jinho Lee et al., *Quantity, Size Distribution, and Characteristics of Cough-Generated Aerosol Produced by Patients with an Upper Respiratory Tract Infection,* 19 AEROSOL AIR QUALITY RESEARCH 840, 840 (2019).
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[24] Lidia J. Morawska, *Droplet Fate in Indoor Environments, or Can We Prevent the Spread of Infection?*, *in* Proceedings of Indoor Air 2005: the 10th International Conference on Indoor Air Quality and Climate 9 (2005).
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[27] Padmanabha P. Simha & Prasana S. Mohan Rao, *Universal Trends in Human Cough Airflows at Large Distances*, 32 PHYSICS FLUIDS 081905-1, 081905-7 (2020).
[28] Rajat Mittal et al., *The Flow Physics of COVID-19*, 894 J. FLUID MECHANICS F2-1, F2-1 (2020).

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than about 10 μm in diameter, while aerosols are those smaller than this size.[29,30] When smaller particles evaporate,[31] they can stay suspended in the air for long periods of time and be inhaled,[32] potentially causing infection deeper in the respiratory tract and at lower concentrations.[33,34] Smaller particles are preferentially generated during higher-velocity respiratory events such as coughing and sneezing, with one study finding that 99.9% of particles emitted by subjects with a cold during coughing were <5 μm in diameter,[35] and another finding that more than 97% of the droplets emitted by healthy volunteers in the study were <1 μm in diameter.[36,37] Exhaled particles <5 μm in diameter have been found to carry the majority of virus in exhaled human breath,[38] and patients with upper respiratory infections emitted significantly greater numbers of particles (5x10^6 compared to 1x10^6, P<0.05) while sick compared to after recovery.[39]

[29] Eunice Y. C. Shiu et al., *Controversy Around Airborne Versus Droplet Transmission of Respiratory Viruses: Implication for Infection Prevention*, 32 CURRENT OPINION INFECTIOUS DISEASES 372, 375 (2019).
[30] J. W. Tang et al., *Factors Involved in the Aerosol Transmission of Infection and Control of Ventilation in Healthcare Premises*, 64 J. HOSP. INFECTION MECHANICS 100, 101 (2006).
[31] Lidia J. Morawska, *Droplet Fate in Indoor Environments, or Can We Prevent the Spread of Infection?*, at 9, *in* Proceedings of Indoor Air 2005: the 10th International Conference on Indoor Air Quality and Climate (2005).
[32] Catharyn T. Liverman, *Understanding the Risk to Healthcare Personnel*, at 30, *in* Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases: Personal Protective Equipment for Healthcare Personnel: Update 2010 (2010), https://www.nap.edu/read/13027/chapter/4#30.
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[35] G. R. Johnson GR et al., *Modality of Human Expired Aerosol Size Distributions*, 42 J. AEROSOL SCI. 839, 844 (2011).
[36] Gustavo Zayas et al., *Cough Aerosol in Healthy Participants: Fundamental Knowledge to Optimize Droplet-Spread Infectious Respiratory Disease Management*, 12 BMC PULMONARY MED. 1, 1 (2012).
[37] Shinhao Yang et al., *The Size and Concentration of Droplets Generated by Coughing in Human Subjects,* 20 J. AEROSOL SCI. 484, 484 (2007) (finding that 82% off droplet nuclei exhaled during coughing were between 0.74–2.12 microns in diameter).
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The primary mode of transmission (aerosol vs. droplet) for viral respiratory infections, including SARS-CoV-2, is controversial and remains unclear.[40,41,42,43,44,45] If aerosol transmission plays a substantial role, the ability of masks to serve as a physical barrier to droplets becomes a less reliable surrogate of efficacy, since air expelled from the lungs necessarily penetrates the mask or flows around its edges, potentially advecting aerosols along with it.

Aerosol transmission has been demonstrated or is considered likely for SARS-CoV,[46] Middle East Respiratory Syndrome (MERS),[47] H1N1 influenza,[48] and respiratory syncytial virus,[49] and a growing body of laboratory, animal, and clinical evidence suggests SARS-CoV-2 is also spread via this mechanism.[50,51] One study found SARS-CoV-2 aerosolizes with equal or greater efficiency than both SARS-CoV-1 and MERS-CoV,[52] and retains stability and infectivity for 16 hours in respirable-sized aerosols.[53] Another study found COVID-19 patients exhale

[40] Eunice Y. C. Shiu et al., *Controversy Around Airborne Versus Droplet Transmission of Respiratory Viruses: Implication for Infection Prevention*, 32 CURRENT OPINION INFECTIOUS DISEASES 372 (2019).
[41] Mahesh Jayaweera et al., *Transmission of COVID-19 Virus by Droplets and Aerosols: A Critical Review on the Unresolved Dichotomy*, 188 ENVTL. RESEARCH 1 (2020).
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[52] Alyssa C. Fears et al., *Persistence of Severe Acute Respiratory Syndrome Coronavirus 2 in Aerosol Suspensions*, 26 EMERGING INFECTIOUS DISEASES INT'L 2168, 2170 (2020).
[53] Neeltje Van Doremalen et al., *Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1*, 382 NEW ENG. J. MED. 1564, 1565 (2020).

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millions of SARS-CoV-2 copies into the surrounding air every hour.[54] Even in the early stages of the illness when coughing or sneezing are uncommon, infectious SARS-CoV-2 aerosols have been found in air samples taken at the foot of patient beds in clinical settings.[55] SARS-CoV-2 viral particles have been detected in low-touch areas (e.g. under beds and on unused window ledges) consistent with sustained aerosol distribution, as well as in most (58%) of air samples taken from hallways outside patient rooms.[56] Evidence of transmission before patients become symptomatic suggests coughing and sneezing are not essential,[57,58,59,60] tending to partially undermine the importance of video evidence showing reductions in droplet dispersion when individuals cough through masks. Observational evidence of 110 SARS-CoV-2 cases in 11 clusters found transmission rates of COVID-19 that were more than 18 times higher in closed environments, where aerosols can more easily remain concentrated, than in open-air environments.[61] In one published report, an index patient often passed by the open door of the secondary patient's apartment—but never went inside.[62]

[54] Jianxin Ma et al., *COVID-19 Patients in Earlier Stages Exhaled Millions of SARS-CoV-2 per Hour*, 72 CLINICAL INFECTIOUS DISEASES e652, e653 (2021).
[55] Joshua L. Santarpia et al., *The Size and Culturability of Patient-Generated SARS-CoV-2 Aerosol*, J. EXPOSURE SCI. & ENVTL. EPIDEMIOLOGY 1, 2 (2020).
[56] Joshua L. Santarpia et al., *Aerosol and Surface Contamination of SARS-CoV-2 Observed in Quarantine and Isolation Care*, 10 SCI. REPORTS 1, 3 (2020).
[57] Nathan W. Furukawa et al., *Evidence Supporting Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 While Presymptomatic or Asymptomatic*, 26 EMERGING INFECTIOUS DISEASES e1, e1 (2020).
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Certain "super-spreader" events also suggest that aerosols serve as an important mode of transmission for SARS-CoV-2.[63,64,65,66] For example, a single index patient at a restaurant in Guangzhou, China infected 4 people sitting at his own table, and 5 strangers sitting at adjacent tables up to 4.6 meters (15 feet) away with whom video evidence confirmed that no close contact was shared.[67] One ward of a Dutch nursing home reported 34 cases (17 of 21 residents; 17 of 34 workers)—despite mask-wearing requirements for healthcare workers and residents' limited mobility—in a week where the Netherlands recorded only 493 cases total; the authors isolated SARS-CoV-2 RNA in living room air conditioners and concluded that transmission was likely due to aerosol transmission and recirculation of contaminated air.[68] At a choir rehearsal in Skagit Valley, Washington, a single infected individual spread SARS-CoV-2 to 53 of 59 attendees—a pattern some have concluded is suggestive of aerosol transmission.[69] Super-spreader events could also be explained by transmission via door handles or other fomites,[70] but substantially higher rates of SARS-CoV-2 positivity have been found in exhaled breath samples (26.9%) than in either indoor air samples (3.8%) or surfaces such as cell phones, floors, and computer

[63] Lidia Morawska & Donald K. Milton, *It Is Time to Address Airborne Transmission of Coronavirus Disease 2019 (COVID-19)*, 71 CLINICAL INFECTIOUS DISEASES 2311 (2020).
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[68] Peter de Man P et al., *Outbreak of Coronavirus Disease 2019 (COVID-19) in a Nursing Home Associated with Aerosol Transmission as a Result of Inadequate Ventilation*, 73 CLINICAL INFECTIOUS DISEASES 170, 171 (2020).
[69] Shelly L. Miller et al., *Transmission of SARS-CoV-2 by Inhalation of Respiratory Aerosol in the Skagit Valley Chorale Superspreading Event*, 31 INDOOR AIR 314, 315–316 (2021).
[70] Michael Klompas et al., *Airborne Transmission of SARS-CoV-2: Theoretical Considerations and Available Evidence*, 324 J. AM. MED. ASS'N 441, 441 (2020).

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keyboards (5.4%).[71] A non-clinical study also supported the conclusion that SARS-CoV-2 is transmitted primarily via droplets or aerosols rather than via fomites, based on transmission to all exposed uninfected hamsters when placed in cages separated by 1.8 cm from cages with infected hamsters that shared a common air supply for 8 hours, but to only 1 of 3 uninfected hamsters exposed one-at-a-time for 48 hours to soiled cages (i.e., fomites).[72]

II. Mechanistic evidence of facemask effectiveness

Much of the evidence supporting public mask wearing is based on the surrogate endpoint of droplet dispersion, reductions in which are hypothesized to correlate with reductions in disease transmission. This intuition is based on the ability of masks—and indeed any sufficiently dense object or material—to act as a physical barrier that reduces the volume of larger respiratory secretions that are projected directly forward from the mask wearer, or the distance that those droplets travel,[73,74] and a robust literature exists documenting the filtration qualities of the various fabrics used to construct face masks.[75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93]

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[71] Jianxin Ma et al., *COVID-19 Patients in Earlier Stages Exhaled Millions of SARS-CoV-2 per Hour*, 72 CLINICAL INFECTIOUS DISEASES e652, e653 (2021).
[72] Sin F. Sia et al., *Pathogenesis and Transmission of SARS-CoV-2 in Golden Hamsters*, 583 NATURE 834, 836 (2020).
[73] Lucia Bandiera et al., *Face Coverings and Respiratory Tract Droplet Dispersion*, 7 ROYAL SOC'Y OPEN SCI. 1, 6 (2020).
[74] Hiroshi Ueki et al., *Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2,* 5 MSPHERE 1 (2020).
[75] Alex Rodriguez-Palacios et al., *Textile Masks and Surface Covers—A Spray Simulation Method and a "Universal Droplet Reduction Model" Against Respiratory Pandemics*, 7 FRONTIERS MED. 1 (2020).
[76] Qing-Xia Ma et al., *Potential Utilities of Mask-Wearing and Instant Hand Hygiene for Fighting SARS-CoV-2*, 92 J. MED. VIROLOGY 1567 (2020).
[77] Kenneth D. Long KD et al., *Measurement of Filtration Efficiencies of Healthcare and Consumer Materials Using Modified Respirator Fit Tester Setup*, 15 PLOS ONE 1 (2020).
[78] Eugenia O'Kelly et al., *Ability of Fabric Face Mask Materials to Filter Ultrafine Particles at Coughing Velocity*, 10 BMJ OPEN 1 (2020).
[79] Weixing Hao et al., *Filtration Performances of Non-medical Materials as Candidates for Manufacturing Facemasks and Respirators*, 229 INT'L J. HYGIENE & ENVTL. HEALTH 1 (2020).
[80] Masayoshi Furuhashi, *A Study on the Microbial Filtration Efficiency of Surgical Face Masks—With Special Reference to the Non-woven Fabric Mask,* 25 BULL. TOKYO MED. & DENTAL UNIV. 7 (1978).
[81] Saraswati A. Rizki & Andree Kurniawan, *Efficacy of Cloth Face Mask in Reducing COVID-19 Transmission: A Literature Review*, 1 KESMAS NAT'L PUB. HEALTH J. 43 (2020).

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Such studies examine the ability of fabric to filter particles as they pass through—rather than around—mask material. If aerosols can cause infection, however, then filtering capability is unlikely to be reliable surrogate for infection control, since exhaled air necessarily either leaks around a mask's edges or passes through it.[94,95,96] Such leakage has been shown to account for the vast majority (~5:1 ratio) of particle penetration of standardized surgical masks,[97] and exhaled air easily passes around the edges of most cloth masks.[98,99,100,101,102] One study of cloth

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[82] Onur Aydin et al., *Performance of Fabrics for Home-Made Masks Against the Spread of COVID-19 Through Droplets: A Quantitative Mechanistic Study*, 40 EXTREME MECHANICS LETTERS 1 (2020).
[83] Mervin Zhao et al., *Materials Selection for Homemade Cloth Face Coverings and Their Filtration Efficiency Enhancement with Triboelectric Charging*, 20 NANO LETTERS 5544 (2020).
[84] Adam F. Parlin et al., *A Laboratory-Based Study Examining the Properties of Silk Fabric to Evaluate Its Potential as a Protective Barrier for Personal Protective Equipment and as a Functional Material for Face Coverings During the COVID-19 Pandemic*, 15 PLOS ONE 1 (2020).
[85] Lukas Maurer et al., *Community Masks During the SARS-CoV-2 Pandemic: Filtration Efficacy and Air Resistance*, 34 J. AEROSOL MED. & PULMONARY DRUG DELIVERY 1 (2021).
[86] Harriet Whiley et al., *Viral Filtration Efficiency of Fabric Masks Compared With Surgical and N95 Masks*, 9 PATHOGENS 1 (2020).
[87] Samy Rengasamy et al., *Simple Respiratory Protection–Evaluation of the Filtration Performance of Cloth Masks and Common Fabric Materials Against 20–1000 nm Size Particles*, 54 ANNALS OCCUPATIONAL HYGIENE 789 (2010).
[88] Christopher D. Zangmeister et al., *Filtration Efficiencies of Nanoscale Aerosol by Cloth Mask Materials Used To Slow the Spread of SARS-CoV-2*, 14 ACS NANO 9188 (2020).
[89] Tara Oberg & Lisa M. Brosseau, *Surgical Mask Filter and Fit Performance*, 36 AM. J. INFECTION CONTROL 276 (2008).
[90] Jasper F. Chan et al., *Surgical Mask Partition Reduces the Risk of Non-contact Transmission in a Golden Syrian Hamster Model for Coronavirus Disease 2019 (COVID-19)*, 71 CLINICAL INFECTIOUS DISEASES 2139, 2139 (2021).
[91] Laura H. Kwong et al., *Review of the Breathability and Filtration Efficiency of Common Household Materials for Face Masks*, 15 ACS NANO 5904 (2021).
[92] Ashish Sharma et al., *Efficacy of Facemasks in Mitigating Respiratory Exposure to Submicron Aerosols*, 422 J. HAZARDOUS MATERIALS 1 (2022).
[93] Monica Gandhi & Linsey C. Marr, *Uniting Infectious Disease and Physical Science Principles on the Importance of Face Masks for COVID-19*, 2 MED 29, 30 (2021).
[94] Michael Klompas et al., *Airborne Transmission of SARS-CoV-2: Theoretical Considerations and Available Evidence*, 324 J. AM. MED. ASS'N 441, 441 (2020).
[95] Julian W. Tang et al., *A Schlieren Optical Study of the Human Cough with and Without Wearing Masks for Aerosol Infection Control*, 6 J. ROYAL SOC'Y INTERFACE S727, S732 (2009).
[96] Siddhartha Verma et al., *Visualizing the Effectiveness of Face Masks in Obstructing Respiratory Jets*, 32 PHYSICS FLUIDS 061708-1, 061708-2 (2020).
[97] Sergey A. Grinshpun et al., *Performance of an N95 Filtering Facepiece Particulate Respirator and a Surgical Mask During Human Breathing: Two Pathways for Particle Penetration*, 6 J. OCCUPATIONAL & ENVTL. HYGIENE 593, 593 (2009).
[98] Patricia M. Holton et al., *Particle Size-Dependent Leakage and Losses of Aerosols in Respirators*, 48 AM. INDUS. HYGIENE ASS'N J. 848 (1987).
[99] Ignazio M. Viola et al., *Face Coverings, Aerosol Dispersion and Mitigation of Virus Transmission Risk*, 2 IEEE OPEN J. ENG'G MED. & BIOLOGY 26, 30 (2021).

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masks simulated leakage and found that a hole equal to ~1% of the mask area decreased mask efficiency by over 60%.[103] Even in professional settings with high-grade, non-cloth masks, a poor fit can allow air to leak.[104,105,106] Double-masking reduces, but does not eliminate, such leakage.[107,108] In a study of N95 respirators, 25% (158 of 643) professional healthcare workers failed to properly fit their mask, despite knowing they were being studied and receiving instructions on how to achieve a proper respirator fit.[109] Unlike respirators, which protect their wearers from airborne particles, surgical masks are intended to protect those other than the wearer, and have a much looser fit. Cloth masks may be looser still, followed by homemade masks.[110,111]

Laboratory evidence supports the ability of masks to serve a source-control function. Multiple studies have demonstrated that masks can reduce the number of bacterial colonies that grow on petri dishes placed in front of subjects who are directed to cough with or without a

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[100] Marianne Van der Sande et al., *Professional and Home-Made Face Masks Reduce Exposure to Respiratory Infections Among the General Population*, 3 PLOS ONE 1, 2 (2008).
[101] Anna Davies et al., *Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic?*, 7 DISASTER MED. & PUB. HEALTH PREPAREDNESS 413, 415 (2013).
[102] Eugenia O'Kelly et al., *Comparing the Fit of N95, KN95, Surgical, and Cloth Face Masks and Assessing the Accuracy of Fit Checking*, 16 PLOS ONE 1, 2 (2021).
[103] Abhiteja Konda et al., *Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks*, 14 ACS NANO 6339, 6345 (2020).
[104] Klaus Willeke et al., *New Methods for Quantitative Respirator Fit Testing with Aerosols*, 42 AM. INDUS. HYGIENE ASS'N 121, 121 (1981).
[105] *PortaCount Plus Respirator Fit Tester and N95-Companion*, TSI INC., https://www.tsi.com/getmedia/e39e2877-cf0d-43d3-8667-b8041f94df55/PortaCount2980083RevE?ext=.pdf (last visited Nov. 11, 2020).
[106] Angela Weber et al., *Aerosol Penetration and Leakage Characteristics of Masks Used in the Health Care Industry*, 21 AM. J. INFECTION CONTROL 167, 172 (1993) (noting that better-performing respirators can increase breathing resistance, increasing the likelihood that particles could be pulled into the mask through face-seal leaks).
[107] Emily E. Sickbert-Bennett et al., *Fitted Filtration Efficiency of Double Masking During the COVID-19 Pandemic*, 181 JAMA INTERNAL MED. 1126, 1126 (2021
[108] Venugopal Arumuru et al., *Double Masking Protection vs. Comfort—A Quantitative Assessment*, 33 PHYSICS FLUIDS 077120 (2021).
[109] Quinn Danyluk et al., *Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?*, 8 J. OCCUPATIONAL & ENVTL. HYGIENE 267, 268 (2011).
[110] Marianne Van der Sande et al., *Professional and Home-Made Face Masks Reduce Exposure to Respiratory Infections Among the General Population*, 3 PLOS ONE 1, 3 (2008).
[111] Catherine M. Clase et al., *Forgotten Technology in the COVID-19 Pandemic: Filtration Properties of Cloth and Cloth Masks—A Narrative Review*, 95 MAYO CLINIC PROC. 2204, 2215 (2020).

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mask,[112,113,114,115 116,117,118] and one study using reverse-transcription polymerase chain reaction to detect viral particles on such dishes found similar results.[119] In a study of surgical masks against influenza virus, viral RNA was detected in 78% (29 of 37 subjects) of exhaled human breath samples collected from subjects wearing masks, versus 95% (35 of 37 subjects) of those without masks.[120]

Most studies evaluating as-worn face mask efficacy use mannequin heads and compare the number of particles collected inside the mannequin's mask to outside it. Under these conditions, cloth masks have been shown to have highly variable filtration qualities. Cotton mask filtration efficiencies have been measured at between 15–40% when worn on mannequin heads, depending on the material used as an insert filter, when placed immediately next to an aerosol generator.[121] In an experiment in which 2 mannequins configured to simulate tidal breathing faced each other in a test chamber at greater distances of 25 cm to 100cm (<10 inches to 3.4 feet), placing a cloth mask on the source mannequin blocked more than 50% of virus transmission ($P<0.05$).[122] In one study in which cloth masks were placed on mannequins during

[112] Anna Davies et al., *Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic?,* 7 DISASTER MED. & PUB. HEALTH PREPAREDNESS 413 (2013).
[113] Brewster C. Doust & Arthur B. Lyon, *Face Masks in Infections of the Respiratory Tract*, 71 J. AM. MED. ASS'N 1216 (1918).
[114] C. G. Paine, *The Aetiology of Puerperal Infection*, 1 BRIT. MED. J. 243 (1935).
[115] R. A. Shooter et al., *A Study of Surgical Masks*, 47 BRIT. J. SURGERY 246 (1959).
[116] V. W. Greene & D. Vesley, *Method for Evaluating Effectiveness of Surgical Masks*, 83 J. BACTERIOLOGY 663 (1962).
[117] Louis B. Quesnel, *The Efficiency of Surgical Masks of Varying Design and Composition*, 62 BRIT. J. SURGERY 936 (1975).
[118] Charles F. McKhann et al., *Hospital Infections: A Survey of the Problem*, 55 AM. J. INFECTIOUS DISEASES CHILDREN 579 (1938).
[119] D. F. Johnson et al., *A Quantitative Assessment of the Efficacy of Surgical and N95 Masks to Filter Influenza Virus in Patients with Acute Influenza Infection*, 49 CLINICAL INFECTIOUS DISEASES 275 (2009).
[120] Donald K. Milton et al., *Influenza Virus Aerosols in Human Exhaled Breath: Particle Size, Culturability, and Effect of Surgical Masks*, 9 PLOS PATHOGEN 1, 2 (2013).
[121] W. C. Hill et al., *Testing of Commercial Masks and Respirators and Cotton Mask Insert Materials Using SARS-CoV-2 Virion-Sized Particulates: Comparison of Ideal Aerosol Filtration Efficiency Versus Fitted Filtration Efficiency*, 20 NANO LETTERS 7642, 7645 (2020).
[122] Hiroshi Ueki et al., *Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2*, 5 MSPHERE 1, 3 (2020).

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simulated speaking or coughing, high-speed imaging showed that less than 0.1% of large droplets (>30 μm) escaped.[123] Another mannequin study found similar results, with masks blocking between 50–98% of 5 micron particles but only 0–55% of 0.5 micron particles when breathing outwards.[124] Cloth masks sewn to CDC specifications offered ~18% inward and 0% outward filtration efficacy at the 0.5 micron size, with inward/outward efficiencies improving as particle size increased.[125]

Surgical masks on mannequin heads tend to outperform cloth masks but still demonstrate variable results. One mannequin study found that between 5%–20% of respiratory secretions were captured by standard surgical masks during simulated tidal breathing due to face mask leakage, while better-fitting surgical masks ("SecureFit Ultra") captured ~50% of outward-moving particles.[126] Another study calculated the leakage of inward-moving particles from surgical masks and found that leakage rates were inversely related to particle size, decreasing from ~78% at 0.3 micron size to ~5% at the 10 micron size.[127] Other fitted filtration studies have reported similar findings.[128,129,130,131] Fewer mannequin studies have been conducting to evaluate the effects of surgical masks on actual viral particles. In one study, researchers aerosolized influenza virus in 0.5 seconds 70 cm in front of a mannequin, collected samples in one minute,

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[123] Lucia Bandiera et al., *Face Coverings and Respiratory Tract Droplet Dispersion*, 7 ROYAL SOC'Y OPEN SCI. 1, 6 (2020).
[124] Jin Pan et al., *Inward and Outward Effectiveness of Cloth Masks, a Surgical Mask, and a Face Shield*, 55 AEROSOL SCI. & TECH. 718, 728 fig.7 (2021).
[125] *Id*.
[126] Rajeev B. Patel et al., *Respiratory Source Control Using a Surgical Mask: An In Vitro Study*, 13 J. OCCUPATIONAL & ENVTL. HYGIENE 569, 575 fig.6 (2016).
[127] Gholamhossein Bagheri et al., *Face-Masks Save Us from SARS-CoV-2 Transmission*, ARXIV 1 (2021), https://arxiv.org/pdf/2106.00375.
[128] Phillip Clapp et al., *Evaluation of Cloth Masks and Modified Procedure Masks as Personal Protective Equipment for the Public During the COVID-19 Pandemic*, 181 JAMA INTERNAL MED. 463, 463 (2021).
[129] William G. Lindsley et al., *Efficacy of Face Masks, Neck Gaiters and Face Shields for Reducing the Expulsion of Simulated Cough-Generated Aerosols*, 55 AEROSOL SCI. & TECH. 449, 449 (2021).
[130] Amy V. Mueller et al., *Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE*, 3 MATTER 950, 950 (2020).
[131] John T. Brooks et al., *Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021*, 70 MORBIDITY & MORTALITY WKLY. REP. 254, 254 (2021).

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and compared the amount of recovered virus from inside and outside the mask.[132] Researchers reported an average 83% reduction in viral particles with a range of 9–98% against particles between 1–200 microns in size, though the study's applicability to long-term mask use in real-life situations is unclear and researchers did not test either cloth masks or surgical masks with ear loops.[133]

Two mechanistic source control studies evaluated the impact of surgical masks against actual SARS-CoV-2 particles. In one study, 7 COVID-19 positive patients were asked to cough five times onto a petri dish placed 20 cm in front of their mouths—researchers reported that, compared to coughing without a mask, surgical masks were associated with reduced viral load in three cases, increased viral load in two cases, and in two cases they did not detect virus in either sample.[134] In another, surgical masks eliminated detectable coronavirus particles in both respiratory droplets and aerosols after infected subjects breathed into an air collection device for 30 minutes, but most (60%) respiratory samples of unmasked individuals also failed to contain detectable virions.[135]

Nonetheless, even partial filtration could be beneficial by reducing viral concentration, which may reduce the chance of transmission and the severity of disease.[136] The infective dose

[132] C. Makison Booth et al., *Effectiveness of Surgical Masks Against Influenza Bioaerosols*, 84 J. HOSP. INFECTION 22, 24 (2013).
[133] *Id.* at 23.
[134] Min-Chul Kim et al., *Effectiveness of Surgical, KF94, and N95 Respirator Masks in Blocking SARS-CoV-2: A Controlled Comparison in 7 Patients*, 52 INFECTIOUS DISEASES 908, 910 (2020).
[135] Nancy H. Leung et al., *Respiratory Virus Shedding in Exhaled Breath and Efficacy of Face Masks*, 26 NATURE MED. 676, 679 tbl.1b (2020).
[136] Monica Gandhi et al., *Masks Do More Than Protect Others During COVID-19: Reducing the Inoculum of SARS-Cov-2 to Protect the Wearer*, 35 GEN. INTERNAL MED. 3063, 3063 (2020).

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for SARS-CoV-2 is not known but some commentators have speculated a number of between 100 and 700 virions.[137]

III. Clinical and observational evidence in the COVID-19 setting

Laboratory evidence is suggestive, but only high-quality clinical evidence can definitively establish the impact of cloth mask wearing under real-world conditions. Unfortunately, only two randomized controlled trials (RCT) have evaluated the efficacy of cloth face masking against the spread of COVID-19.

One study of 4862 participants in Denmark ("DANMASK") who reported being outside the home for more than 3 hours per day found no statistically significant difference between a group receiving a recommendation to wear a surgical mask when outside the home and the control group (1.8% (n=42) of the masked intervention group became infected vs. 2.1% (n=53) of the control group).[138] The DANMASK study relied on self-reported adherence,[139] was not designed to test the efficacy of masks as source control,[140] and did not consider whether COVID-19 positive participants were infected in the home,[141] among other limitations.[142,143]

A second, high-quality, cluster-randomized study of more than 342,000 adults spread across 600 villages in rural Bangladesh found that placement in the study's intervention group

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[137] Sedighe Karimzadeh et al., *Review of Infective Dose, Routes of Transmission, and Outcome of COVID-19 Caused by the SARS-CoV-2 Virus: Comparison with Other Respiratory Viruses*, 149 EPIDEMIOLOGY & INFECTION 1, 6 (2021).
[138] Henning Bundgaard et al., *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial*, 174 ANNALS INTERNAL MED. 335, 335 (2021).
[139] Christine Laine et al., *The Role of Masks in Mitigating the SARS-CoV-2 Pandemic: Another Piece of the Puzzle*, 174 ANNALS INTERNAL MED. 419, 419 (2021).
[140] Vinay Prasad, *Here's How to Think About the Danish Mask Study*, MEDPAGE TODAY, Nov. 18, 2020, https://www.medpagetoday.com/blogs/vinay-prasad/89778 (last visited Sep. 5, 2021).
[141] *Comments on DANMASK-19 Study*, ANNALS INTERNAL MED., https://www.acpjournals.org/doi/10.7326/M20-6817 (last visited Sep. 5, 2021).
[142] Thomas R. Frieden & Shama Cash-Goldwasser, *Of Masks and Methods*, 174 ANNALS INTERNAL MED. 421, 421 (2021).
[143] Henning Bundgaard et al., *Face Masks for the Prevention of COVID-19-Rationale and Design of the Randomised Controlled Trial DANMASK-19*, 67 DANISH MED. J. 1 (2020).

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increased mask-wearing by 28.8% (from 13.3 to 42.3%),[144] with participants in control villages (n=13,893) reporting a 1% higher rate of symptoms of COVID-like illness than participants in intervention villages (n=13,273) (8.6% v. 7.6%; P=0.000).[145] Similar relative rate differences were noted for the study's primary outcome, symptomatic seroprevalence (positive blood test plus COVID-19 symptoms), with control and intervention prevalence rates of 0.80% and 0.71%, respectively (P=0.043).[146] Researchers also reported results by mask type, finding that surgical masks reduced symptomatic seroprevalence rates by 0.09% compared to controls (0.67% vs. 0.76%, P=0.043), but that cloth masks did not offer a statistically significant rate reduction (cloth mask: 0.74%, control: 0.76%, P=0.540).[147] A secondary endpoint of symptoms without serologic confirmation favored face masking generally,[148] but this endpoint is highly bias susceptible and the difference in the cloth mask subgroup, although borderline statistically significant, was less than 1% (cloth mask group: 7.9% v. 8.6%, p=0.048). Communities assigned to masking may report symptoms differently, and the more rigorous endpoint of laboratory-confirmed prior SARS-CoV-2 infection found no benefit.

The Bangladesh cluster RCT is applicable to the unique circumstances of the region. Natural immunity at the outset of the study was very low due to low case numbers, vaccination was largely absent, and children and schools were not included. Unfortunately, this trial is limited in its ability to inform regions with higher rates of natural immunity, higher rates of

[144] Jason Abaluck et al., *The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh*, at 18, WORKING PAPER, Aug. 31, 2021, https://www.poverty-action.org/sites/default/files/publications/Mask_RCT____Symptomatic_Seropositivity_083121.pdf (last visited Sep. 4, 2021).
[145] *Id.* at 22.
[146] *Id.* at 23.
[147] *Id.*
[148] *Id.* at 24.

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vaccination, or school policies. A large RCT (n= ~40,000) in Guinea-Bissau on community cloth face mask use against COVID-19 is ongoing.[149]

The remainder of the available clinical evidence is primarily limited to non-randomized observational data, which are subject to confounding. Several studies of so-called "natural experiments"[150] found suggestive results of mask effectiveness by comparing case rates in locations implementing mask mandates with those that did not. A widely-cited U.S. study by Lyu et al. of state-wide executive orders requiring masks during the early months of the COVID-19 pandemic found reductions in the average daily county-level growth rate of between 0.9 and 2.0 percentage points during each of a series of 5-day periods beginning 1 day after signing the mask order (days 1–5, 6–10, 11–15, 16–20, and 21+),[151] but declines began sooner than the mean 5.8-day incubation period would suggest could be plausibly connected to mask usage,[152] and researchers did not attempt to measure actual mask usage or the impact of mask mandates on mobility. The researchers' estimates that state mandates prevented up to 450,000 cases (and, assuming a 1% case fatality rate, 4,500 deaths) by May 22, 2020 were repeated in news media despite the researchers' statement that their estimates "should be viewed cautiously."[153] A widely-cited, non-peer-reviewed analysis from Goldman Sachs based in part on mask mandate

[149] *Locally Produced Cloth Face Mask and COVID-19 Like Illness Prevention*, U.S. NAT'L LIBRARY OF MED., https://clinicaltrials.gov/ct2/show/NCT04471766 (last visited Nov. 16, 2020).
[150] Mark Petticrew et al., *Natural Experiments: An Underused Tool for Public Health?*, 119 PUB. HEALTH 751 (2005).
[151] Wei Lyu & George L. Wehby, *Community Use of Face Masks and COVID-19: Evidence from a Natural Experiment of State Mandates in the US*, 39 HEALTH AFFAIRS 1419, 1422 (2020).
[152] Conor McAloon et al., *Incubation Period of COVID-19: A Rapid Systematic Review and Meta-Analysis of Observational Research*, 10 BMJ OPEN 1, 6 fig.3 (2020).
[153] Wei Lyu & George L. Wehby, *Community Use of Face Masks and COVID-19: Evidence from a Natural Experiment of State Mandates in the US*, 39 HEALTH AFFAIRS 1419, 1423 (2020).

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data from the Lyu et al. study concluded a national mask mandate could reduce the daily growth rate in infections in states without a mandate from 2.9% to 1%.[154]

Another study of data from 24 counties (23%) in Kansas that abided by the governor's mask mandate (or adopted their own) and 81 counties (77%) that opted out of the mandate found a decline in incidence from 17 to 16 per 100,000 in the former and an increase from 6 to 12 per 100,000 in the latter.[155] However, the choice of opting in or out of the mask mandate suggests different attitudes toward COVID-19 that may have affected other behavioral choices, and six cities in non-mask mandated counties also had mask ordinances in place at the time.[156] In at least 13 (54%) of the 24 mandated counties, mask mandates occurred alongside other mandated or recommended county-level mitigation strategies (e.g., gathering size limitations).[157] Notably, both sets of counties experienced large increases in case rates in the month following the publication of this study.[158]

Other natural experiment studies have similarly taken advantage of differential timing of mask mandates or other interventions to determine the effects of mask wearing on COVID-19 infection rates, generally finding that mask mandates substantially reduced the growth rate of infections and deaths.[159,160,161,162,163,164,165,166,167] Although some of these studies attempt to

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[154] J. Hatzius et al., *Face Masks and GDP*, GOLDMAN SACHS, June 29, 2020, https://www.goldmansachs.com/insights/pages/face-masks-and-gdp.html (last visited Sep. 5, 2021).
[155] Miriam E. Van Dyke et al., *Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate—Kansas, June 1–August 23, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1777, 1779 tbl. (2020).
[156] *Id.* at 1779.
[157] *Id.* at 1778.
[158] @youyanggu, Twitter (Dec. 12, 2020), https://twitter.com/youyanggu/status/1339306972189843456. ("A CDC paper last month found that Kansas counties with mask mandates saw a decrease in cases in Aug, while counties without mandates saw an increase. Since then, both groups saw a huge surge. Counties w/mandates are doing a bit better, but it's difficult to determine causation.")
[159] Victor Chernozhukov et al., *Causal Impact of Masks, Policies, Behavior on Early Covid-19 Pandemic in the U.S*, 220 J. ECONOMETRICS 23, 23 (2021).
[160] Alexander Karaivanov et al., *Face Masks, Public Policies and Slowing the Spread of Covid-19: Evidence from Canada*, 78 J. HEALTH ECON. 1, 1 (2021).
[161] Timo Mitze et al., *Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Method Approach*, 117 PROC. NAT'L ACAD. SCI. 32293, 32293 (2020).

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control for behavioral changes by using, e.g., Google mobility data, those data may not capture key aspects of mobility changes, such as selective reductions in mobility by those individuals exhibiting symptoms (e.g., due to increased social stigma of coughing or knowledge that one will face a temperature screening), greater physical distancing within retail establishments or other locations,[168] or the availability of curbside or no-contact pickup. These studies also cannot easily control for non-mobility related measures that may correlate with mask mandates, such as reductions in verbal communication when masks are worn, increased use of sanitary wipes, installation of clear plastic barriers, customer capacity limitations, or adjustments to equipment settings that improve indoor ventilation or air filtration. In cases where mask mandates occurred alongside other public health interventions, such as school or business closure or shelter-in-place restrictions, disambiguating the effects of one component is challenging. Most studies readily admit to limitations such as these.

Country comparisons suffer from similar potential confounding. A multivariate analysis of 196 countries found that only four country-level characteristics correlated in a statistically significant manner with coronavirus mortality rates: duration since first COVID-19 case (coefficient: 0.1782, P<0.001), percentage of population over age 60 (coefficient: 0.0691, P<0.001), obesity prevalence (coefficient: 0.0196, P=0.02), and time since first mask

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[162] M. S. Gallaway et al., *Trends in COVID-19 Incidence After Implementation of Mitigation Measures – Arizona, January 22-August 7, 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1460, 1462 (2020).
[163] Vincent C. Cheng et al., *The Role of Community-wide Wearing of Face Mask for Control of Coronavirus Disease 2019 (COVID-19) Epidemic Due to SARS-CoV-2*, 81 J. INFECTION 107, 109–12 (2020).
[164] Xiaowen Wang et al., *Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers*, 324 J. AM. MED. ASS'N 703, 703 (2020).
[165] Heesoo Joo et al., *Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020*, 70 MORBIDITY & MORTALITY WKLY. REP. 212 (2021).
[166] Gery P. Guy et al., *Association of State-Issued Mask Mandates and Allowing On-Premises Restaurant Dining with County-Level COVID-19 Case and Death Growth Rates — United States, March 1–December 31, 2020,* 70 MORBIDITY & MORTALITY WKLY. REP. 350 (2021).
[167] Dhaval Adjodah et al., *Association Between COVID-19 Outcomes and Mask Mandates, Adherence, and Attitudes*, 16 PLOS ONE 1, 1 (2021).
[168] Gyula Seres et al., *Face Mask Use and Physical Distancing Before and After Mandatory Masking: Evidence from Public Waiting Lines*, (No. SP II 2020-305) WZB DISCUSSION PAPER 1, 1–2 (2020).

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recommendation (coefficient: -0.1266, P<0.001).[169] However, the authors concede that "[s]urveys and observational data of mask-wearing by the public [were] unavailable for most countries" and that the simultaneous adoption of health policies can make it "difficult to tease out the relative importance of each."[170]

Another study compared the mask-wearing rate of people in multiple countries from March to April 2020 with coronavirus fatalities and concluded that the mask non-wearing rate in mid-March explained up to 72% of the variation in COVID-related deaths by mid-May.[171] The study's authors also noted that cultural differences may explain much of the differences in infection rates; in Japan, for example, most people do not talk on public transit which may reduce exhaled aerosols[172] and there is evidence to suggest that mask-wearing in Japan also correlates with other positive hygiene practices, such as hand washing and vaccination.[173]

Several observational studies have attempted to correlate mask-wearing with COVID-19 infection rates in contexts other than state- or country-wide government mask mandates, but suffer from similar potential confounding.[174] For example, studies examining the transmission of SARS-CoV-2 on airplanes have suggested lower rates of secondary cases on flights with masking compared to those without it,[175] but it is unclear whether differences in other factors such as passenger spacing, flight duration, passenger follow-up efforts, cough intensity of infected patients, or pre- or post-flight infection rates played a role. Flight conditions are also

[169] Christopher T. Leffler et al., *Association of Country-wide Coronavirus Mortality with Demographics, Testing, Lockdowns, and Public Wearing of Masks,* 103 AM. J. TROPICAL MED. & HYGIENE 2400, 2406 tbl.4 (2020).
[170] *Id.* at 2407.
[171] Daisuke Miyazawa & Gen Kaneko, *Face Mask Wearing Rate Predicts Country's COVID-19 Death Rates*, MEDRXIV 1, 16 (2020), https://www.medrxiv.org/content/10.1101/2020.06.22.20137745v4.full.pdf.
[172] *Id.* at 15.
[173] Koji Wada et al., *Wearing Face Masks in Public During the Influenza Season May Reflect Other Positive Hygiene Practices in Japan*, 12 BMC PUB. HEALTH 1, 3 (2012).
[174] Chris Kenyon, *Widespread Use of Face Masks in Public May Slow the Spread of SARS CoV-2: An Ecological Study*. MEDRXIV 1, 1 (2020), https://www.medrxiv.org/content/10.1101/2020.03.31.20048652v1.full.pdf.
[175] David O. Freedman & Annelies Wilder-Smith, *In-Flight Transmission of SARS-CoV-2: A Review of the Attack Rates and Available Data on the Efficacy of Face Masks*, 27 J. TRAVEL MED. 1, 6 (2020).

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atypical in terms of passenger density, air filtration, the presence of pressurized cooling vents, and severely restricted mobility, limiting the ability to generalize any findings to the community context. Of 382 sailors on board the aircraft carrier USS Theodore Roosevelt who volunteered to complete a questionnaire (27% of the 1417 total sailors on board), those self-reporting "face covering" had a lower rate of SARS-CoV-2 infection than those who did not (55.8% vs. 80.8%), but other self-reported behaviors also correlated in a statistically significant manner with lower infection rates, including avoidance of common areas (53.8% vs. 67.5%) and increased distancing from others (54.7% vs. 70.0%).[176] A large U.S. cohort study (n=198,077) found similar results, with individuals who responded via Smartphone app to surveys as "always" wearing facemasks outside the home 62% less likely to report COVID-19 infection, although the study could not exclude the possibility that those "always" reporting mask wearing also engaged in other personal risk reduction measures.[177] Similar studies (one in the U.S. and two international) also found correlations between positive responses to mask survey questions and reduced infection rates, and had similar limitations.[178,179,180] A study in Hong Kong found 11 clusters of COVID-19 were related to mask-off settings (i.e. eating, karaoke, religious activities, etc.) while only 3 were related to mask-on (3 clusters) settings (i.e. workplace).[181] However, such mask-off activities may be inherently more risky than the mask-on workplace considered in the

[176] Daniel C. Payne et al., *SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members – USS Theodore Roosevelt, April 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 714, 718 tbl. (2020).
[177] Sohee Kwon et al., *Association of Social Distancing and Face Mask Use with Risk of COVID-19*, 12 NATURE COMMC'NS 1, 7 (2021).
[178] Benjamin Rader et al., *Mask-Wearing and Control of SARS-CoV-2 Transmission in the USA: A Cross-Sectional Study*, 3 LANCET DIGITAL HEALTH. E148, E154 (2021).
[179] Gavin Leech et al., *Mass Mask-Wearing Notably Reduces COVID-19 Transmission,* MEDRXIV 1, 6 (2021), https://www.medrxiv.org/content/10.1101/2021.06.16.21258817v1.full.pdf.
[180] Ashwin Aravindakshan et al., *The Impact of Mask-Wearing in Mitigating the Spread of COVID-19 During the Early Phases of the Pandemic,* MEDRXIV 1, 1 (2021), https://www.medrxiv.org/content/10.1101/2020.09.11.20192971v2.full.pdf.
[181] Vincent C. Cheng et al., *The Role of Community-wide Wearing of Face Mask for Control of Coronavirus Disease 2019 (COVID-19) Epidemic Due to SARS-CoV-2*, 81 J. INFECTION 107, 109 (2020).

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study, such as by involving larger numbers of people within a given unit of area, longer durations of contact, or greater face-to-face communication.

Without randomization, natural experiments and other observational evidence provide only weak evidence of effectiveness.[182] Even when they reveal meaningfully different infection rates, the groups being compared may not possess similar characteristics, preventing causal inference. For example, geographic comparisons do not account for the possibility that, in locations where legislators have sufficient political support to enact mask mandates, populations are likely to have different attitudes about COVID-19 that could affect behavior other than mask-wearing.[183] Four natural experiment studies measured mask usage rates, but each was based on self-reported surveys which are prone to bias and may not reflect actual behavior. One study, for example, found that while only 12% of individuals surveyed admitted to not wearing a mask, 90% were observed not wearing one, a finding the authors described as a "large and statistically significant discrepancy."[184] Lower case rates following mask mandates could be mediated by differential propensities to respond to new information with, for example, increased hand hygiene, voluntary business restrictions, physical distancing, or reduced time away from home or participation in certain activities. It is possible that mask mandates reduce infection rates by prompting media coverage or statements of public health officials that increase public awareness, or reducing the willingness of individuals to enter public spaces where masks are required rather than reducing transmission when they enter those spaces.[185,186]

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[182] *Using Face Masks in the Community: First Update*, Feb. 15, 2021, EUR. CTR. FOR DISEASE PREVENTION & CONTROL, https://www.ecdc.europa.eu/en/publications-data/using-face-masks-community-reducing-covid-19-transmission (last visited Sept. 5, 2021).
[183] William F. Maloney & Temel Taskin, *Determinants of Social Distancing and Economic Activity During COVID-19: A Global View*, WORLD BANK POL'Y RESEARCH WORKING PAPER 1, 3 (2020).
[184] Aleksandra Jakubowski et al., *Self-reported vs Directly Observed Face Mask Use in Kenya*, 4 JAMA NETWORK OPEN 1, 3 (2021).
[185] Daniel J. McGrail et al., *Enacting National Social Distancing Policies Corresponds with Dramatic Reduction in COVID19 Infection Rates*, 15 PLOS ONE 1, 1 (2020).

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Although some studies attempted to control for potentially confounding variables, it is unlikely that researchers were able to account for all of them or know which were most important, such as simultaneous public health interventions, the publication of new COVID-related research investigations, changes in the capacity to contact trace, the availability and use of more-rapid or less-expensive diagnostics, or attendance at large-scale public gatherings related to social causes, political rallies, or sporting events. Some studies used self-reporting to measure health behaviors (such as social distancing and mask wearing), but mask mandates could increase social pressure to report or overestimate adherence.

Several retrospective cohort studies have attempted to analyze behaviors among people who were either diagnosed with COVID-19 or had known SARS-CoV-2-positive contacts. One such study of 124 families found that family members reported wearing a mask "all the time" after illness onset more frequently in the 83 families without secondary cases than in the 41 families with such secondary cases (45.8% vs. 19.5%, P=.02).[187] However, members of families without secondary cases also more frequently ate separately after illness onset (65.1% vs. 39.0%, P=.008), more frequently self-isolated after illness onset (69.9% vs. 51.2%, P=.05), more frequently self-isolated within 2 days of illness onset (31.3% vs. 14.6%, P=.05), more frequently had more than 1 hour of ventilation (opening of windows) per day (76.5% vs. 57.5%, P=.02), and less frequently had incidents of "close contact" (within 1 meter) with the primary case (8.7% vs. 30.0%, P<0.001),[188] suggesting that many other behavioral factors could be relevant. A retrospective case-control study (n=1050) in Thailand found similar results and had similar

[186] Laura Matrajt & Tiffany Leung, *Evaluating the Effectiveness of Social Distancing Interventions to Delay or Flatten the Epidemic Curve of Coronavirus Disease*, 26 EMERGING INFECTIOUS DISEASES 1740, 1740 (2020).
[187] Yu Wang et al., *Reduction of Secondary Transmission of SARS-CoV-2 in Households by Face Mask Use, Disinfection and Social Distancing: A Cohort Study in Beijing, China*, 5 BMJ GLOBAL HEALTH 1, 5 tbl.1 (2020).
[188] *Id.*

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limitations.[189] Interviews were conducted one to three months after index patient contact, possibly exacerbating recall bias and sample size selection issues.[190]

Several case reports support the use of masks. A report by the Centers for Disease Control and Prevention described 2 Missouri hair stylists who wore masks while symptomatic with COVID-19 and saw 139 clients, none of whom became ill.[191] However, exposure to the index patient was short (median: 15 minutes), clients faced away, and variables such as hand hygiene, extent of conversation, common surfaces available for touching, disinfection of those surfaces, shared locations where masks were doffed and donned, etc., were not evaluated. The report also suffered from diagnostic limitations: only 67 (48%) clients received PCR tests with the remainder reporting no symptoms, testing was offered on day 5 potentially leading to false negatives due to COVID-19's incubation period, and clients exposed during highest viral shedding time (2-3 days before symptoms appear; number of clients not reported) were not included. These limitations in the absence of prospective design, randomization, and control make causal inference challenging.

IV. Clinical evidence from illnesses other than COVID-19

In addition to the two RCTs in the COVID-19 setting, at least 14 RCTs have assessed the relationship between mask-wearing and other respiratory infections (**Table 1**). Five of these took place in communal living settings, eight in household settings, and one in a hospital.

Communal living RCTs

[189] Pawinee Doung-Ngern et al., *Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand*, 26 EMERGING INFECTIOUS DISEASES 2607, 2607 (2020).
[190] *Id.* at 2609.
[191] M. J. Hendrix et al., *Absence of Apparent Transmission of SARS-CoV-2 from Two Stylists After Exposure at a Hair Salon with a Universal Face Covering Policy – Springfield, Missouri, May 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 930, 930 (2020).

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Four of the 5 RCTs examining the effectiveness of mask-wearing in communal settings failed to find statistically significant results. A 3-arm cluster-randomized study of rates of influenza-like illnesses (ILI) among 1178 students in University of Michigan residence halls failed to find a benefit from wearing face masks alone compared to an unmasked control group (11.7% (46/392) vs. 13.8% (51/370); adjusted cumulative rate ratio [RR]: 1.10),[192] but found that masks plus hand hygiene did provide benefit (8.9% (31/349) vs. 13.8% (51/370); RR: 0.78),[193] consistent with findings in an earlier similar cluster-randomized study by the same researchers.[194] A 3-arm study of 995 Hajj pilgrims randomized into health education (n=292, 29%), health education plus face mask (n=257, 26%), and control (n=446, 45%) groups reported adherence rates of 52% and 81% in its intervention arms, respectively, but found no association between face mask wearing compliance and the chance of developing an acute respiratory infection in 225 individuals within one week of returning (OR: 0.97).[195] In a pilot study of 164 Hajj pilgrims, 53% (28/53) no-mask contacts sleeping immediately adjacent to patients with known ILIs became symptomatic, while only 31% (11/36) of masked contacts did so (P=.04).[196] However, a much larger (n=7687) randomized controlled follow-up study by the same research group not only failed to show a statistically significant benefit for mask wearing, but the per-protocol analysis showed higher point estimates for mask wearers compared to non-mask wearers for both clinical respiratory infections (12% (97/828) vs. 9% (141/1497); odds ratio

[192] Allison E. Aiello et al., *Facemasks, Hand Hygiene, and Influenza Among Young Adults: A Randomized Intervention Trial*, 7 PLOS ONE 1, 6 tbls.3, S1, and S5 (2012).
[193] *Id.*
[194] Allison E. Aiello et al., *A Randomized Intervention Trial of Mask Use and Hand Hygiene to Reduce Seasonal Influenza-Like Illness and Influenza Infections Among Young Adults in a University Setting*, 14 INT'L J. INFECTIOUS DISEASES 491 (2010).
[195] Ebtihal Z. Abdin et al., *Effect of Use of Face Mask on Hajj-Related Respiratory Infection Among Hajjis from Riyadh: A Health Promotion Intervention Study*, 12 SAUDI EPIDEMIOLOGY BULL. 27, 27–28 (2005).
[196] Osamah Barasheed et al., *Pilot Randomised Controlled Trial to Testing Facemasks Effectiveness in Preventing Influenza-Like Illness Transmission Among Hajj Pilgrims,* 14 INFECTIOUS DISORDERS DRUG TARGETS 110, 113 tbl.1 (2014).

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[OR]: 1.3) and laboratory-confirmed respiratory infections (50% (46/93) vs. 41% (50/122); OR: 1.2).[197] While a subsequent meta-analysis of 13 mostly cohort and cross-sectional studies looking at face mask use among Hajj pilgrims reported a statistically significant decrease in respiratory infections (RR: 0.89; P<.01), it cautioned that facemask effectiveness was still "inconclusive due to great heterogeneity in study [design]" and included only two RCTs in its analysis.[198]

Household RCTs

All of the eight RCTs examining the impact of face masks in household settings failed to find statistically significant results in intention-to-treat analyses, with one reporting a significant decrease in a sub-group, per-protocol analysis. Most of these studies recruited patients shortly after diagnosis with an ILI, randomized them into a treatment category, and then traced the number of household contacts who then become ill. The studies varied in whether or not the intervention group required mask-wearing for the index patient (source control), other household members, or both groups.

Two RCTs looked at the utility of facemasks as source-control measures to prevent secondary infection in household settings and neither study reported protective effects. One of these took place in France, and found that when index cases wore surgical face masks for the five days following diagnosis, there was no statistically significant difference in transmission compared to households in which index cases did not wear a mask (16.2% (24/148) vs. 15.8% (25/158)).[199] A nearly identical study in China that randomized 245 ILI index cases to mask (n=123) and no mask (n=122) groups—while only requiring mask-wearing until symptom

[197] Mohammad Alfelali et al., *Facemask Against Viral Respiratory Infections Among Hajj Pilgrims: A Challenging Cluster-Randomized Trial*, 15 PLOS ONE 1, 7 (2020).
[198] Osamah Barasheed et al., *Uptake and Effectiveness of Facemask Against Respiratory Infections at Mass Gatherings: A Systematic Review*, 47 INT'L J. INFECTIOUS DISEASES 105, 109 (2016).
[199] Laetitia Canini et al., *Surgical Mask to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 5 PLOS ONE 1, 5 (2010).

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abatement—found no statistically significant effects on intra-household rates of clinical respiratory illness (0.19% (4/2098) vs. 0.29% (6/2036)) or ILI (0.05% (1/2098) vs. 0.15% (3/2036)).[200]

One household RCT conducted in Australia attempted to determine the protective effect of masks for the wearer. The study, involving 245 adults in 145 families in which the index case was a child diagnosed with an ILI and in which parents were randomized to wear a surgical, P2 (an N95 equivalent), or no mask, showed no significant differences in secondary ILI infection rates at the individual level (surgical mask: 19/94 (20%); P2 mask: 14/92 (15%)) compared to the control group (16/100 (16%)).[201] A pre-planned per-protocol analysis found a statistically significant decrease (P=.015) in infection rates among adherent mask users (RR: 0.26),[202] but adherence was low (38% (36/94) of surgical and 46% (42/92) of P2 mask users reported wearing masks "most or all" of the time on the intervention's first day),[203] and adherent participants may have been more likely to engage in other protective behaviors.

Five RCTs evaluated the effects of mask wearing by all household members on secondary infection rates, with mixed results. A Thai study followed child influenza cases in 442 households with 1147 household members, randomized families into hand-washing (n= 292), hand-washing plus face masks (n=291), and control arms (n=302), and reported higher secondary ILI rates based on self-reported symptoms of 17% (50/292) in the hand-washing arm and 18% (51/291) in the hand-washing plus mask arm—compared to only 9% (26/302) in the control arm, and there were no significant differences in the primary outcome measure of

[200] Chandini R. MacIntyre et al., *Cluster Randomised Controlled Trial to Examine Medical Mask Use as Source Control for People with Respiratory Illness*, 6 BMJ OPEN 1, 5 tbl.2 (2016).
[201] Chandini R. MacIntyre et al., *Face Mask Use and Control of Respiratory Virus Transmission in Households*, 15 EMERGING INFECTIOUS DISEASES 233, 238 tbl.4 (2009).
[202] *Id.* at 237.
[203] *Id.* at 236.

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laboratory-confirmed secondary influenza.[204] A pilot study of 198 Hong Kong households found no statistically significant benefit on intra-household secondary influenza infection rates when all household contacts wore masks (5.9%, 12/205) or were educated and given hand hygiene materials (6.6%, 4/61), compared to controls (6.0%, 5/84).[205] A larger, follow-up study by the same group also found no statistically significant benefit for PCR-confirmed secondary influenza infections when all household contacts wore masks and practiced hand hygiene ("M+HH"; 7.0%, 18/258) compared to hand hygiene alone ("HH"; 5.4%, 14/257), or a control arm with neither intervention (10.0%, 28/279; 3-group P value: 0.22);[206] these results were consistent when using two additional clinical definitions of flu (3-group P-values of 0.40 and 0.28).[207] In a pre-planned, sub-group analysis of households that implemented interventions within 36 hours of symptom onset, 3-group P values reported statistically significant differences under two of three illness criteria, although the M+HH group still underperformed the HH-alone group in most cases (PCR-confirmed: HH 5.4% (7/130), M+HH 4.0% (6/149); Clinical Definition 1: HH 10.8% (14/130), M+HH 18.1% (27/149); Clinical Definition 2: HH 3.1% (4/130), M+HH 4.7% (7/149)).[208] A German study implementing a similar protocol reported protective benefits of masks in its per-protocol analysis, but not its intention-to-treat analysis, finding that compared to the unmasked group, the face mask-only group had a 70% reduced chance (OR: 0.3, P=.04) of secondary infection in household contacts (n=218) against RT-PCR-confirmed influenza, but not

[204] James M. Simmerman et al., *Findings from a Household Randomized Controlled Trial of Hand Washing and Face Masks to Reduce Influenza Transmission in Bangkok, Thailand: Household Randomized Controlled Trial of Hand Washing and Face Masks*, 5 INFLUENZA & OTHER RESPIRATORY VIRUSES 256, 263 tbl.2 (2011).
[205] Benjamin J. Cowling et al., *Preliminary Findings of a Randomized Trial of Non-pharmaceutical Interventions to Prevent Influenza Transmission in Households*, 3 PLOS ONE 1, 7 tbl.2 (2008).
[206] Benjamin J. Cowling et al., *Facemasks and Hand Hygiene to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 151 ANNALS INTERNAL MED. 437, 442 tbl.3 (2009).
[207] *Id.*
[208] *Id.*

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influenza-like illness (OR: 0.5, P=.3).[209] A 19-month study of 617 New York City households that randomized families into three cohorts—hand sanitizer ("HS", n=205), HS plus face mask ("HS + mask", n=201), and an educational control group (n=211)—and followed them for 19 months while tracking respiratory infection rates found that the HS + mask group (OR: 0.82; 95% CI 0.70-0.97) outperformed the HS alone group (OR: 1.01; 95% CI 0.85-1.21), compared to the reference educational group.[210]

Healthcare settings

RCT evidence of face mask efficacy in healthcare settings is limited. One small RCT (n=32) of healthcare workers at a Japanese hospital found no statistically significant difference between mean number of days of cold symptoms reported by surgical face mask wearers (mean=16.1 days) and non-wearers (mean=14.3 days; P=.81) during the winter season.[211] And although surgical masks are ubiquitously worn during surgery because they are believed to prevent infection,[212,213,214] multiple studies have reported that the use of surgical masks as source control in operating theaters has not proven to reduce surgical site infection—with a Cochrane meta-analysis reporting mask v. no-mask infection rates of 1.8% (13/706) vs. 1.4% (10/723;

[209] Thorsten Suess et al., *The Role of Facemasks and Hand Hygiene in the Prevention of Influenza Transmission in Households: Results from a Cluster Randomised Trial; Berlin, Germany, 2009–2011*, 12 BMC INFECTIOUS DISEASES 1, 10 tbl.5 (2012).
[210] Elaine L. Larson et al., *Impact of Non-pharmaceutical Interventions on URIs and Influenza in Crowded, Urban Households*, 125 PUB. HEALTH REP. 178, 186 tbl.5 (2010).
[211] Joshua L. Jacobs et al., *Use of Surgical Face Masks to Reduce the Incidence of the Common Cold Among Health Care Workers in Japan: A Randomized Controlled Trial*, 37 AM. J. INFECTION CONTROL 417, 419 tbl.3 (2009).
[212] Neil W. Orr, *Is a Mask Necessary in the Operating Theatre*?, 63 ANNALS ROYAL COLL. SURGEONS ENG. 390 (1981).
[213] N. J. Mitchell & S. Hunt, *Surgical Face Masks in Modern Operating Rooms—A Costly and Unnecessary Ritual?,* 18 J. HOSP. INFECTION 239 (1991).
[214] M. G. Romney, *Surgical Face Masks in the Operating Theatre: Re-examining the Evidence*, 47 J. HOSP. INFECTION 251 (2001).

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P>.05),[215] 0% (0/10) vs. 30% (3/10; P>.05),[216] and 10.5% (33/313) vs. 9.1% (31/340; P>.05)[217] from studies conducted in its literature review.[218]

Comparing types of masks

At least ten studies evaluate the clinical efficacy of different types of masks compared to one another, but without a no-mask control group most provide little insight into mask efficacy. Four RCTs, four meta-analyses, and one prospective cohort study found surgical masks were non-inferior to N95s for protection against respiratory infections,[219,220,221,222,223,224,225,226,227] and one found evidence that N95s provide greater protection than medical masks against self-

[215] Th G. Tunevall, *Postoperative Wound Infections and Surgical Face Masks: A Controlled Study*, 15 WORLD J. SURGERY 383 (1991).
[216] *See* also Geoffrey V. Chamberlain & Elizabeth Houang, *Trial of the Use of Masks in the Gynaecological Operating Theatre*, 66 ANNALS ROYAL COLL. SURGEONS ENG. 432 (1984) (finding an increased infection rate after major abdominal surgery when the surgical team did not wear masks (3 of 5 subjects) compared to when they did wear masks (0 of 4 subjects), but the finding was not statistically significant and the researchers also found higher bacterial counts in air samples taken during masked versus unmasked procedures (154 vs. 96 colony forming units)).
[217] Joan Webster et al., *Use of Face Masks by Non-scrubbed Operating Room Staff: A Randomized Controlled Trial*, 80 ANZ J. SURGERY 169 (2010).
[218] Marina Vincent & Peggy Edwards, *Disposable Surgical Face Masks for Preventing Surgical Wound Infection in Clean Surgery*, 4 COCHRANE DATABASE SYS. REV. 1, 8 (2016).
[219] Mark Loeb et al., *Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers: A Randomized Trial,* 302 J. AM. MED. ASS'N 1865, 1870 (2009).
[220] Chandini R. MacIntyre et al., *A Randomized Clinical Trial of Three Options for N95 Respirators and Medical Masks in Health Workers*, 187 AM. J. RESPIRATORY & CRITICAL CARE MED. 960, 963 (2013) (finding that surgical mask use was not inferior to targeted N95 use).
[221] Lewis J. Radonovich et al., *N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial*, 322 J. AM. MED. ASS'N 824, 830 (2019).
[222] Youlin Long et al., *Effectiveness of N95 Respirators Versus Surgical Masks Against Influenza: A Systematic Review and Meta-Analysis*, 13 J. EVIDENCE-BASED MED. 93, 98 (2020).
[223] Jessica J. Bartoszko et al., *Medical Masks vs N95 Respirators for Preventing COVID-19 in Healthcare Workers: A Systematic Review and Meta-Analysis of Randomized Trials*, 14 INFLUENZA & OTHER RESPIRATORY VIRUSES 365 368 (2020).
[224] Tom Jefferson et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses (Review),* 11 COCHRANE DATABASE SYS. REV. 1, 6–7 (2020).
[225] Jeffrey D. Smith et al., *Effectiveness of N95 Respirators Versus Surgical Masks in Protecting Health Care Workers from Acute Respiratory Infection: A Systematic Review and Meta-Analysis*, 188 CAN. MED. ASS'N J. 567, 572 (2016).
[226] Sabine Haller et al., *Use of Respirator vs. Surgical Masks in Healthcare Personnel and Its Impact on SARS-CoV-2 Acquisition – A Prospective Multicentre Cohort Study*, MEDRXIV 1 (2021), https://www.medrxiv.org/content/10.1101/2021.05.30.21258080v1.full.pdf.
[227] Katarzyna Barycka et al., *Comparative Effectiveness of N95 Respirators and Surgical/Face Masks in Preventing Airborne Infections in the Era of SARS-CoV2 Pandemic: A Meta-Analysis of Randomized Trials*, 15 PLOS ONE 1 (2020).

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reported clinical respiratory illness but not ILI.[228] However, a recent review found that evidence that N95s protect healthcare workers from clinical respiratory infections at all is "low-quality."[229] One meta-analysis of particular note, an April 2020 preprint of a Cochrane review of clinical evidence for both surgical and N95 masks, "did not find any differences in the clinical effectiveness of either type of mask in the setting of respiratory viral infection transmission to healthcare workers,"[230] although the review's final November version omitted this language.[231]

One RCT compared continually worn cloth masks with surgical masks in the healthcare setting, finding cloth masks were associated with ILI infection rates 13-times higher (13/569 or 2.28% for cloth masks; 1/580 or 0.17% for surgical masks) than surgical masks (RR=13.00).[232] The study has been criticized because it provided new surgical masks more frequently than cloth masks and lacked washing protocols for cloth masks,[233,234] but may provide insight into the effectiveness of community masking where washing protocols are similarly absent and reuse is frequent. A post-hoc, sub-group analysis of this data concluded that the difference in infection rates were largely explained by washing protocols—participants who hand-washed their cloth masks (77%) as opposed to using the hospital laundry (13%) reported infection rates more than

[228] Vittoria Offeddu et al., *Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis*, 65 CLINICAL INFECTIOUS DISEASES 1934, 1938 (2017).
[229] Primiano Iannone et al., *The Need of Health Policy Perspective to Protect Healthcare Workers During COVID-19 Pandemic. A GRADE Rapid Review on the N95 Respirators Effectiveness*, 15 PLOS ONE 1, 1 (2020).
[230] Tom Jefferson et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses. Part 1 – Face Masks, Eye Protection and Person Distancing: Systematic Review and Meta-Analysis*, MEDRXIV 1, 12 (2020), https://www.medrxiv.org/content/10.1101/2020.03.30.20047217v2.full.
[231] Tom Jefferson et al., *Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses (Review),* 11 COCHRANE DATABASE SYS. REV. 1 (2020).
[232] Chandini R. MacIntyre et al., *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*, 5 BMJ OPEN 1, 6 tbl.2 (2015).
[233] Jeremy Howard et al., *Face Masks Against COVID-19: An Evidence Review*, 118 PROCEEDINGS NAT'L ACAD. SCI. 1, 7 (2021).
[234] Chandini R. MacIntyre & S. J. Hasanain, *Community Universal Face Mask Use During the COVID 19 Pandemic—From Households to Travellers and Public Spaces*, 27 J. TRAVEL MED. 1, 2 (2020).

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twice as high (OR: 2.04) as the hospital laundry group.[235] A mask-comparison study of 1441 Chinese healthcare workers failed to find a statistically significant benefit to either N95 (Clinical Respiratory Illness [CRI]: 3.9%, P=.085; Influenza-like Illness [ILI]: 0.3%, P=.068; Lab-confirmed virus [LCV]: 1.4%, P=.02; Influenza [flu]: 0.3%, P=.051) or surgical face masks (CRI: 6.7%, P=.52; ILI: 0.6%, P=.33; LCV: 2.6%, P=.67; Flu: 1.0%, P=.73), compared to a convenience no-mask group (CRI: ~8.7%; ILI: ~1.7%; LCV: ~3.1%; Flu: ~1.3%) using four different disease outcomes (except for greater protections from N95s as compared to no masks with lab-confirmed viruses), but all point estimates favored mask-wearing.[236] The no-mask comparison group was a non-randomized convenience group composed of individuals from nine different hospitals, limiting the ability to draw reliable conclusions.

Observational studies of SARS-CoV-1 and pandemic influenza

Fourteen non-randomized observational studies conducted during the 2003 SARS-CoV-1 ("SARS") and 2009 H1NI epidemics provide mixed correlational evidence for the efficacy of face masks against the spread of viral infections, but suffer from various types of potential bias and other limitations. Three SARS case-control studies and one H1NI cross-sectional survey were undertaken outside the healthcare setting. One case-control study of patients in Beijing found that just 27% (26/94) of probable cases "always" wore a mask when going outside, compared to 43% (121/281) of uninfected controls (RR 0.3),[237] but controls were identified by sequential digit dialing to achieve "neighborhood matching," a method that may be likely to identify individuals who leave the home less frequently. Similarly, a case-control study of

[235] Chandini R. MacIntyre et al., *Contamination and Washing of Cloth Masks and Risk of Infection Among Hospital Health Workers in Vietnam: A Post Hoc Analysis of a Randomised Controlled Trial*, 10 BMJ OPEN 1, 4 (2020).
[236] Chandini R. MacIntyre et al., *A Cluster Randomized Clinical Trial Comparing Fit-Tested and Non-Fit-Tested N95 Respirators to Medical Masks to Prevent Respiratory Virus Infection in Health Care Workers: RCT of Face Masks in Health Worker*s, 5 INFLUENZA & OTHER RESPIRATORY VIRUSES 170, 176 tbl.3 (2011).
[237] Jiang Wu et al., *Risk Factors for SARS Among Persons Without Known Contact with SARS Patients, Beijing, China*, 10 EMERGING INFECTIOUS DISEASES 210, 213 tbl.1 (2004).

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probable SARS-positive patients in Hong Kong found that cases wore masks less frequently than controls (27.9% (92/330) vs. 58.7% (387/660)), but identified controls through random digit dialing. In addition, cases in the Hong Kong study were less likely than controls to report disinfecting living quarters thoroughly (46.6% (154/330) vs. 74.5% (492/660)) and washing hands >11 times a day (18.4% (61/330) vs. 33.7% (223/660)), suggesting possible confounding.[238] A survey of 7,448 Korean school-aged children during the H1N1 pandemic found that, of 466 respondents reporting "continuous" mask use, only 3% (14) were diagnosed with H1N1, compared to 5.8% (164/2819) of irregular users and 5.7% (239/4164) of non-users (P=.04), but the authors cautioned that the cross-sectional design precluded confirmation of a causal relationship.[239] A study in Vietnam (n=65) during the SARS-CoV-1 outbreak found that 7 of 154 (or 1 in 22) unmasked people who had known contact with a SARS-positive index case contracted SARS, compared to none (of 9) people who reported wearing a mask,[240] but a 1 in 22 chance yields a 72% probability that, of a sample of 7 non-mask-wearing individuals, none would contract the disease.

Due primarily to ease of recruitment and outbreak patterns, the 10 remaining studies recruited SARS and H1N1-positive workers in healthcare settings. Six case-control studies were conducted during the SARS-CoV-1 epidemic. A study of 758 healthcare workers caring for patients with SARS at a hospital in Guangzhou, China found that those reporting that they wore 2 multi-layer cotton masks were diagnosed with SARS 10.9% (59/541) of the time compared to

[238] Joseph T. Lau et al., *SARS Transmission, Risk Factors, and Prevention in Hong Kong*, 10 EMERGING INFECTIOUS DISEASES 587, 590 tbl.2 (2004).
[239] Choon O. Kim et al., *Is Abdominal Obesity Associated with the 2009 Influenza a (H1N1) Pandemic in Korean School-Aged Children?*, 6 INFLUENZA & OTHER RESPIRATORY VIRUSES 313, 315 tbl.1 (2012).
[240] P. A. Tuan et al., *SARS Transmission in Vietnam Outside of the Health-Care Setting*, 135 EPIDEMIOLOGY & INFECTION 392, 397 tbl.2 (2007).

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27.6% (32/116) for those reporting wearing 1 multi-layer mask (P<0.001),[241] but there was no unmasked comparison group and the researchers concluded that they "did not find that wearing double layers of . . . multilayered cotton masks . . . [was] associated with being protected from SARS."[242] A univariate analysis of 477 Beijing hospital workers found that 5.5% (15/274) of those reporting that they wore 16-layer cotton surgical masks also had SARS compared to 17.7% (36/203) for those not reporting wearing this type of mask (P<0.001), but the same study failed to show efficacy for 12-layer cotton surgical masks (6.5% (8/123) vs. 12.1% (43/354), P=.07), N95 masks (6.1% (2/33) vs. 11.0% (49/444), P=.37), or disposable masks (11.6% (11/95) vs. 10.5% (40/382)).[243] A case-control study of 29 SARS-positive cases and 98 non-SARS controls at a hospital in Hanoi, Vietnam reported that cases wore masks less frequently than controls (32% (8/25) vs. 38.9% (35/90); P=.01),[244] but the authors cautioned that recall bias is particularly relevant where an exposure (mask usage) has a strong intuitive causal link with outcome, also noting that the results were likely less accurate than would be obtained in a blinded or matched case-control study.[245] A case-control study of 13 SARS-infected and 241 non-infected staff members at various Hong Kong hospitals found that cases wore masks much less often than controls (15% (2/13) vs. 70% (169/241); P=.0001).[246] In a study of 320 subjects hospitals in Hanoi, Vietnam, a multivariate logistic regression analysis of 85 (27%) of those subjects found a 12.6-fold protective effect associated with continuous mask-wearing compared to no mask wearing (aOR: 12.6, P<.01), but it is unclear how the 85 subjects were selected and whether the

[241] Wei-Qing Chen et al., *Which Preventive Measures Might Protect Health Care Workers from SARS?*, 9 BMC PUB. HEALTH 1, 5 tbl.3 (2009).
[242] *Id.* at 7.
[243] Wei Liu et al., *Risk Factors for SARS Infection Among Hospital Healthcare Workers in Beijing: A Case Control Study*, 14 TROPICAL MED. & INT'L HEALTH 52, 55 tbl.2 (2009) (raw numbers back-calculated from Table 2 data).
[244] Hiroshi Nishiura et al., *Rapid Awareness and Transmission of Severe Acute Respiratory Syndrome in Hanoi French Hospital, Vietnam,* 73 AM. J. TROPICAL MED. & HYGIENE 17, 20 tbl.2 (2005).
[245] *Id.* at 22.
[246] W. H. Seto et al., *Effectiveness of Precautions Against Droplets and Contact in Prevention of Nosocomial Transmission of Severe Acute Respiratory Syndrome (SARS)*, 361 LANCET 1519, 1520 tbl.2 (2003).

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selection process created a risk of bias, and interviews were conducted 7 or more months after the beginning of the SARS epidemic, creating a risk of reporting bias.[247]

Four observational studies of healthcare workers were conducted during the H1N1 influenza pandemic. A case-control study at a hospital in Hong Kong found that in the 4 cases neither the index patients nor the exposed persons wore a mask (or could not recall whether they wore a mask), while among controls approximately two-thirds of index patients wore masks (0% (0/4) vs. 63.9% (532/832), P=.01).[248] Similarly, a case-control study at a hospital in Kobe, Japan found that 96% (79/82) of controls "always" wore masks but only 80% (4/5) of cases, a difference that was not statistically significant.[249] A case-control study of healthcare workers in Beijing during the H1N1 pandemic did not show a benefit associated with continuous mask-wearing: 71.6% (146/204) of controls wore masks most of their working time vs. 72.5% (37/51) of cases.[250]

A Cochrane meta-analysis of 7 of the above case-control studies conducted during the SARS-CoV-1 epidemic found that 39.4% (268/681) of cases reported mask wearing compared to 62.0% (1573/2535) of controls.[251] The authors concluded that "simple mask-wearing was highly effective (OR 0.32)," but also cautioned that 6 of the 7 studies had a medium or high risk of bias, and these 6 studies provided over 96% of the total number of cases and controls in the meta-analysis.[252] A more recent meta-analysis of 8 studies from the H1N1 influenza pandemic

[247] Ayako Nishiyama et al., *Risk Factors for SARS Infection Within Hospitals in Hanoi, Vietnam*, 61 JAPANESE J. INFECTIOUS DISEASE 388, 389 tbl.2 (2008).
[248] Vincent C. Cheng et al., *Prevention of Nosocomial Transmission of Swine-Origin Pandemic Influenza Virus A/H1N1 by Infection Control Bundle*, 74 J. HOSP. INFECTION 271 (2010).
[249] Takao Toyokawa et al., *Seroprevalence of Antibodies to Pandemic (H1N1) 2009 Influenza Virus Among Health Care Workers in Two General Hospitals After First Outbreak in Kobe, Japan*, 63 J. INFECTION 281, 286 tbl.5 (2011).
[250] Yi Zhang et al., *Associated with the Transmission of Pandemic (H1N1) 2009 Among Hospital Healthcare Workers in Beijing, China*, 7 INFLUENZA & OTHER RESPIRATORY VIRUSES 466, 469 tbl.2 (2013).
[251] Tom Jefferson et al., *Interventions for the Interruption or Reduction of the Spread of Respiratory Viruses*, 7 COCHRANE DATABASE SYS. REV. 1, 108 (2011) (Analysis 1.3).
[252] *Id.* at 11.

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concluded that, overall, "facemask use was not significantly protective," and also cautioned that most studies included in the analysis had a moderate to high risk of bias.[253] Specific biases mentioned in these meta-analyses included, among others, selection bias, reporting bias, publication bias, and ascertainment bias, as well as concerns over non-specific definitions of what constituted "exposure," potential confounding of unmeasured protective (or harmful) behaviors, and lack of an adequate description of controls. Additionally, the infection dynamics of SARS-COV-1 and pandemic influenza differ from SARS-CoV-2, limiting the extent of insight these studies can provide. Ten of the 14 available studies evaluated exposures only in high-risk healthcare settings, which may differ from community interactions in duration, proximity, and frequency. Considered in view of available RCT evidence, such weaknesses place observational mask data in a skeptical light.

V. Meta-analyses

We identified 32 systematic reviews and meta-analyses evaluating the effects of community face masking against respiratory viral transmission. Of 16 quantitative meta-analyses (**Table 2**), 8 were critical or equivocal as to whether existing evidence was sufficient to support a public recommendation of masks, and the remaining 8 supported a public mask intervention on the basis of existing evidence primarily due to the precautionary principle—i.e., based on the assumption that masks might help and are unlikely to harm—and on the basis of observational or other indirect evidence. Of the 15 solely qualitative reviews identified by the authors, seven concluded that evidence for the use of community masking was weak,[254,255,256,257,258,259,260] seven

[253] Patrick Saunders-Hastings et al., *Effectiveness of Personal Protective Measures in Reducing Pandemic Influenza Transmission: A Systematic Review and Meta-Analysis*, 20 EPIDEMICS 1, 6 (2017).
[254] Roger Chou et al., *Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings: A Living Rapid Review*, 173 ANNALS INTERNAL MED. 542, 553 (2020) ("[T]he evidence on mask use and risk for SARS-CoV-2 infection is very sparse.").
[255] Monica Taminato et al., *Homemade Cloth Face Masks as a Barrier Against Respiratory Droplets–Systematic Review*, 33 ACTA PAULISTA ENFERMAGEM 1, 8 (2020) ("[A]ny face mask, regardless of filtering efficiency . . . will

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cautiously concluded that mask benefits outweigh risks in various settings, often conceding that the evidence was only of low to moderate quality,[261,262,263,264,265,266,267] and one unequivocally concluded that facemasks were beneficial.[268] Despite their varying conclusions, these 15

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have a marginal impact if not used in connection to other measures, such as . . . social distancing . . . and regular hand hygiene.").

[256] Samir Benkouiten et al., *Non-pharmaceutical Interventions for the Prevention of Respiratory Tract Infections During Hajj Pilgrimage*, 12 TRAVEL MED. & INFECTIOUS DISEASE 429, 437 (2014) (characterizing the results of face mask studies in preventing respiratory illnesses as "contradictory").

[257] Ali Mostafaei et al., *Can Wearing a Face Mask Protect from COVID-19? A Systematic Review*, 14 IRANIAN J. MED. MICROBIOLOGY 101, 104 (2020) (describing the level of evidence that facemasks alone provide protection against respiratory infection as "low to moderate").

[258] Faisal bin-Reza et al., *The Use of Masks and Respirators to Prevent Transmission of Influenza: A Systematic Review of the Scientific Evidence,* 6 INFLUENZA & OTHER RESPIRATORY VIRUSES 257, 265 (2012) ("[T]here is a limited evidence base to support the use of masks and/or respirators in healthcare or community settings.").

[259] Benjamin J. Cowling et al., *Face Masks to Prevent Transmission of Influenza Virus: A Systematic Review*, 138 EPIDEMIOLOGY & INFECTION 449, 455 (2010) ("There is little evidence to support the effectiveness of face masks to reduce the risk of infection.").

[260] Amir Qaseem et al., *Use of N95, Surgical, and Cloth Masks to Prevent COVID-19 in Health Care and Community Settings: Living Practice Points From the American College of Physicians (Version 1)*, 173 ANNALS INTERNAL MED. 642, 646 tbl.4 (2020) ("The evidence is very uncertain about the effectiveness of cloth masks . . . compared with no masks on the risk for SARS-CoV-1 infection."); *see also id.* at 647 ("The CDC does not consider cloth masks as PPE [personal protective equipment] in health care settings, given the lack of evidence of their effectiveness against transmission of SARS-CoV-2.").

[261] Jeremy Howard et al., *Face Masks Against COVID-19: An Evidence Review,* 118 PROCEEDINGS NAT'L ACAD. SCI. 1, 6 (2021) ("The positive impact of public mask wearing . . . is 'scientifically plausible but uncertain'.").

[262] Mehr Jain et al., *Efficacy and Use of Cloth Masks: A Scoping Review*, 12 CUREUS 1, 10 (2020) ("Cloth masks are shown to have limited inward protection in healthcare settings where viral exposure is high but may be beneficial for outward protection in low-risk settings and use by the general public where no other alternatives to medical masks are available.").

[263] Milena Santos et al., *Are Cloth Masks a Substitute to Medical Masks in Reducing Transmission and Contamination? A Systematic Review,* 34 BRAZILIAN ORAL RESEARCH 1, 15 (2020) ("Cloth masks seem to provide some degree of protection" but "the quality of evidence about efficiency is very low to moderate.").

[264] Chandini R. MacIntyre & Abrar A. Chughtai, *A Rapid Systematic Review of the Efficacy of Face Masks and Respirators Against Coronaviruses and Other Respiratory Transmissible Viruses for the Community, Healthcare Workers and Sick Patients*, 104 INT'L J. NURSING STUDIES 1, 5 (2020) (Use of masks as source control is "a sensible recommendation given the suggestion of protection.").

[265] Mary Abboah-Offei et al., *A Rapid Review of the Use of Face Mask in Preventing the Spread of COVID-19*, 3 INT'L J. NURSING STUDIES ADVANCES 1, 26 (2020) ("[T]he efficacy of some face mask types . . . such as . . . cloth has not been established . . . .").

[266] P. B. Smith et al., *A Scoping Review of Surgical Masks and N95 Filtering Facepiece Respirators: Learning from the Past to Guide the Future of Dentistry*, 131 SAFETY SCI. 1, 6 (2020) ("Current sterilization measures are not sufficient to permit routine reuse of facemasks.").

[267] Maria C. de Camargo et al., *Effectiveness of the Use of Non-woven Face Mask to Prevent Coronavirus Infections in the General Population: A Rapid Systematic Review*, 25 CIENCIA & SAUDE COLETIVA 3365, 3374 (2020) ("The results regarding masks effectiveness were conflicting.").

[268] Madhu Gupta et al., *The Use of Facemasks by the General Population To Prevent Transmission of COVID 19 Infection: A Systematic Review*, MEDRXIV 1 (2020), https://www.medrxiv.org/content/10.1101/2020.05.01.20087064v1.full.pdf.

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qualitative reviews are largely redundant of one another and chiefly evaluate evidence already discussed above.

The meta-analyses largely analyzed the same RCTs as one another but used different methodologies and sometimes included different non-RCT observational studies. None of these studies considered the SARS-CoV-2 virus specifically, and most looked at surgical—not cloth—face mask use in community settings.

VI. Evidence suggestive of face mask harm

Although high-quality evidence may eventually support recommendations to wear masks that are currently based on the precautionary principle or optimistic interpretations of observational data that have potentially important limitations, it is important to consider the an alternate possibility: that community masking may accelerate rather than reduce transmission of infectious disease. Although some evidence suggests masks may cause non-infection-related harms, such as breathing difficulties,[269,270] psychological burdens,[271] impaired communication,[272,273] skin irritation or breakdown,[274,275] and headaches,[276] the most concerning potential harm to health is an increased rate of disease spread.

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[269] Jian H. Zhu et al., *Effects of Long-Duration Wearing of N95 Respirator and Surgical Facemask: A Pilot Study*, 4 J. LUNG PULMONARY & RESPIRATORY RESEARCH 97, 97 (2014) (discussing nasal resistance as a result of physiology changes due to N95s).

[270] Mina Bakhit et al., *Downsides of Face Masks and Possible Mitigation Strategies: A Systematic Review and Meta-Analysis,* 11 BMJ OPEN 1, 9 tbl.2 (2021).

[271] Jennifer L. Scheid et al., *Commentary: Physiological and Psychological Impact of Face Mask Usage during the COVID-19 Pandemic*, 17 INT'L J. ENVTL. RESEARCH & PUB. HEALTH 6655 (2020).

[272] Divya Swaminathan & Shoba S. Meera, *Masks Mask Communication – Communicating with Children in Health Care Settings*, 88 INDIAN J. PEDIATRICS 283 (March 2021).

[273] Katharina Hufner et al., *On the Difficulties of Building Therapeutic Relationships when Wearing Face Masks*, 138 J. PSYCHOSOMATIC RESEARCH 110226 (2020).

[274] Elisheva Rosner, *Adverse Effects of Prolonged Mask Use Among Healthcare Professionals During COVID-19*, 6 J. INFECTIOUS DISEASE EPIDEMIOLOGY 1 (2020).

[275] Jeff Donovan & Sandy Skotnicki-Grant, *Allergic Contact Dermatitis from Formaldehyde Textile Resins in Surgical Uniforms and Nonwoven Textile Masks*, 18 DERMATITIS 40, 40 (2007).

[276] Jonathan J. Ong et al., *Headaches Associated with Personal Protective Equipment–A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19*, 60 HEADACHE: THE J. HEAD & FACE PAIN 864, 864 (2020) (finding that most healthcare workers in the study develop "de novo PPE-associated headaches" as a result of wearing PPE including facemasks).

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A number of studies have found higher point estimates of infection among mask wearers, some of which were statistically significant (**Table 3**). A study of healthcare workers returning from the Hajj reported that intermittent use of face masks was associated with a higher rate of acute respiratory tract infections than not wearing masks (34% (42/122) vs. 22% (4/18)), but also found that using masks "all the time" was associated with a lower infection rate (16% (18/110)).[277] Another Hajj study reported that "[u]nvaccinated pilgrims in the Facemask group had a higher rate of CRI than their counterpart in the Control group (13% versus 10%, P=0·03)."[278]

Multiple household studies have found higher instances of respiratory sickness in masked intervention groups than in unmasked controls. In one household source-control medical mask trial, point estimates of the primary outcome measure of ILI in the intention-to-treat analysis were higher in the surgical mask group than in the no mask group (22.3% (21/94) vs. 16.0% (16/100)), but the results were not statistically significant and adherence was poor.[279] In a study of 509 households comprised of 2,788 individual members, households in the hand sanitizer group included significantly more members without any reported upper respiratory symptoms compared to the hand sanitizer plus face mask group (57.6% (545/946) vs. 38.7% (363/938), P<0.01).[280] In the Thai study discussed previously, there were higher point estimates of the primary outcome measure of laboratory-confirmed secondary infections among members in the hand washing plus mask group compared to the control group (23% (66/291) vs. 19% (58/302), n.s.), higher rates of such infections at the household level (35% vs. 22%), and in an analytic

[277] Saeed Al-Asmary et al., *Acute Respiratory Tract Infections Among Hajj Medical Mission Personnel, Saudi Arabia*, 11 INT'L J. INFECTIOUS DISEASE 268, 270 tbl.2 (2007).
[278] Mohammad Alfelali et al., *Facemask Against Viral Respiratory Infections Among Hajj Pilgrims: A Challenging Cluster-Randomized Trial*, 15 PLOS ONE 1, 8 (2020).
[279] Chandini R. MacIntyre et al., *Face Mask Use and Control of Respiratory Virus Transmission in Households*, 15 EMERGING INFECTIOUS DISEASES 233, 238 tbl.4 (2009).
[280] Elaine L. Larson et al., *Impact of Non-pharmaceutical Interventions on URIs and Influenza in Crowded, Urban Households*, 125 PUB. HEALTH REP. 178, 184 tbl.2 (2010).

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subset of 348 households with 885 members (with 94 co-index households removed), a statistically significant increase in ILI for those in the mask group (OR: 2.15, P=0.004) that the researchers described as "twofold in the opposite direction from the hypothesized protective effect."[281]

In a cluster-randomized trial of cloth masks compared with medical masks in healthcare workers, rates of ILI in the cloth mask intervention arm, where 56.8% of workers wore a mask more than 70% of the time, were more than 3 times higher compared to the "standard practice" control arm, where 23.6% did so (2.3% (13/569) vs. 0.7% (3/458)).[282] Researchers noted that because the Institutional Review Board deemed it unethical to ask participants not to use a mask (presumably because of beliefs about the effectiveness of masks in preventing infection), they were unable to include a no-mask control group.[283]

VII. Discussion

Taken as a whole, the available mechanistic and clinical evidence leaves substantial uncertainty as to whether, to what extent, and under what circumstances community-wide use of cloth face masks helps to reduce infection rates of SARS-CoV-2. The voluminous mechanistic evidence clearly demonstrates that masks reduce some measures of droplet transmission, such as the distance that larger droplets travel, and it is known that such droplets contain SARS-CoV-2. Images showing respiratory droplets expelled during sneezing or coughing have been used to elicit visceral reactions of the public, and a series of articles in the *New York Times* featured

[281] James M. Simmerman et al., *Findings from a Household Randomized Controlled Trial of Hand Washing and Face Masks to Reduce Influenza Transmission in Bangkok, Thailand: Household Randomized Controlled Trial of Hand Washing and Face Masks*, 2011 5 INFLUENZA & OTHER RESPIRATORY VIRUSES 256, 262 (2011).
[282] Chandini R. MacIntyre et al., *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*, 5 BMJ OPEN 1, 6 tbl.2 (2015).
[283] *Id.* at 2.

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Virginia Tech professor Linsey Marr explaining in simple language how mask fibers "create a haphazard obstacle course through which air . . . must navigate," thus filtering the air.[284]

However, such surrogates of efficacy have not been demonstrated to correlate with infection outcomes, and therefore fail to show that masks reduce the true measure of interest, namely, the spread of respiratory illness. It is also not clear that these studies have adequately replicated real-world conditions even as to the surrogate of droplet transmission. Mannequin faces are unmoving and tend to be tested under conditions that generate particle sizes and air speeds that may not reflect the variable nature of human speech or breathing. For example, in a study co-authored by Linsey Marr, a constant rate of air flow was used, mannequin heads were placed in a chamber designed to minimize disruptions to air flow, and masks sometimes covered the mannequins' eyes.[285] Mannequins were also placed only 13 inches apart, relevant perhaps for crowded subway cars, but far closer than traditional conceptions of personal space would allow.[286] In real life it also is considered socially unacceptable to cough directly into someone's face at close range without at least averting the head or covering the cough. Although evidence is limited, one study comparing coughing into a mask versus the crook of the elbow demonstrated similar results in both the size and number of expelled droplets.[287]

Clinical evidence also fails to demonstrate that face masks are an effective intervention against the spread of respiratory illness. There have been 2 large-scale RCTs evaluating the use of facemasks at limiting the spread of SARS-CoV-2. One failed to show a statistically significant

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[284] Katherine J. Wu, *One Mask Is Good. Would Two Be Better?*, *N.Y. Times*, Jan. 12, 2021, https://www.nytimes.com/2021/01/12/health/coronavirus-masks-transmission.html.
[285] Jin Pan, Charbel Harb, Weinan Leng & Linsey C. Marr, *Inward and Outward Effectiveness of Cloth Masks, a Surgical Mask, and a Face Shield*, , MEDRXIV 1, 16 (2021), https://www.medrxiv.org/content/10.1101/2020.11.18.20233353v1.full.pdf.
[286] Vikas Mehta, *The New Proxemics: COVID-19, Social Distancing, and Sociable Space*, 25 J. URBAN DESIGN 669 (2020) (noting that traditional notions of personal space span 4 to 12 feet for acquaintances).
[287] Gustavo Zayas et al., *Effectiveness of Cough Etiquette Maneuvers in Disrupting the Chain of Transmission of Infectious Respiratory Diseases*, 13 BMC PUB. HEALTH 1, 8 (2013).

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benefit to those randomized to wear high-quality surgical masks in both the intention-to-treat and per protocol (i.e., excluding those who reported not wearing masks as specified in the protocol) analyses. The other failed to find a statistically significant benefit to cloth masks, but found an 11% relative reduction in COVID-19 prevalence for surgical masks that was marginally statistically significant, with the confidence interval spanning 0% to 22%. In the latter trial, absolute reductions in COVID-19-like illness associated with mask-wearing were only 1% (reduced from 8.6% in control villages to 7.6% in intervention villages), while absolute reductions in symptomatic seroprevalence were less than 0.1% (from 0.76% in control villages to 0.68% in intervention village), raising questions about whether resources devoted to mask production, awareness, utilization, and enforcement could be deployed to greater public health benefit if directed at alternate interventions, such as vaccination, contact-tracing, or isolation. This study also does not apply to children, as they were excluded, showed mask compliance waned drastically after the study period was complete, and may not extrapolate to settings disparate from rural Bangladesh, which at the time of this study had no available vaccination and very low rates of natural immunity.

In non-healthcare settings, of the 14 RCTs identified by the authors that evaluated face mask efficacy compared to no-mask controls in protecting against respiratory infections other than COVID-19, 13 failed to find statically significant benefits from facemask use under intention-to-treat analyses. In communal living settings, four of five RCTs failed to show statistically significant benefits to masking, and the promising results of the fifth study were not confirmed when its authors sought to replicate the results in a much larger follow-up trial. Of eight RCTs that evaluated face mask efficacy against respiratory illness transmission in non-healthcare household settings, all eight failed to find a statistically significant benefit for the use

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of face masks alone compared to controls in their intention-to-treat analyses, and only three found statistically significant benefit in highly selective sub-group analyses (**Table 1**).

While there is observational evidence that facemasks protect against SARS-CoV-1 and SARS-CoV-2, especially in healthcare settings, this evidence is confounded by other variables. Study limitations and potential confounders are often stated by study authors, but tend to be truncated or omitted when study results are reported to the public.[288]

We are not the first to evaluate the body of available evidence regarding mask use and conclude that the evidence fails to clearly support a benefit from mask wearing. Of 16 quantitative meta-analytical analyses evaluating facemask use in non-healthcare, non-mass gathering settings, only two reported statistically significant benefits of facemask use alone compared to no-mask controls, and those results were largely due to inclusion of the observational SARS-CoV-1 data discussed above.

Some evidence suggests masks cause higher infection rates

Studies of other respiratory illnesses raise the possibility that masks could actually cause higher infection rates under some circumstances, although as with the evidence for masks in general, the existing evidence fails to clearly support this hypothesis and the point estimates of harm could simply be the result of chance. However, the explanation of chance is similarly applicable to the non-significant point estimates of benefit found in some studies, which have frequently been interpreted as supportive of mask efficacy on the rationale that the studies had insufficient statistical power.[289,290,291,292,293,294]

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[288] Apoorva Mandavilli, *The Price for Not Wearing Masks: Perhaps 130,000 Lives*, N.Y. TIMES, Oct. 23, 2020, https://www.nytimes.com/2020/10/23/health/covid-deaths.html.
[289] Julii Brainard et al., *Community Use of Face Masks and Similar Barriers to Prevent Respiratory Illness Such as COVID-19: A Rapid Scoping Review*, 25 EUROSURVEILLANCE 1, 12 (2020).
[290] Chandini R. MacIntyre & Abrar A. Chughtai, *A Rapid Systematic Review of the Efficacy of Face Masks and Respirators Against Coronaviruses and Other Respiratory Transmissible Viruses for the Community, Healthcare Workers and Sick Patients*, 104 INT'L J. NURSING STUDIES 1, 4 (2020).

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The World Health Organization has noted the possibility that mask wearing could accelerate disease spread by providing a false sense of security that induces individuals to forego standard sanitary measures,[295] although this concern is contested[296] and the evidence is mixed. In one study, mask wearing was associated with reductions of physical distancing when the experimenter asked passersby for directions, particularly if the experimenter was wearing clothes suggestive of high social status,[297,298] Another study, however, have found passersby increased distance from an experimenter standing on the side of a pathway if the experimenter was wearing a mask, particularly if the mask was homemade and accompanied by goggles.[299]

Mask use could also lead to higher infection rates by encouraging other behavioral changes, such as by providing perceived license to engage in high-risk activities. As with physical distancing, the evidence is mixed. In the United States, a review of location data aggregated from multiple phone apps found that mask mandates were associated with 20-30 minutes of increased daily time outside the home and increase restaurant visitation,[300] while in

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[291] Chandini R. MacIntyre et al., *Cluster Randomised Controlled Trial to Examine Medical Mask Use as Source Control for People with Respiratory Illness*, 6 BMJ OPEN 1, 6 (2016).
[292] Mandy Wang et al. *A Cluster-Randomised Controlled Trial to Test the Efficacy of Facemasks in Preventing Respiratory Viral Infection Among Hajj Pilgrims*, 5 J. EPIDEMIOLOGY & GLOBAL HEALTH 181, 182 (2015).
[293] Laetitia Canini et al., *Surgical Mask to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 5 PLOS ONE 1, 5 (2010).
[294] Allison E. Aiello et al., *Facemasks, Hand Hygiene, and Influenza Among Young Adults: A Randomized Intervention Trial*, 7 PLOS ONE 1, 7 (2012).
[295] *Advice on the Use of Masks [in] the Community, During Home Care and in Health Care Settings in the Context of the Novel Coronavirus (2019-Ncov) Outbreak: Interim Guidance*, WORLD HEALTH ORG., Jan. 29, 2020, at 1, https://apps.who.int/iris/handle/10665/330987 (last visited Sep. 5, 2021).
[296] Eleni Mantzari et al., *Is Risk Compensation Threatening Public Health in the Covid-19 Pandemic?*, 370 BMJ m2913 (2020).
[297] Martin Aranguren, *Face Mask Use Conditionally Decreases Compliance With Physical Distancing Rules Against COVID-19: Gender Differences in Risk Compensation Pattern*, ANNALS BEHAVIORAL MED. (2021), https://doi.org/10.1093/abm/kaab072.
[298] *See also* Alice Cartaud et al., *Wearing a Face Mask Against COVID-19 Results in a Reduction of Social Distancing*, 15 PLOS ONE 1, 1 (2020) (online experiment in which subjects must assess whether the distance to a happy, angry, neutral, or masked virtual character is appropriate).
[299] Massimo Marchiori, *COVID-19 and the Social Distancing Paradox: Dangers and Solutions*, ARXIV 1, 6 (2020), https://arxiv.org/pdf/2005.12446.
[300] Youpei Yan et al., *Do Face Masks Create a False Sense of Security? A COVID-19 Dilemma*, MEDRXIV 1, 16 (2020), https://www.medrxiv.org/content/10.1101/2020.05.23.20111302v2.full.pdf.

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Germany a review of Google's location data showed small reductions in visits to grocery stores and small decreases in time spent outside the home following mask mandates.[301] Both studies relied on mask mandates rather than actual mask wearing, and neither used randomization nor measured physical distancing.

Even if masks do not affect individual behavior choices for ordinary activities such as visiting grocery stores or working from home, they could lower social inhibitions for engaging in potentially high-risk outlier events such as political rallies, civic demonstrations, professional conferences, and sporting events.[302] They could also provide businesses and government leaders with political cover to "reopen the economy safely," including the reopening of restaurants, bars, health facilities, schools, and other locations where large numbers of people congregate.

Masks could also accelerate disease spread in other ways. For example, the auditory difficulties engendered by masks combined with their obfuscation of lip movements could cause wearers to talk more loudly (which yields greater numbers of droplets[303]), lean to the side of plastic barriers while speaking, or approach more closely to hear or be heard, undermining the reductions in droplet movement that masks provide. This concern is particularly relevant for the aged or others who have impaired hearing and who may also be at higher risk of severe COVID-19 infection.[304] Although masks appear to reduce the distance traveled by larger droplets, one

[301] Roxanne Kovacs et al., *Compulsory Face Mask Policies Do Not Affect Community Mobility in Germany*, ECONSTOR WORKING PAPER (2020), http://hdl.handle.net/10419/218945 (last visited Aug. 9, 2021).
[302] William F. Maloney & Temel Taskin, *Determinants of Social Distancing and Economic Activity During COVID-19: A Global View*, WORLD BANK POL'Y RESEARCH WORKING PAPER 1, 11 (2020) ("[W]earing masks makes individuals feel more in control and protected and hence, the net impact is to increase mobility.").
[303] Phillip Anfinrud et al., *Visualizing Speech-Generated Oral Fluid Droplets with Laser Light Scattering*, 382 NEW ENG. J. MED. 2061, 2062 (2020).
[304] Joshua Chodosh et al., *Face Masks Can Be Devastating for People with Hearing Loss*, 370 BMJ 1, 1 (2020).

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study found that neck gaiter-type masks can disperse large droplets into a multitude of smaller droplets, which the authors noted "might be counterproductive."[305]

Increased facial touching is also a concern.[306] In one study, 75% of participants reported mask discomfort,[307] and another study reported that 20% of mask wearers experience facial itch,[308] both of which may lead to increased facial touching. Although some studies have reported decreased facial touching associated with mask wearing, these studies had important limitations, such as lacking randomization and blinding,[309] not including indoor spaces,[310] and excluding subjects who touched their faces to don, doff, or adjust their masks.[311]

Contamination of the hands can occur when masks are removed or reused.[312,313] Mask studies may therefore overestimate mask benefit and underestimate harm, since most provide subjects with fresh masks at frequent intervals, sometimes including multiple masks per day.[314,315] By contrast, it is unclear how often cloth masks are washed during community use, leading to the possibility that they are inadvertently serving as homemade disease cultures with

[305] Emma P. Fischer et al., *Low-Cost Measurement of Face Mask Efficacy for Filtering Expelled Droplets During Speech*, 6 SCI. ADVANCES 1, 3 (2020).
[306] Terri Rebmann et al., *Physiologic and Other Effects and Compliance with Long-term Respirator Use Among Medical Intensive Care Unit Nurses*, 41 AM. J. INFECTION CONTROL 1218 (2013).
[307] Laetitia Canini et al., *Surgical Mask to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 5 PLOS ONE 1, 5 (2010).
[308] Jacek C. Szepietowski et al., *Face Mask-induced Itch: A Self-questionnaire Study of 2,315 Responders During the COVID-19 Pandemic*, 100 ACTA DERMATO-VENEREOLOGICA 1, 2 fig.1 (2020).
[309] Tiffany L. Lucas, *Frequency of Face Touching With and Without a Mask in Pediatric Hematology/oncology Health Care Professionals*, 67 PEDIATRIC BLOOD & CANCER e28593 (2020).
[310] Yong-Jian Chen et al., *Comparison of Face-Touching Behaviors Before and During the Coronavirus Disease 2019 Pandemic*, 3 JAMA NETWORK OPEN e2016924 (2020).
[311] Lasse S. Liebst et al., *Face-touching Behaviour as a Possible Correlate of Mask-Wearing: A Video Observational Study of Public Place Incidents During the COVID-19 Pandemic*, TRANSBOUNDARY & EMERGING DISEASES (2021), https://pubmed.ncbi.nlm.nih.gov/33817991/ (online ahead of print).
[312] Tyler M. Brady et al., *Transfer of Bacteriophage MS2 and Fluorescein from N95 Filtering Facepiece Respirators to Hands: Measuring Fomite Potential*, 14 J. OCCUPATIONAL & ENVTL. HYGIENE 898, 904 (2017).
[313] Lisa Casanova et al., *Virus Transfer from Personal Protective Equipment to Health care Employees' Skin and Clothing*, 14 EMERGING INFECTIOUS DISEASES 1291, 1292–93 (2008).
[314] E.g., Allison E. Aiello et al., *Facemasks, Hand Hygiene, and Influenza Among Young Adults: A Randomized Intervention Trial*, 7 PLOS ONE 1, 2 (2012).
[315] E.g., Mohammad Alfelali et al., *Facemask Against Viral Respiratory Infections Among Hajj Pilgrims: A Challenging Cluster-Randomized Trial*, 15 PLOS ONE 1, 4 (2020).

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the potential to contaminate surfaces when they are temporarily removed. Clean masks can come in contact with contaminated surfaces such as restaurant tables, bathroom shelving, handbag contents, or coat pockets and then be placed on the face.[316,317] For healthy individuals, the dampness of an otherwise clean cloth mask may increase the likelihood of contact contamination and the need for mask adjustment.

VIII. Conclusion

We reviewed the mechanistic, observational, and clinical evidence relevant to the use of cloth face masks in community settings to limit the spread of respiratory infections, and in particular the novel SARS-CoV-2 coronavirus. In each area, we found existing evidence inadequate to demonstrate clear benefit (or harm). Mechanistic evidence shows a clear benefit as measured by laboratory surrogates, but it is not clear to what extent those surrogates are relevant to the clinical question of infection rate or offset by behavioral factors. Uncontrolled observational studies are confounded by numerous known and unknown variables, and most considered mask mandates or self-reported mask wearing as the key variable rather than actual mask usage. The infection dynamics of SARS-CoV-2 differ from SARS-CoV-1 and other respiratory illnesses, meaning that much of the evidence, even if suggestive, has uncertain relevance to SARS-CoV-2. Recommendations to impose mask mandates based on the precautionary principle fail to account for the possibility that masks cause harm,[318] or that masks may have varying benefits and risks in different settings.

Notwithstanding the lack of evidence, in the midst of a pandemic policymakers and public health officials cannot wait until high-quality evidence is generated. However, if they

[316] Nikolaos I. Stilianakis & Yannis Drossinos, *Dynamics of Infectious Disease Transmission by Inhalable Respiratory Droplets*, 7 J. ROYAL SOC'Y INTERFACE 1, 1 (2010).
[317] Alex W. Chin et al., *Stability of SARS-CoV-2 in Different Environmental Conditions*, 1 LANCET MICROBE e10 (2020).
[318] Trisha Greenhalgh et al., *Face Masks for the Public During the COVID-19 Crisis*, 369 BMJ 1 (2020).

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determine based on limited evidence that community masking policies are appropriate, it is an ethical imperative to refrain from portraying the evidence as stronger than it actually is. Estimates of lives that could potentially be saved, if provided, must be carefully balanced with appropriate disclosure of study limitations and uncertainties. Some models supporting community face masking suggest large beneficial effects,[319,320] but these models are based on assumptions that face masks reduce SARS-CoV-2 transmission by 40–50%[321,322,323]—assumptions that are not adequately supported by existing data. More generally, given the low quality of evidence, the absence of statistically significant benefit indicated by most randomized controlled trials, and the possible harm suggested by a few studies, scientists and public health officials must take care not to apply a double standard to available studies—emphasizing projections of lives saved when evidence suggests benefit, while focusing on study limitations rather than outcomes when the evidence suggests harm or the absence of benefit.

Overconfident portrayal of evidence could also stifle research agendas, making it difficult to reevaluate previously-held but insufficiently supported positions.[324,325] Early in the pandemic, pressure exerted on public officials to offer immediate solutions led to rhetoric that outpaced the evidence. Once officials or others became publicly committed to a position on masks, it became difficult to advocate for high-quality evidence generation, leading to a situation in which, despite

[319] Steffen E. Eikenberry et al., *To Mask or Not to Mask: Modeling the Potential for Face Mask Use by the General Public to Curtail the COVID-19 Pandemic*, 5 INFECTIOUS DISEASE MODELLING 293, 296 (2020).
[320] Richard Stutt et al., *A Modelling Framework to Assess the Likely Effectiveness of Facemasks in Combination with 'Lock-Down' in Managing the COVID-19 Pandemic*, 476 PROCEEDINGS ROYAL SOC'Y 1, 2 (2020).
[321] Emmanuela Gakidou et al., *Global Projections of Potential Lives Saved from COVID-19 Through Universal Mask Use*, MEDRXIV 1, 16 fig.2 (2020), https://www.medrxiv.org/content/10.1101/2020.10.08.20209510v2.full.pdf.
[322] IHME Covid Forecasting Team, *Modeling COVID-19 Scenarios for the United States*, 27 NATURE MED. 94, 95 (2021).
[323] Tatiana Filonets et al., *Investigation of the Efficiency of Mask Wearing, Contact Tracing, and Case Isolation During the COVID-19 Outbreak*, 10 J. CLINICAL MED. 1, 5 (2021).
[324] Dyani Lewis, *COVID-19 Rarely Spreads Through Surfaces. So Why Are We Still Deep Cleaning?*, 590 NATURE 26, 26 (2021).
[325] *Science Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html (last visited Apr. 20, 2020).

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the prevalence of masking policies, only two randomized trials have been performed to address the question of face mask efficacy for SARS-CoV-2. Until it is clear whether and in what circumstances masks provide net benefit (or cause net harm), ethical concerns should not foreclose Institutional Review Boards from approving trials that are randomized, blinded, and controlled. Reliance on randomized evidence is not only a common practice for other clinical interventions[326] (there have been at least 28 randomized controlled trials around the world of hydroxychloroquine, for example[327]), but is a fundamental point of distinction between modern medicine and that of centuries past.

The well-known distinction between absence of evidence and evidence of absence applies to the COVID-19 context.[328] If face masks save lives—or even if it is reasonably likely that they do—such measures are appropriate and compassionate. Simultaneously, higher quality evidence can be gathered. This rationale applies to all unproven interventions, and has served as a basis for the FDA's expanded access program and the various Right-to-Try laws.[329] Yet as with medicines, the use of unproven non-drug technologies is not without potential harm. Users of the technology can acquire a false sense of security that causes the substitution of unproven or less effective measures for measures for which better evidence may be available, such as physical distancing, improved indoor ventilation, and vaccination.[330] If later evidence proves the intervention useless or harmful, the experience can undermine public trust.[331] The technology

[326] Margaret McCartney, *We Need Better Evidence on Non-drug Interventions for COVID-19*, 370 BMJ 1, 1 (2020).
[327] Cathrine Axfors et al., *Mortality Outcomes with Hydroxychloroquine and Chloroquine in COVID-19: An International Collaborative Meta-Analysis of Randomized Trials*, 12 NATURE COMMC'NS 1, 1 (2021).
[328] Shuo Feng et al., *Rational Use of Face Masks in the COVID-19 Pandemic*, 8 LANCET RESPIRATORY MED. 434, 435 (2020).
[329] *See generally* Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 NEW ENG. J. MED. 279 (2015) (describing the FDA's expanded access program).
[330] Graham P. Martin et al., *Science, Society, and Policy in the Face of Uncertainty: Reflections on the Debate Around Face Coverings for the Public During COVID-19*, 30 CRITICAL PUB. HEALTH 1, 1 (2020).
[331] Brit Trogen et al., *Adverse Consequences of Rushing a SARS-CoV-2 Vaccine: Implications for Public Trust*, 323 J. AM. MED. ASS'N 2460, 2460 (2020).

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itself may cause harm through mechanisms that are not yet well understood, or cause economic, environmental or other harms that indirectly impact health. For example, although masks are individually inexpensive, the collective costs of producing and distributing an adequate and continuous supply of masks to a global community of 7.8 billion people is not trivial, nor are the environmental harms that result when they are discarded.[332,333]

More than a century after the 1918 influenza pandemic, examination of the efficacy of masks has produced a large volume of mostly low- to moderate-quality evidence that has largely failed to demonstrate their value in most settings. Ideally, high-quality evidence will eventually provide clarification. When repeated attempts are undertaken to demonstrate an expected or desired outcome, there is a risk of declaring the effort resolved once results consistent with preconceived notions are generated, regardless of the number or extent of previous failures. Scientists and public health officials should exercise caution to ensure that this potential bias does not lead to a cessation of research once the first high-quality study demonstrating mask efficacy is reported.

[332] Kajanan Selvaranjan et al., *Environmental Challenges Induced by Extensive Use of Face Masks During COVID-19: A Review and Potential Solutions*, 3 ENVTL. CHALLENGES 100039 (2021).
[333] V.C. Shruti et al., *Reusable Masks for COVID-19: A Missing Piece of the Microplastic Problem During the Global Health Crisis*, 161 MARINE POLLUTION BULL. 111777 (2020).

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Table 1. RCT evidence for the efficacy of face masks against respiratory virus transmission.

	Authors (Year) [Context]	Intention-To-Treat (ITT) Outcomes [Statistical Significance in ITT Outcome]	Selected Secondary Outcomes
1	Aiello et al.[334] (2010) [U. Mich. dorms]	Influenza-like illness (ILI) was cumulatively reported in 26.2% (99/378) of the mask group, 25.1% (92/367) of mask plus hand hygiene (HH), and 32.1% (177/552) of controls. Neither group's reductions were statistically significant before (mask v. control, P=.25; mask plus HH, P=.10) or after adjustment for covariates (mask v. control, P=.19; mask plus HH, P=.08). [Statistical Significance: No]	Reported statistically significant point reductions in adjusted ILI for both mask and mask + HH groups compared to controls in study weeks 3-6 (RRs of 0.49–0.72 with P values from 0.01–0.05).
2	Aiello et al.[335] (2012) [U. Mich. dorms]	ILI was cumulatively reported in 11.7% (46/392) of the mask group, 8.9% (31/349) of mask plus hand hygiene (HH), and 13.8% (51/370) of controls. Neither group's reductions were statistically significant before (mask v. control, P=.52; mask plus HH, P=.10) or after adjustment for covariates (mask v. control, P=.42; mask plus HH, P=.13). [Statistical Significance: No]	Like the 2010 study, reported statistically significant point reductions in adjusted ILI for the mask + HH group compared to controls in study weeks 3-6 (RRs of 0.25–0.40 with P values from 0.01–0.03). However, no statistically significant point reductions were reported for the mask group only.
3	Abdin et al.[336] (2005) [Hajj pilgrims]	Study of acute respiratory infection (ARI) in 995 Hajj pilgrims with a compliance rate of 81% in its health education plus face mask arms found "no association [ ] observed between compliance with face mask wearing and developing ARI (OR 0.97, 95% CI 0.73-1.28)." [Statistical Significance: No]	N/A
4	Barasheed et al.[337] (2014) [Hajj pilgrims]	Pilot study that reported 53% (28/53) of masked contacts who slept next to known sick patients subsequently developed ILIs compared to 31% (11/36) of masked contacts (P=0.04). [Statistical Significance: Yes]	Reported a statistically significant decrease in ILIs among the subgroup of masked contacts who reported wearing their masks >8 hours/day (P=0.01) compared to both controls and contacts who reported mask use <8 hours/day.
5	Alfelali et al.[338] (2020) [Hajj Pilgrims]	Follow-up study to Barasheed et al.'s pilot RCT above; reported no statistically significant difference in viral respiratory infections (VRIs) among masked tents (41.6%, 149/358) compared to control tents (43.8%, 128/292; P=.18). [Statistical Significance: No]	In a per-protocol analysis (that only considered daily mask wearers in the intervention group and non-mask wearers in the control group), failed to find statistically significant differences "against laboratory-confirmed viral respiratory infections (OR

[334] Allison E. Aiello et al., *A Randomized Intervention Trial of Mask Use and Hand Hygiene to Reduce Seasonal Influenza-Like Illness and Influenza Infections Among Young Adults in a University Setting*, 14 INT'L J. INFECTIOUS DISEASES 491, 495-6 (2010).

[335] Allison E. Aiello et al., *Facemasks, Hand Hygiene, and Influenza Among Young Adults: A Randomized Intervention Trial*, 7 PLOS ONE 1, 6 tbls.3, S1, and S5 (2012).

[336] Ebtihal Z. Abdin et al., *Effect of Use of Face Mask on Hajj-Related Respiratory Infection Among Hajjis from Riyadh: A Health Promotion Intervention Study*, 12 SAUDI EPIDEMIOLOGY BULL. 27, 27–28 (2005).

[337] Osamah Barasheed et al., *Pilot Randomised Controlled Trial to Testing Facemasks Effectiveness in Preventing Influenza-Like Illness Transmission Among Hajj Pilgrims,* 14 INFECTIOUS DISORDERS DRUG TARGETS 110, 113 tbl.1 (2014).

[338] Mohammad Alfelali et al., *Facemask Against Viral Respiratory Infections Among Hajj Pilgrims: A Challenging Cluster-Randomized Trial*, 15 PLOS ONE 1, 7 (2020).

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			1.2, 95% CI 0.9–1.7, p = 0.26) nor against clinical respiratory infection (OR 1.3, 95% CI 1.0–1.8, p = 0.06)."
6	Canini et al.[339] (2010) [Households in France]	Study where index cases in households wore surgical masks for five days following diagnosis; reported secondary ILI case rates of 16.2% (24/148) in the mask group versus 15.8% (25/158) in the control group with no statistical difference (P=1.00). [Statistical Significance: No]	Also reported no decreases in ILIs in households where masks were worn within 24 hours of symptom onset, (18.1% (15/83) masked vs. 15.7% (7/108) control; P=0.70) and found no association between various measures of mask adherence and incidence of ILI among household contacts (P=0.098–0.31).
7	Macintyre et al.[340] (2009) [Households in Australia]	Reported no significant differences between surgical or P2 (N95 equivalent) masks for secondary ILI infection rates at the individual (surgical mask: 20% (19/94), P=0.46; P2 mask: 15% (14/92), P=1.0; control: 16% (16/100)) or household levels (surgical mask: 32% (15/47), P=0.50; P2 mask: 22% (10/46), P=0.81; control: 24% (12/50)). [Statistical Significance: No]	Per-protocol analysis found a statistically significant decrease (RR: 0.26, P=.015) in infection rates among adherent mask users but adherence was low (only 38% (36/94) of surgical and 46% (42/92) of P2 mask users reported wearing masks "most or all" of the time on the intervention's first day).
8	Macintyre et al.[341] (2016) [Households in China]	Study where index cases in households wore surgical masks for seven days following diagnosis, using three different primary outcomes: clinical respiratory illness (CRI), lab-confirmed viral infection (LCVI), and influenza-like illness (ILI). Reported lower outcome rates for masked groups in all outcomes, with none reaching statistical significance. For CRI, mask group rates of 0.19% (4/2098) versus 0.29% (6/2036) for controls (RR: 0.65, 95% CI 0.18–2.29). For LCVI, mask group rates of 0.05% (1/2098) versus 0.05% (1/2036) for controls (RR: 0.97, 95% CI .06–15.5). For ILI, mask group rates of 0.05% (1/2098) versus 0.15% (3/2036) for controls (RR: 0.03–3.11). [Statistical Significance: No]	In a per-protocol analysis, reported a statistically significant hazard ratio (HR) decrease for CRIs in masked groups (HR: 0.22, 95% CI 0.06–0.86), but not for ILIs (HR: 0.18, 0.02–1.73) or LCVIs (HR: 0.11, 95% CI 0.01–4.40).
9	Simmerman et al.[342] (2011) [Households in Thailand]	Reported no statistically significant differences on lab-confirmed, intra-household secondary influenza infection between handwashing (23%, 66/292), handwashing plus masks (23%, 66/291), and control groups (19%, 58/302; 3-group adjusted Chi-square: 0.63). Using ILI secondary attack rate as a primary measure, reported increases in ILI rates in handwashing (17%, 50/292) and handwashing plus mask groups (18%, 51/291) compared to controls (9%, 26/302; 3-group adjusted Chi-square: 0.01). [Statistical Significance: No]	None notable.
10	Cowling et al.[343]	Reported no statistically significant benefit on intra-	Reported no statistically significant

[339] Laetitia Canini et al., *Surgical Mask to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 5 PLOS ONE 1, 5 (2010).
[340] Chandini R. MacIntyre et al., *Face Mask Use and Control of Respiratory Virus Transmission in Households*, 15 EMERGING INFECTIOUS DISEASES 233, 238 tbl.4 (2009).
[341] Chandini R. MacIntyre et al., *Cluster Randomised Controlled Trial to Examine Medical Mask Use as Source Control for People with Respiratory Illness*, 6 BMJ OPEN 1, 5–7, tbl. 2, 4 (2016).
[342] James M. Simmerman et al., *Findings from a Household Randomized Controlled Trial of Hand Washing and Face Masks to Reduce Influenza Transmission in Bangkok, Thailand: Household Randomized Controlled Trial of Hand Washing and Face Masks*, 5 INFLUENZA & OTHER RESPIRATORY VIRUSES 256, 263 tbl.2 (2011).

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	(2008) [Households in Hong Kong]	household secondary influenza infection rates when all household contacts wore masks (5.9%, 12/205) or were educated and given hand hygiene materials (6.6%, 4/61), compared to controls (6.0%, 5/84; P=0.99). Also found no differences (P=0.52–1.0) using three different clinical definitions of influenza. [Statistical Significance: No]	variation in secondary infection rates when interventions were implemented within 36 hours of symptom onset using lab or clinical influenza diagnostic criteria (P=0.44–0.69).
11	Cowling et al.[344] (2009) [Households, /Hong Kong]	Follow-up study of Cowling et al. (2008) above; reported no statistically significant benefit for PCR-confirmed secondary influenza infections when all household contacts wore masks and practiced hand hygiene ("MH"; 7.0%, 18/258) compared to hand hygiene alone ("HH"; 5.4%, 14/257), or a control arm with neither intervention (10.0%, 28/279; 3-group P value: 0.22). Also found no differences using two different clinical diagnostic criteria (3-group P-values of 0.40 and 0.28). [Statistical Significance: No]	In a pre-planned, sub-group analysis of households that implemented interventions within 36 hours of symptom onset, 3-group P values reported statistically significant differences under two of three illness criteria, although the MH group still underperformed the HH-alone group in most cases (PCR-confirmed: HH 5.4% (7/130), MH 4.0% (6/149); Clinical Definition 1: HH 10.8% (14/130), MH 18.1% (27/149); Clinical Definition 2: HH 3.1% (4/130), MH 4.7% (7/149)).
12	Suess et al.[345] (2007) [Households in Germany]	Reported no statistically significant differences, with lab-confirmed secondary infection rates of 9% (6/69) in the mask, 15% (10/67) in the mask plus hand hygiene (MH), and 23% (19/82) in the control group (P=0.18), and secondary clinical ILI rates of 9% (6/69) in the mask, 9% (6/67) in the MH group, and 17% (14/82) in controls (P=0.37). [Statistical Significance: No]	In a per-protocol analysis, found a statistically significant decrease in the OR of the masked group compared to controls (OR: 0.3, P=0.04) in lab-confirmed influenza, but not clinical ILI cases (OR: 0.5, P=0.3).
13	Larson et al.[346] (2010) [Households in New York City]	Reported unadjusted secondary URI/ILI/influenza rates of 0.137 for education, 0.144 for education plus hand sanitizer (HS), and 0.124 for education plus mask plus hand sanitizer (MHS) with no reported P values, but "a significant decrease. . . [in MHS] compared with the Education group." In the primary multivariate regression analysis, found "no significant differences in rates of infection by intervention group" with P values ranging from 0.19–0.89. [Statistical Significance: No]	In a secondary adjusted model, reported intervention group as significantly impacting infection rate with a 3-group P value of 0.02 between the MHS group (OR: 0.82; 95% CI 0.70-0.97), the HS alone group (OR: 1.01; 95% CI 0.85-1.21), and the educational reference group.
14	Jacobs et al.[347] (2009) [Hospital workers in Japan]	Reported no statistically significant difference between mean number of days of cold symptoms reported by surgical face mask wearers (mean=16.1 days) and non-wearers (mean=14.3 days; P=0.81) during the winter season. [Statistical Significance: No]	In a univariate analysis, reported the only significantly predictive factor of mean days with cold symptoms was living with children under 16 years old (P=0.02).

[343] Benjamin J. Cowling et al., *Preliminary Findings of a Randomized Trial of Non-pharmaceutical Interventions to Prevent Influenza Transmission in Households*, 3 PLOS ONE 1, 7 tbl.2 (2008).
[344] Benjamin J. Cowling et al., *Facemasks and Hand Hygiene to Prevent Influenza Transmission in Households: A Cluster Randomized Trial*, 151 ANNALS INTERNAL MED. 437, 442 tbl.3 (2009).
[345] Thorsten Suess et al., *The Role of Facemasks and Hand Hygiene in the Prevention of Influenza Transmission in Households: Results from a Cluster Randomised Trial; Berlin, Germany, 2009–2011*, 12 BMC INFECTIOUS DISEASES 1, 10 tbl.5 (2012).
[346] Elaine L. Larson et al., *Impact of Non-pharmaceutical Interventions on URIs and Influenza in Crowded, Urban Households*, 125 PUB. HEALTH REP. 178, 185-6 tbls.4-5 (2010).
[347] Joshua L. Jacobs et al., *Use of Surgical Face Masks to Reduce the Incidence of the Common Cold Among Health Care Workers in Japan: A Randomized Controlled Trial*, 37 AM. J. INFECTION CONTROL 417, 419 tbl.3 (2009).

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15	Bundgaard et al.[348] (2021) [adult community members in Denmark]	The primary outcome of SARS-CoV-2 infection (either laboratory-confirmed, or a hospital-based diagnosis) occurred in 42 (1.8%) of 2392 participants in the mask group and 53 (2.1%) of 2470 in the control group (P=0.38). [Statistical Significance: No]	Nine participants (0.5%) were positive for at least 1 of the 11 respiratory viruses other than SARS-CoV-2, compared with 11 participants (0.6%) in the control group (P=0.87).
16	Abaluck et al. (2021) [cluster-randomized communities in Bangladesh]	The primary outcome of symptomatic SARS-CoV-2 seroprevalence was 0.76% in control villages and 0.68% in intervention (i.e., both cloth and surgical mask) villages. [Statistical Significance: Yes]	Excluding surgical mask villages, symptomatic SARS-CoV-2 seroprevalence was 0.76% in control villages and 0.74% in cloth mask villages (P=0.54)

[348] Henning Bundgaard et al., *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial*, 174 ANNALS INTERNAL MED. 335 (2021).

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Table 2. Quantitative meta-analytical evidence for the efficacy of community masking against respiratory viral infections.

Authors Year	Total studies [non-healthcare settings] (RCTs) Key findings	[characterization] Supporting text
Gómez-Ochoa et al.[349] 2021	5 [5] (5) Brief letter to the editor that reanalyzed the data from the Chaabna et al. meta-analysis, but only included studies that used face mask use alone compared against a control group. The authors found no significant differences between medical facemasks use only and controls in the odds of developing laboratory-confirmed influenza (9.6% (27/274) vs. 9.7% (50/515)) and influenza-like illness (13.7% (58/423) vs. 14.9% (100/673)).	[critical] "Because of these divergent results and the lack of high-quality research…, strong recommendations for facemask use in the community context should be issued with caution…."
Aggarwal et al.[350] 2020	9 [9] (9) Using results from 9 non-healthcare RCTs, found that mask use, both with hand hygiene (P=.714) and without (P=.226), was not associated with lower rates of ILI infection in community settings.	[equivocal] "Available evidence does not confirm a protective effect of face mask usage alone in a community setting against influenza-like illnesses (and potentially, the COVID-19)."
Brainard et al.[351] 2020	31 [16] (12) Did not report any statistically significant results when analyzing RCT data. Reported that mask use was not associated with statistically significant reductions in ILIs when used by a well person (11.2% (116/1032) vs. 12.1% (127/1046), P=.68), when used as source control by an ill person in a home setting (5.6% (25/450) vs. 6.2% (28/453), P=.87), or when used by all parties in a home with a sick individual (11.0% (79/715) vs. 12.0% (107/890), P=.43). Authors reported significant reductions in multiple observational study types including cross-sectional (22.3% (2771/12418) vs. 34.1% (7287/21353), P=.003), case-control (18.4% (128/694) vs. 40.5% (327/807), P=.02), and pre-post (3.3% (15/454) vs. 10.3% (95/920), P<.001), but not in cohort studies (13.8% (248/1795) vs. 20.4% (640/3131), P=.52).	[supportive] "The quality of the evidence is problematic. . . [o]ur best estimate is that the effect of wearing a face mask is between the effects seen in RCTs and the effects seen in cohort studies, or around 6 to 15% reduction in disease transmission."[352]

[349] Sergio A. Gómez-Ochoa & Taulant Muka, *Meta-Analysis on Facemask Use in Community Settings to Prevent Respiratory Infection Transmission Shows No Effect*, 103 INT'L J. INFECTIOUS DISEASE 257, 257 (2021).
[350] Nishant Aggarwal et al., *Facemasks for Prevention of Viral Respiratory Infections in Community Settings: A Systematic Review and Meta-Analysis,* 103 INDIAN J. PUB. HEALTH S192, S198 (2020).
[351] Julii Brainard et al., *Community Use of Face Masks and Similar Barriers To Prevent Respiratory Illness Such As COVID-19: A Rapid Scoping Review*, 25 EUROSURVEILLANCE 1, 1 (2020).
[352] A pre-print version of the paper concluded that evidence was "not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19," but this conclusion was changed in the final version to simply state that "[s]tudies specifically addressing COVID-19 infection are required." *See* Julii S. Brainard et al., *Facemasks and Similar Barriers to Prevent Respiratory Illness Such as COVID-19: A Rapid Systematic Review*, MEDRXIV 1, 1 (2020), https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1.full.pdf.

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Chaabna et al.[353] 2020	12 [12] (10) Reported a significant protective effect of medical facemask use when evaluated in conjunction with other interventions (e.g. handwashing) (6.8% (273/4029) vs. 9.8% (458/4677), 95% CI 0.54–0.81). Did not report data for facemask use alone compared to control groups.	[supportive] "There is no available direct evidence in humans . . . for recommending cloth facemask use" but "[o]verall… there is enough evidence to show that medical facemasks are effective in community settings…."
Chu et al.[354] 2020	172 [3] (0) Using data from six observational studies on SARS-CoV-1, reported a statistically significant reduction in infections associated with face masks (adjusted OR: 0.33) compared to no mask controls. Four of the studies were in healthcare settings and one of the studies reported aerosol generating procedures. In a separate analysis, the authors reported statistical reductions in non-health-care settings on the basis of three observational studies from the SARS-CoV-1 epidemic (15.2% (37/244) vs. 21.0% (101/481); OR: 0.56).	[supportive] "[D]irect evidence is limited" but "[t]he use of face masks was protective for both healthcare workers and people in the community . . . , with both the frequentist and Bayesian analyses lending support to face mask use irrespective of setting . . . .
Jefferson et al.[355] 2020	15 [7] (15) Analyzing 15 RCTs, found no reductions in ILIs (RR 0.93, 95% CI 0.83-1.05) or influenzas (RR 0.84, 95% CI 0.61-1.17) for masks in the general population or healthcare workers (RR 0.37, 95% CI 0.05-2.50).	[equivocal] "We are uncertain whether wearing masks or N95/P2 respirators helps to slow the spread of respiratory viruses."
Liang et al.[356] 2020	21 [8] (6) Using data from both observational and RCT studies, the authors reported a significant protective effect on lab-confirmed respiratory viral infection (5.9% (307/5217) vs. 12.1% (419/3469), P<.00001). In non-healthcare settings, using RCT and observational data, the authors reported statistically significant effects (6.1% (111/1812) vs. 11.3% (227/2008), P=.002) with moderate heterogeneity between the studies (I^2=45%, P=.08). The authors did not consider RCT-only data, although if they had, between-group differences would have declined (5.4% (44/816) vs. 7.8% (77/989)).	[supportive] "The present systematic review and meta-analysis showed the general efficacy of masks in preventing the transmission of RVIs [respiratory viral infections]."
Ollila et al.[357] 2020	5 [5] (5) Analyzing data from 5 RCTs, reported strong and statistically significant results in favor of face mask	[supportive] "[Four] out of 17 studies supported the use of masks in the intention-to-treat

[353] Karima Chaabna et al., *Facemask Use in Community Settings to Prevent Respiratory Infection Transmission: A Rapid Review and Meta-Analysis,* 104 INT'L J. INFECTIOUS DISEASE 198, 205 (2021).
[354] Derek K. Chu et al., *Physical Distancing, Face Masks, and Eye Protection to Prevent Person-to-Person Transmission of SARS-CoV-2 and COVID-19: A Systematic Review and Meta-Analysis*, 395 LANCET 1973, 1984 (2021).
[355] Tom Jefferson et al., *Interventions for the Interruption or Reduction of the Spread of Respiratory Viruses*, 7 COCHRANE DATABASE SYS. REV. 1, 108 (2011).
[356] Mingming Liang et al., *Efficacy of Face Mask in Preventing Respiratory Virus Transmission: A Systematic Review and Meta-Analysis*, 36 TRAVEL MED. & INFECTIOUS DISEASE 1, 7 (2020).
[357] Hanna M. Ollila et al., *Face Masks Prevent Transmission of Respiratory Diseases: A Meta-Analysis of Randomized Controlled Trials*, MEDRXIV 1, 12 (2020), https://www.medrxiv.org/content/10.1101/2020.07.31.20166116v2.full.pdf.

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	efficacy at maximum follow up (7.8% (297/3793) vs. 18.4% (704/3830); RR: 0.608). However, for 2 of the 5 papers studied the authors utilize data from face mask + other intervention arms instead of available data from face mask-only arm. These risk ratios are considerably different (0.78 and 0.88 instead of 1.10 and 0.92, respectively) and the involved groups constitute 14.3% (542/3793) and 16.4% (629/3830) of each treatment group, which would likely alter the final result.	analysis." "Despite . . . small effect sizes in the individual studies, the findings did support use of face masks."
Perski et al.[358] 2020	21 [11] (11) Authors considered 10 observational studies and 11 RCTs (only one of which found a reduction in self-reported ILIs in participants wearing face masks) and, using a Bayesian analysis, reported a "moderate likelihood of a small effect for the wearing of face masks" in reducing self-reported ILI (cumulative posterior odds=3.61), but determined that evidence was equivocal as to clinically- and laboratory-confirmed infections (cumulative posterior odds of 1.07 and 1.22, respectively).	[equivocal] RCT evidence was "equivocal on whether facemask wearing in community settings reduces the transmission of clinically- or laboratory-confirmed viral respiratory infections." "RCTs and observational studies have found an effect on self-reported symptoms, but this may be the result of reporting bias and confounding."
Wang et al.[359] 2020	15 [15] (5) Using 15 non-healthcare studies (10 observational and 5 RCTs), authors reported a slightly decreased pooled odds ratio (OR: 0.96, 95% CI 0.8–1.15) but the results were not statistically significant.	[critical] "Our review found that SMs [surgical masks] were not associated to ARI [acute respiratory illnesses] incidence, indicating that SMs may be ineffective . . . when worn by an uninfected individual in the general community. However, given the weak methodologies across studies assessed and the possibility of residual confounding, an absence of evidence cannot be simply regarded as an evidence of absence."
Xiao et al.[360] 2020	14 [14] (14) Incorporating data from 10 RCTs in non-healthcare settings, reported no statistically significant effect for the use of masks on laboratory-confirmed influenza (2.3% (29/1276) vs. 3.3% (51/1567), P=.25).	[critical] "We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility."
Li et al.[361]	6 [1] (0)	[supportive]

[358] Olga Perski et al., *Face Masks to Prevent Community Transmission of Viral Respiratory Infections: A Rapid Evidence Review Using Bayesian Analysis*, QEIOS 1, 15, https://www.qeios.com/read/1SC5L4 (last visited Oct. 21, 2020).
[359] Min X. Wang et al., *Effectiveness of Surgical Face Masks in Reducing Acute Respiratory Infections in Non-Healthcare Settings: A Systematic Review and Meta-Analysis*, 7 FRONTIERS MED. 1, 20 (2020).
[360] Jingyi Xiao et al., *Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures*, 26 EMERGING INFECTIOUS DISEASES 967, 972 (2020).
[361] Yanni Li et al., *Face Masks To Prevent Transmission of COVID-19: A Systematic Review and Meta-Analysis,* 49 AM. J. INFECTION CONTROL 900, 904–5 (2021).

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2021	Using data from 6 COVID-19 case-control studies—5 in healthcare settings—to report a significantly-reduced risk of infection (11.4% (82/718) vs. 20.0% (202/1008); OR: 0.38). However, in the only non-HCW study considered the results were non-significant (12.8% (29/227) vs. 16.9% (102/602); OR: 0.72, 95% CI: 0.46–1.12).	"Face masks reduced the risk of COVID-19 infection by 70% for health care workers," but the "included original studies did not make . . . adjustments for possible confounding factors, such as . . . hand hygiene" and the two most heavily weighted studies involved exclusively N95 masks or primarily non-cloth masks.
Tabatabaeizadeh[362] 2020	4 [1] (0) Authors used data from 4 observational COVID-19 studies to conclude that mask-wearing is correlated with statistically significant risk ratio decrease of 0.12. However, 70.8% (n=5442) of the study's total participants (n=7688) came from a single paper where participants used N95 respirators, not facemasks.	[supportive] "[U]se of the face mask was associated significantly with a decrease [sic] risk of SARS-CoV-2 infection" but "[t]he non-randomized design of the included studies in this meta-analysis" was an "important limitation."
Coclite et al.[363] 2021	13 [13] (3) Authors used data from 3 RCTs and 10 observational papers to conduct two separate meta-analyses. Concluded that neither RCT data (11.7% (187/1598) vs. 11.2% (272/2419); RR: 0.97, P=0.85) nor any of the observational data (cross-sectional: 20.2% (1302/6438) vs. 17.2% (1714/9975); RR: 0.90, 95% CI: 0.74–1.10) (case-control: 19.9% (138/694) vs. 40.5% (327/807); RR: 0.59, 95% CI: 0.34–1.03) (prospective: 20.5% (88/429) vs. 58.4% (310/531); RR: 0.55, 95% CI: 0.11–2.75)) were statistically significant.	[supportive] "We found very low-certainty evidence that wearing a face mask is associated with a reduced risk of primary infection in RCTs as well as in observational studies." "The results… support[] the use of face masks for reducing the transmission and acquisition of respiratory viral infections in the community."
Abdullahi et al.[364] 2020	2 [3] (5) Considering data from 2 RCTs and 3 observational studies in the SARS-CoV-1 and influenza contexts, authors failed to find a statistically significant benefit of face mask use (18.7% (142/758) vs. 33.1% (480/1451); RR: 0.78, P=0.52).	[equivocal] "On the intervention on face masks, there are contested discussions…. However, WHO acknowledges that the wearing of masks by the general public has been impactful in reducing previous severe pandemics."
Nanda et al.[365] 2021	7 [7] (7) Incorporating data from 7 RCTs (all previously discussed) evaluating ILI transmission, found no significant difference in infection between mask and no-mask groups (2.8% (37/1301) vs. 3.6% (57/1592); RR: 1.00, P=0.93).	[equivocal] "The available preclinical findings limited clinical and indirect evidence suggests biological plausibility that face masks may reduce the spread of SARS-CoV-2. The available clinical trial evidence shows no significant difference in limiting transmission [of] respiratory viral illnesses, but the evidence is of poor quality."

[362] Seyed-Amer Tabatabaeizadeh, *Airborne Transmission of COVID-19 and the Role of Face Mask to Prevent It: A Systematic Review and Meta-Analysis*, 26 EUR. J. MED. RESEARCH 1, 4, 5 (2021).
[363] Daniela Coclite et al., *Face Mask Use in the Community for Reducing the Spread of COVID-19: A Systematic Review*, 7 FRONTIERS MED. 1, 8–11 (2021).
[364] Leila Abdullahi et al., *Community Interventions in Low- and Middle-Income Countries to Inform COVID-19 Control Implementation Decisions in Kenya: A Rapid Systematic Review*, 15 PLOS ONE 1, 16, 22 (2020).
[365] Akriti Nanda et al., *Efficacy of Surgical Masks or Cloth Masks in the Prevention of Viral Transmission: Systematic Review, Meta-Analysis, and Proposal for Future Trial*, 14 J. EVIDENCE-BASED MED. 97 (2021).

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Table 3. Studies suggesting an association of face masks with higher rates of infection

Authors	Year	Study type (N)	Results suggestive of harm	Conclusions
Alfelali et al.[366]	2019	Cluster-randomized trial (7,687)	Unvaccinated pilgrims had higher CRI (clinical respiratory infection) rates than counterparts in the control group (13% versus 10%, P=0.03).	"[A]llocation to facemask use was not associated with reduced laboratory-confirmed viral respiratory infections or clinical respiratory infections."
MacIntyre et al.[367]	2015	Cluster-randomized trial (1607)	Rates of ILI in cloth mask intervention arm were more than 3 times higher compared to the "standard practice" control arm (2.3% (13/569) vs. 0.7% (3/458)).	Future research should examine "cloth masks, but until such research is carried out cloth masks should not be recommended." The authors "recommend that infection control guidelines be updated about cloth mask use [referring to its risks] to protect the occupational health and safety of [healthcare workers]."
Simmerman et al.[368]	2011	Cluster-randomized trial (885)	More laboratory-confirmed secondary infections among members in the hand washing plus mask group compared to the control group (23% (66/291) vs. 19% (58/302), n.s.), higher rates at the household level (35% vs. 22%) and, in a separate sub-group analysis, higher rates of ILI among those in the mask group (OR: 2.15, P=0.004) that the researchers described as "twofold in the opposite direction from the hypothesized protective effect."	Reported that "[i]nfluenza transmission was not reduced by interventions to promote hand washing and face mask use."
Larson et al.[369]	2010	Cluster-randomized trial (509 households)	Households in the hand sanitizer group included significantly more members without any reported upper respiratory symptoms compared to the hand sanitizer plus face mask group (57.6% (545/946) vs. 38.7% (363/938), P<0.01)	Did not have sufficient data to support mask wearing but nevertheless concluded that "[m]ask wearing is a promising non-pharmaceutical intervention . . ."
MacIntyre et al.[370]	2009	Cluster-randomized trial (145)	Point estimates of the primary outcome measure of ILI were higher in the surgical mask group than in the no mask group (22.3% vs. 16.0%), but the results were not statistically significant.	Authors "found that distributing masks during seasonal winter influenza outbreaks is an ineffective control measure characterized by low adherence" and stated that masks may only have efficacy "where a larger adherence may be

[366] Mohammad Alfelali et al., *Facemask Against Viral Respiratory Infections Among Hajj Pilgrims: A Challenging Cluster-Randomized Trial*, 15 PLOS ONE 1, 7 (2020).
[367] Chandini R. MacIntyre et al., *A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*, 5 BMJ OPEN 1, 8 (2015).
[368] James M. Simmerman et al., *Findings from a Household Randomized Controlled Trial of Hand Washing and Face Masks to Reduce Influenza Transmission in Bangkok, Thailand: Household Randomized Controlled Trial of Hand Washing and Face Masks*, 5 INFLUENZA & OTHER RESPIRATORY VIRUSES 256, 256 (2011).
[369] Elaine L. Larson et al., *Impact of Non-pharmaceutical Interventions on URIs and Influenza in Crowded, Urban Households*, 125 PUB. HEALTH REP. 178, 189 (2010).
[370] Chandini R. MacIntyre et al., *Face Mask Use and Control of Respiratory Virus Transmission in Households*, 15 EMERGING INFECTIOUS DISEASES 233, 238 (2009).

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				expected, such as during a severe influenza pandemic or other emerging infection."
Al-Asmary et al.[371]	2007	Nested case-control (375)	Intermittent use of face masks associated with a higher rate of acute respiratory tract infections than not wearing masks (34% (42/122) vs. 22% (4/18)).	"The common practice among pilgrims and medical personnel of using surgical facemasks to protect themselves against ARI [acute respiratory infections] should be discontinued."

[371] Saeed Al-Asmary et al., *Acute Respiratory Tract Infections Among Hajj Medical Mission Personnel, Saudi Arabia*, 11 INT'L J. INFECTIOUS DISEASE 268, 271 (2007).

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Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota

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Abstract

There is still considerable debate about whether mask mandates in the K-12 schools limit transmission of SARS-CoV-2 in children attending school. Randomized data about the effectiveness of mask mandates in children is still entirely lacking. Our study took advantage of a unique natural experiment of two adjacent K-12 school districts in Fargo, North Dakota, one which had a mask mandate and one which did not in the fall of the 2021-2022 academic year. In the winter, both districts adopted a masks-optional policy allowing for a partial crossover study design. We observed no significant difference between student case rates while the districts had differing masking policies (IRR 0.99; 95% CI: 0.92 to 1.07) nor while they had the same mask policies (IRR 1.04; 95% CI: 0.92 to 1.16). The IRRs across the two periods were also not significantly different (p = 0.40). Our findings contribute to a growing body of literature which suggests school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students.

Introduction

School districts across the nation have implemented mask mandates for children in the hope of reducing COVID-19 transmission, but the impact of school-based mask mandates on COVID-19 transmission in children is not fully established. While observational studies of school mask mandates have had conflicting results, randomized studies have failed to detect an impact of masking on participants under 50 years of age [1-6]. Here we report the results of a natural experiment in two large K-12 school districts in Fargo, North Dakota, Fargo Public Schools (FPS) and West Fargo Public Schools (WF), to estimate the association between school mask mandates and COVID-19 infections. Our study population is unique because the districts are adjacent to each other in the same county and have similar student demographics, COVID-19 mitigation policies and staff vaccination rates. At the start of the Fall 2021 semester, FPS mandated masks and WF did not. On January 17, 2022, FPS also moved to a mask optional policy, creating a unique natural experiment to study school-based mask mandates.

Results

Table 1 shows school characteristics, total number of positive student tests and the COVID-19 risk mitigation measures implemented by each district. Both school districts had similar COVID-19 mitigation policies, although FPS had more stringent rules for quarantining close contacts. WF also had higher percentages of low-income and minority students. Figure 1 shows that overall trends in COVID-19 incidence among students were similar in the two districts. From August 26, 2021, to January 17, 2022, cumulative incidence in the mask compulsory school district was almost identical to cumulative incidence in the mask-optional district (WF: 1596/12,254 [13.0%; 95% CI: 12.4, 13.6]); FPS: 1475/11,419 [12.9% 95% CI: 12.3, 13.6%]). IRR 0.99; 95% CI: 0.92, 1.07). Post January 17, 2022, when both districts had mask-optional policies, case rates were also not significantly different (WF: 622/12,254 [5.1%; 95% CI: 4.7, 5.5]; FPS: 600/11,419 [5.3%; 95% CI: 4.9, 5.7]). IRR 1.04; 95% CI: 0.92, 1.16). The IRRs across the two periods were also not statistically significantly different (p value = 0.40). Based on an incidence rate of 13%, we had 80% power to detect a 1.2% difference in incidence between the districts.

Discussion

This study found that K-12 school mask mandates were not associated with significantly lower COVID-19 student case rates. This is consistent with adult randomized data on community cloth masking [6], multiple observational studies of school mask mandates [1,2,3] and a systematic review of medical or surgical cloth masking for influenza [8]. Studies of school-based mask mandates are particularly prone to bias [9] as student cases detected within the school may be at least 20x more likely to have been contracted outside of school than in [10]. Other observational studies have reported a negative association between school mask mandates and SARS-CoV-2 cases [11,12,13] but may have had important methodological limitations [9,14].

The strengths of the study include the similarities of the two K-12 districts including size, adjacent location within a county, similar demographics, and COVID-19 policies beyond masking. Second, the study includes a partial crossover design with the mask mandate district dropping its mandate during the study period. The partial crossover should have revealed the presence of any major confounding effect. The lack of significant difference between the districts however persisted post partial crossover, when both districts had masks-optional policies. Based on the size of our study and the incidence rate during the study period, we had 80% power to detect a 1.2% difference in incidence between the districts, so if we failed to detect a benefit of mask mandates, that benefit would have been very small. An additional strength of this study is it includes a relatively long study period with data from both the delta and omicron waves.

The study also has limitations. We did not have information on the number of tests performed by each school district, although both school districts had similar testing access and policies. Second, this study did not specifically evaluate in-school transmission. We also did not have data on the types of masks being worn or on masking adherence rates in the two school districts; however, parents and administrators indicated via personal communication with SH, masking was near universal in the district with a mask mandate and 5% or less in the masks-optional district [15]. In conclusion, school mask mandates were not found to be associated with significantly lower student SARS-CoV-2 case rates. This is consistent with a growing body of scientific literature and should be taken into consideration and weighed with the harms and discomfort of masking in the educational setting.

Methods

We obtained data on student enrollment, masking policies, masking compliance, demographic information and COVID-19 mitigation measures from district administrators and official school district websites. We obtained publicly available data on new student COVID-19 case rates in each school district from August 26, 2021, to March 2, 2022, from the North Dakota Department of Health website [https://www.health.nd.gov/k-12-school-dashboard]. We determined the COVID-19 student case rates and incidence rate ratio (IRR) as well as 95% confidence intervals (CI) for case rates between the districts, both while FPS had a mask mandate and WF did not and then when FPS dropped their mandate on January 17, 2022, (after which both districts had mask-optional policies). The study is not considered human subjects research as the data were not collected specifically for this study and do not have subject identifiers. We used Stata Version 17 and UCSF Sample Size Calculator [7] for the analysis. A post-hoc power calculation was performed using ClinCalc. Our report follows the STROBE reporting guidelines for observational studies.

Declarations

Acknowledgements

We would like to thank Emily J Allen, PhD, for her graphic design assistance. This study received funding from the University of Southern California.

Author Contributions

SH, TH and NS conceived the study design, SH, JS and NS collected the data, NS, JS and TH analysed the data and NS and TH interpreted the results. All authors reviewed the manuscript.

Competing Interests

TH has provided expert testimony for multiple lawsuits involving SARS-CoV-2 in-school transmission and student mask mandates. Otherwise, the authors declare no relevant competing interests.

Data availability

The raw data used for our calculations are available online at https://github.com/tracybethhoeg/North-Dakota-Mask-Study

The data used in this analysis are also publicly available North Dakota Department of Health website available at https://www.health.nd.gov/k-12-school-dashboard , accessed March 31, 2022. Information on enrollment from school district websites. WFPS: https://www.west-fargo.k12.nd.us/site/default.aspx?PageType=3&DomainID=22&ModuleInstanceID=11253&ViewID=6446EE88-D30C-497E-9316-3F8874B3E108&RenderLoc=0&FlexDataID=24239&PageID=37 accessed March 31, 2022. FPS: https://www.fargo.k12.nd.us/page/365 accessed March 31, 2022.

Ethics declarations

According to the NIH's Human Subjects Research Decision Tool (https://grants.nih.gov/policy/humansubjects/hs-decision.htm), this study was IRB exempt.

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Table 1

Table 1: School district characteristics and COVID-19 risk mitigation measures in Fall 2021 in study school districts

School Policies and Characteristics	West Fargo Public School District (School District with mask optional policy)	Fargo Public School District (School district with mandatory masking till Jan 17, 2022 and mask optional thereafter)
Student Enrollment in August 2021[a]	12,254	11,419
Total Number (% [95% CI]) of students testing positive up to 1/17/22	1596 (13.0% [12.4, 13.6])	1475 (12.9% [12.3, 13.6])
Total Number (% [95% CI]) of Students Testing Positive After 1/17/22	622 (5.1% [4.7, 5.5])	600 (5.3% [4.9, 5.7])
Average Class Size[b]	21-Elementary School, 23-Middle School, 23-High School	18.7-Elementary School, 21.2 Middle School, 20.1 High School
Race/Ethnicity of Students in 2021-2022 School Year[c]	71% White, 17% African American, Asian 4%, Hispanic 4%	69% White, 16% African American, Asian 4%, Hispanic 6%
Fraction of Low-Income students in 2021-2022 School Year[c]	23%	18%
Staff vaccination rate at school year start[b]	74.5%	77.6%
Face covering required when using district provided transportation[d]	Yes	Yes
Mandatory physical distancing[d]	No	No
Regular cleaning of high touch surfaces[d]	Yes	Yes
Does the school conduct routine COVID testing of all children? [d]	No. Children are given the option to use a rapid test on certain times and days at school sites. Children need parent permission and need to preregister. Children who develop symptoms at school have the option to test with parent permission when parent picks up child from school.	No. The district has 2 testing sites where students and their families can get tested, but it is voluntary. A parent needs to escort their student to the site or have a permission slip filed in.

School activities, events, assemblies, and gatherings allowed[d]	Yes	Yes
Has the school upgraded ventilation systems? [d]	Yes, iMod air filtration units have been installed in every school	Yes, Needlepoint Bi-polar Ionization units have been installed in each school buildings HVAC system.
Symptomatic students sent home[d]	Yes	Yes
How long are COVID+ children required to stay at home? [d]	10 days	10 days
When can symptomatic children return to school? [d]	Students with symptoms other than loss of taste or smell can return when they have been symptom free for 24 hours without use of medications. Students with loss of taste or smell can return after 10 days or the following day after a negative test	Students can return after 10 days from onset or date of negative COVID test whichever is earlier, and free of fever for 24 hours with improving symptoms.
Are children in the same classroom as COVID+ case required to quarantine? [d]	No, a notification is sent to all children in the classroom and parents are asked to monitor their children for symptoms	Not all of them. Only individuals who are close contacts (close contact being anyone within 6ft for 15 cumulative minutes or more in one day) and unmasked (unmasked contacts generally originate from lunch or snack times) are required to quarantine or go through testing protocol to remain in school.
Are “close contacts” required to quarantine? [d]	Only symptomatic individuals or persons who are unvaccinated and unwilling to do a rapid test every other day for seven days need to quarantine	Only unmasked close contacts are required to quarantine or submit to every other day testing to remain in school

Notes:

[a] Information from school district websites. WFPS: https://www.west-fargo.k12.nd.us/site/default.aspx?PageType=3&DomainID=22&ModuleInstanceID=11253&ViewID=6446EE88-D30C-497E-9316-3F8874B3E108&RenderLoc=0&FlexDataID=24239&PageID=37 accessed March 31, 2022.
FPS: https://www.fargo.k12.nd.us/page/365 accessed March 31, 2022.

[b] Information from communication with school administrators.

[c] Information from official portal for North Dakota state government.
WFPS: https://insights.nd.gov/Education/District/EnrollmentDemographics/09006 accessed March 31, 2022.
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[d] Information from school COVID-19 protocols. WFPS: https://www.west-fargo.k12.nd.us/cms/lib/ND02203445/Centricity/Domain/2935/COVID%20Health%20and%20Safety%20Protocols%202021-22.pdf accessed March 31, 2022. FPS: https://drive.google.com/file/d/1qyn7DNvCnSuKszHqM8C8BTAixmnCbToS/view accessed March 31, 2022.

Figures

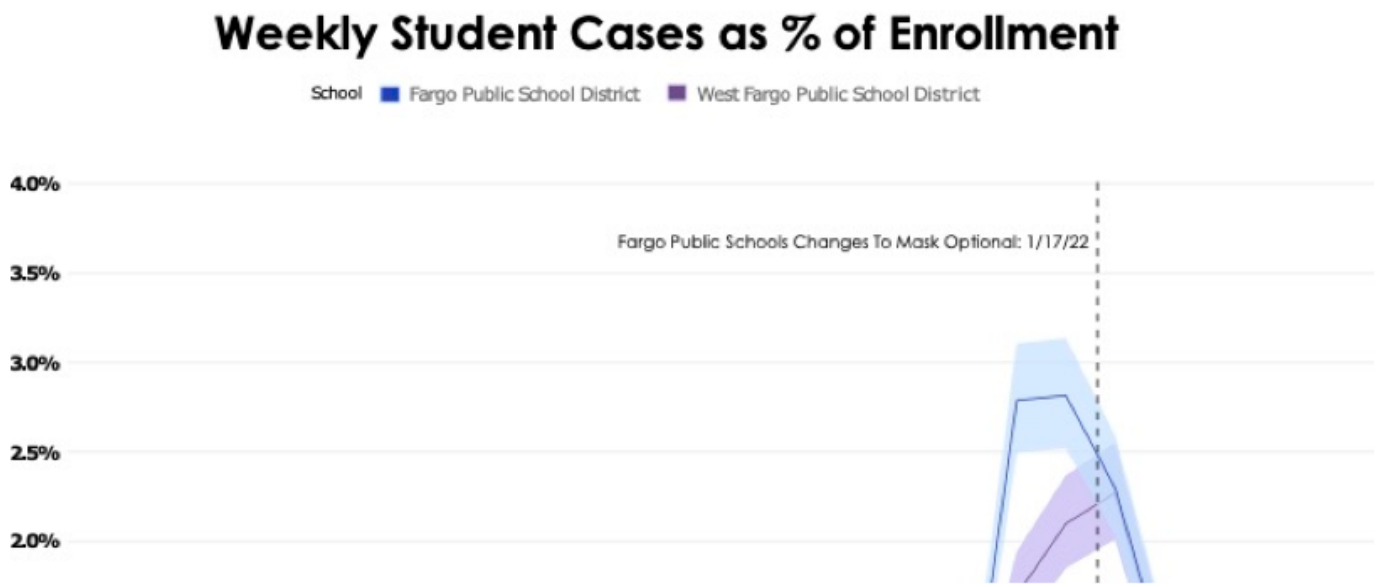


Figure 1

Weekly COVID-19 Incidence in School Districts Since Start of 2021 School Year

Notes: Shaded region represents 95% confidence intervals. Information on new student COVID-19 cases from North Dakota Department of Health website available at https://www.health.nd.gov/k-12-school-dashboard , accessed March 31, 2022. Information on enrollment from school district websites. WFPS: https://www.west-fargo.k12.nd.us/site/default.aspx?PageType=3&DomainID=22&ModuleInstanceID=11253&ViewID=6446EE88-D30C-497E-9316-3F8874B3E108&RenderLoc=0&FlexDataID=24239&PageID=37 accessed March 31, 2022. FPS: https://www.fargo.k12.nd.us/page/365 accessed March 31, 2022.

BMJ Open

A cluster randomised trial of cloth masks compared with medical masks in healthcare workers

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ABSTRACT

Objective: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks.

Setting: 14 secondary-level/tertiary-level hospitals in Hanoi, Vietnam.

Participants: 1607 hospital HCWs aged ≥18 years working full-time in selected high-risk wards.

Intervention: Hospital wards were randomised to: medical masks, cloth masks or a control group (usual practice, which included mask wearing). Participants used the mask on every shift for 4 consecutive weeks.

Main outcome measure: Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection.

Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

Conclusions: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated.

Trial registration number: Australian New Zealand Clinical Trials Registry: ACTRN12610000887077.

Strengths and limitations of this study

- The use of cloth masks is widespread around the world, particularly in countries at high-risk for emerging infections, but there have been no efficacy studies to underpin their use.
- This study is large, a prospective randomised clinical trial (RCT) and the first RCT ever conducted of cloth masks.
- The use of cloth masks are not addressed in most guidelines for health care workers—this study provides data to update guidelines.
- The control arm was 'standard practice', which comprised mask use in a high proportion of participants. As such (without a no-mask control), the finding of a much higher rate of infection in the cloth mask arm could be interpreted as harm caused by cloth masks, efficacy of medical masks, or most likely a combination of both.

INTRODUCTION

The use of facemasks and respirators for the protection of healthcare workers (HCWs) has received renewed interest following the 2009 influenza pandemic,[1] and emerging infectious diseases such as avian influenza,[2] Middle East respiratory syndrome coronavirus (MERS-coronavirus)[3 4] and Ebola virus.[5] Historically, various types of cloth/cotton masks (referred to here after as 'cloth masks') have been used to protect HCWs.[6] Disposable medical/surgical masks (referred to here after as 'medical masks') were introduced into healthcare in the mid 19th century, followed later by respirators.[7] Compared with other parts of the world, the use of face masks is more prevalent in Asian countries, such as China and Vietnam.[8–11]

In high resource settings, disposable medical masks and respirators have long since replaced the use of cloth masks in hospitals. Yet cloth masks remain widely used

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globally, including in Asian countries, which have historically been affected by emerging infectious diseases, as well as in West Africa, in the context of shortages of personal protective equipment (PPE).[12 13] It has been shown that medical research disproportionately favours diseases of wealthy countries, and there is a lack of research on the health needs of poorer countries.[14] Further, there is a lack of high-quality studies around the use of facemasks and respirators in the healthcare setting, with only four randomised clinical trials (RCTs) to date.[15] Despite widespread use, cloth masks are rarely mentioned in policy documents,[16] and have never been tested for efficacy in a RCT. Very few studies have been conducted around the clinical effectiveness of cloth masks, and most available studies are observational or in vitro.[6] Emerging infectious diseases are not constrained within geographical borders, so it is important for global disease control that use of cloth masks be underpinned by evidence. The aim of this study was to determine the efficacy of cloth masks compared with medical masks in HCWs working in high-risk hospital wards, against the prevention of respiratory infections.

METHODS

A cluster-randomised trial of medical and cloth mask use for HCWs was conducted in 14 hospitals in Hanoi, Vietnam. The trial started on the 3 March 2011, with rolling recruitment undertaken between 3 March 2011 and 10 March 2011. Participants were followed during the same calendar time for 4 weeks of facemasks use and then one additional week for appearance of symptoms. An invitation letter was sent to 32 hospitals in Hanoi, of which 16 agreed to participate. One hospital did not meet the eligibility criteria; therefore, 74 wards in 15 hospitals were randomised. Following the randomisation process, one hospital withdrew from the study because of a nosocomial outbreak of rubella.

Participants provided written informed consent prior to initiation of the trial.

Randomisation

Seventy-four wards (emergency, infectious/respiratory disease, intensive care and paediatrics) were selected as high-risk settings for occupational exposure to respiratory infections. Cluster randomisation was used because the outcome of interest was respiratory infectious diseases, where prevention of one infection in an individual can prevent a chain of subsequent transmission in closed settings.[8 9] Epi info V.6 was used to generate a randomisation allocation and 74 wards were randomly allocated to the interventions.

From the eligible wards 1868 HCWs were approached to participate. After providing informed consent, 1607 participants were randomised by ward to three arms: (1) medical masks at all times on their work shift; (2) cloth masks at all times on shift or (3) control arm (standard practice, which may or may not include mask use). Standard practice was used as control because the IRB deemed it unethical to ask participants to not wear a mask. We studied continuous mask use (defined as wearing masks all the time during a work shift, except while in the toilet or during tea or lunch breaks) because this reflects current practice in high-risk settings in Asia.[8]

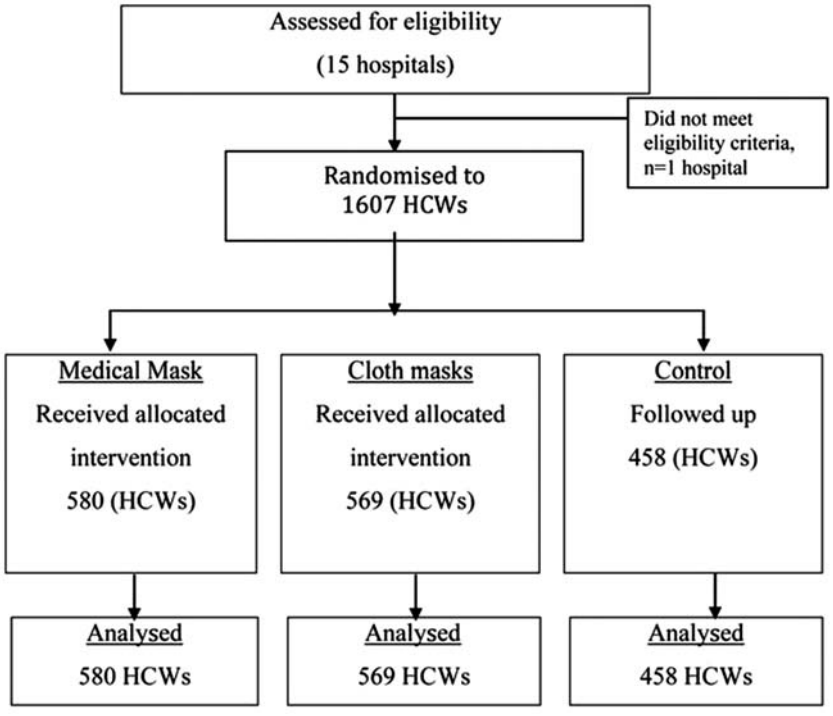


Figure 1 Consort diagram of recruitment and follow-up (HCWs, healthcare workers).

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The laboratory results were blinded and laboratory testing was conducted in a blinded fashion. As facemask use is a visible intervention, clinical end points could not be blinded. Figure 1 outlines the recruitment and randomisation process.

Primary end points

There were three primary end points for this study, used in our previous mask RCTs:[8 9] (1) Clinical respiratory illness (CRI), defined as two or more respiratory symptoms or one respiratory symptom and a systemic symptom;[17] (2) influenza-like illness (ILI), defined as fever ≥38°C plus one respiratory symptom and (3) laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex reverse transcriptase PCR (RT-PCR) for 17 respiratory viruses: respiratory syncytial virus (RSV) A and B, human metapneumovirus (hMPV), influenza A (H3N2), (H1N1)pdm09, influenza B, parainfluenza viruses 1–4, influenza C, rhinoviruses, severe acute respiratory syndrome (SARS) associated coronavirus (SARS-CoV), coronaviruses 229E, NL63, OC43 and HKU1, adenoviruses and human bocavirus (hBoV).[18–23] Additional end points included compliance with mask use, defined as using the mask during the shift for 70% or more of work shift hours.[9] HCWs were categorised as 'compliant' if the average use was equal or more than 70% of the working time. HCW were categorised as 'non-compliant' if the average mask use was less than 70% of the working time.

Eligibility

Nurses or doctors aged ≥18 years working full-time were eligible. Exclusion criteria were: (1) Unable or refused to consent; (2) Beards, long moustaches or long facial hair stubble; (3) Current respiratory illness, rhinitis and/or allergy.

Intervention

Participants wore the mask on every shift for four consecutive weeks. Participants in the medical mask arm were supplied with two masks daily for each 8 h shift, while participants in the cloth mask arm were provided with five masks in total for the study duration, which they were asked to wash and rotate over the study period. They were asked to wash cloth masks with soap and water every day after finishing the shifts. Participants were supplied with written instructions on how to clean their cloth masks. Masks used in the study were locally manufactured medical (three layer, made of non-woven material) or cloth masks (two layer, made of cotton) commonly used in Vietnamese hospitals. The control group was asked to continue with their normal practices, which may or may not have included mask wearing. Mask wearing was measured and documented for all participants, including the control arm.

Data collection and follow-up

Data on sociodemographic, clinical and other potential confounding factors were collected at baseline. Participants were followed up daily for 4 weeks (active intervention period), and for an extra week of standard practice, in order to document incident infection after incubation. Participants received a thermometer (traditional glass and mercury) to measure their temperature daily and at symptom onset. Daily diary cards were provided to record number of hours worked and mask use, estimated number of patient contacts (with/without ILI) and number/type of aerosol-generating procedures (AGPs) conducted, such as suctioning of airways, sputum induction, endotracheal intubation and bronchoscopy. Participants in the cloth mask and control group (if they used cloth masks) were also asked to document the process used to clean their mask after use.

We also monitored compliance with mask use by a previously validated self-reporting mechanism.[8] Participants were contacted daily to identify incident cases of respiratory infection. If participants were symptomatic, swabs of both tonsils and the posterior pharyngeal wall were collected on the day of reporting.

Sample collection and laboratory testing

Trained collectors used double rayon-tipped, plastic-shafted swabs to scratch tonsillar areas as well as the posterior pharyngeal wall of symptomatic participants. Testing was conducted using RT-PCR applying published methods.[19–23] Viral RNA was extracted from each respiratory specimen using the Viral RNA Mini kit (Qiagen, Germany), following the manufacturer's instructions. The RNA extraction step was controlled by amplification of a RNA house-keeping gene (amplify pGEM) using real-time RT-PCR. Only extracted samples with the house keeping gene detected by real-time RT-PCR were submitted for multiplex RT-PCR for viruses.

The reverse transcription and PCRs were performed in OneStep (Qiagen, Germany) to amplify viral target genes, and then in five multiplex RT-PCR: RSVA/B, influenza A/H3N2, A(H1N1) and B viruses, hMPV (reaction mix 1); parainfluenza viruses 1–4 (reaction mix 2); rhinoviruses, influenza C virus, SARS-CoV (reaction mix 3); coronaviruses OC43, 229E, NL63 and HKU1 (reaction mix 4); and adenoviruses and hBoV (reaction mix 5), using a method published by others.[18] All samples with viruses detected by multiplex RT-PCR were confirmed by virus-specific mono nested or hemi-nested PCR. Positive controls were prepared by in vitro transcription to control amplification efficacy and monitor for false negatives, and included in all runs (except for NL63 and HKU1). Each run always included two negatives to monitor amplification quality. Specimen processing, RNA extraction, PCR amplification and PCR product analyses were conducted in different rooms to avoid cross-contamination.[19 20]

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Filtration testing

The filtration performance of the cloth and medical masks was tested according to the respiratory standard AS/NZS1716.[24] The equipment used was a TSI 8110 Filter tester. To test the filtration performance, the filter is challenged by a known concentration of sodium chloride particles of a specified size range and at a defined flow rate. The particle concentration is measured before and after adding the filter material and the relative filtration efficiency is calculated. We examined the performance of cloth masks compared with the performance levels—P1, P2 (=N95) and P3, as used for assessment of all particulate filters for respiratory protection. The 3M 9320 N95 and 3M Vflex 9105 N95 were used to compare against the cloth and medical masks.

Sample size calculation

To obtain 80% power at two-sided 5% significance level for detecting a significant difference of attack rate between medical masks and cloth masks, and for a rate of infection of 13% for cloth mask wearers compared with 6% in medical mask wearers, we would need eight clusters per arm and 530 participants in each arm, and intracluster correlation coefficient (ICC) 0.027, obtained from our previous study.[8] The design effect (deff) for this cluster randomisation trial was 1.65 (deff=1+(m −1)×ICC=1+(25−1)×0.027=1.65). As such, we aimed to recruit a sample size of 1600 participants from up to 15 hospitals.

Analysis

Descriptive statistics were compared among intervention and control arms. Primary end points were analysed by intention to treat. We compared the event rates for the primary outcomes across study arms and calculated p values from cluster-adjusted χ^2 tests[25] and ICC.[25 26] We also estimated relative risk (RR) after adjusting for clustering using a log-binomial model under generalised estimating equation (GEE) framework.[27] We checked for variables which were unequally distributed across arms, and conducted an adjusted analysis accordingly. We fitted a multivariable log-binomial model, using GEE to account for clustering by ward, to estimate RR after adjusting for potential confounders. In the initial model, we included all the variables that had p value less than 0.25 in the univariable analysis, along with the main exposure variable (randomisation arm). A backward elimination method was used to remove the variables that did not have any confounding effect.

As most participants in the control arm used a mask during the trial period, we carried out a post-hoc analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). For this analysis, controls who used both types of mask (n=245) or used N95 respirators (n=3) or did not use any masks (n=2) were excluded. We fitted a multivariable log-binomial model, to estimate RR after adjusting for potential confounders. As we pooled data of participants from all three arms and analysed by mask type, not trial arm, we did not adjust for clustering here. All statistical analyses were conducted using STATA V.12.[28]

Owing to a very high level of mask use in the control arm, we were unable to determine whether the differences between the medical and cloth mask arms were due to a protective effect of medical masks or a detrimental effect of cloth masks. To assist in interpreting the data, we compared rates of infection in the medical mask arm with rates observed in medical mask arms from two previous RCTs,[8 9] in which no efficacy of medical masks could be demonstrated when compared with control or N95 respirators, recognising that seasonal and geographic variation in virus activity affects the rates of exposure (and hence rates of infection outcomes) among HCWs. This analysis was possible because the trial designs were similar and the same outcomes were measured in all three trials. The analysis was carried out to determine if the observed results were explained by a detrimental effect of cloth masks or a protective effect of medical masks.

RESULTS

A total of 1607 HCWs were recruited into the study. The participation rate was 86% (1607/1868). The average number of participants per ward was 23 and the mean age was 36 years. On average, HCWs were in contact with 36 patients per day during the trial period (range 0–661 patients per day, median 20 patients per day). The distribution of demographic variables was generally similar between arms (table 1). Figure 2 shows the primary outcomes for each of the trial arms. The rates of CRI, ILI and laboratory-confirmed virus infections were lowest in the medical mask arm, followed by the control arm, and highest in the cloth mask arm.

Table 2 shows the intention-to-treat analysis. The rate of CRI was highest in the cloth mask arm, followed by the control arm, and lowest in the medical mask arm. The same trend was seen for ILI and laboratory tests confirmed viral infections. In intention-to-treat analysis, ILI was significantly higher among HCWs in the cloth masks group (RR=13.25 and 95% CI 1.74 to 100.97), compared with the medical masks group. The rate of ILI was also significantly higher in the cloth masks arm (RR=3.49 and 95% CI 1.00 to 12.17), compared with the control arm. Other outcomes were not statistically significant between the three arms.

Among the 68 laboratory-confirmed cases, 58 (85%) were due to rhinoviruses. Other viruses detected were hMPV (7 cases), influenza B (1 case), hMPV/rhinovirus co-infection (1 case) and influenza B/rhinovirus co-infection (1 case) (table 3). No influenza A or RSV infections were detected.

Compliance was significantly higher in the cloth mask arm (RR=2.41, 95% CI 2.01 to 2.88) and medical masks

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Table 1 Demographic and other characteristics by arm of randomisation

Variable	Medical mask (% and 95% CI) (n=580)	Cloth mask (% and 95% CI) (n=569)	Control (% and 95% CI) (n=458)
Gender (male)	112/580	133/569	112/458
	19.3 (16.2 to 22.8)	23.4 (20.0 to 27.1)	24.5 (20.6 to 28.7)
Age (mean)	36 (35.6 to 37.3)	35 (34.6 to 36.3)	36 (35.1 to 37.0)
Education (postgraduate)	114/580	99/569	78/458
	19.7 (16.5 to 23.1)	17.4 (14.3 to 20.8)	17.0 (13.7 to 20.8)
Smoker (current/ex)	78/580	79/569	66/458
	13.4 (10.8 to 16.5)	13.9 (11.1 to 17.0)	14.4 (11.3 to 18.0)
Pre-existing illness*	66/580	70/569	47/458
	11.4 (9.0 to 14.2)	12.3 (9.8 to 15.3)	10.3 (7.8 to 13.4)
Influenza vaccination (yes)	21/580	21/569	15/458
	3.6 (2.4 to 5.4)	3.7 (2.4 to 5.6)	3.3 (2.0 to 5.3)
Staff (doctors)	176/580	165/569	134/458
	30.3 (26.6 to 34.3)	29.0 (25.3 to 32.9)	29.3 (25.1 to 33.7)
Number of hand washings per day (geometric mean)†	14 (13.8 to 15.4)	11 (10.9 to 11.9)	12 (11.5 to 12.7)
Number of patients had contact with (median and range)‡	21 (0 to 540)	21 (0 to 661)	18 (3 to 199)

*Includes asthma, immunocompromised and others.
†'Hand wash' variable was created by taking average of the number of hand washes performed by a healthcare worker (HCW) over the trial period. The variable was log transformed for the multivariate analysis.
‡'Number of patients had contact with' variable was created by taking average of the number of patients in contact with a HCW over the trial period. Median and range is presented in the table.

arm (RR=2.40, 95% CI 2.00 to 2.87), compared with the control arm. Figure 3 shows the percentage of participants who were compliant in the three arms. A post-hoc analysis adjusted for compliance and other potential confounders showed that the rate of ILI was significantly higher in the cloth mask arm (RR=13.00, 95% CI 1.69 to 100.07), compared with the medical masks arm (table 4). There was no significant difference between the medical mask and control arms. Hand washing was significantly protective against laboratory-confirmed viral infection (RR=0.66, 95% CI 0.44 to 0.97).

In the control arm, 170/458 (37%) used medical masks, 38/458 (8%) used cloth masks, and 245/458 (53%) used a combination of both medical and cloth masks during the study period. The remaining 1% either reported using a N95 respirator (n=3) or did not use any masks (n=2).

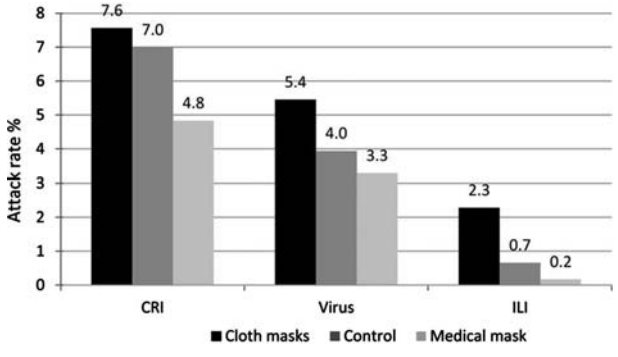


Figure 2 Outcomes in trial arms (CRI, clinical respiratory illness; ILI, influenza-like illness; Virus, laboratory-confirmed viruses).

Table 5 shows an additional analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). In the univariate analysis, all outcomes were significantly higher in the cloth mask group, compared with the medical masks group. After adjusting for other factors, ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) remained significantly higher in the cloth masks group compared with the medical masks group.

Table 6 compares the outcomes in the medical mask arm with two previously published trials.[8 9] This shows that while the rates of CRI were significantly higher in one of the previously published trials, the rates of laboratory-confirmed viruses were not significantly different between the three trials for medical mask use.

On average, HCWs worked for 25 days during the trial period and washed their cloth masks for 23/25 (92%) days. The most common approach to washing cloth masks was self-washing (456/569, 80%), followed by combined self-washing and hospital laundry (91/569, 16%), and only hospital laundry (22/569, 4%). Adverse events associated with facemask use were reported in 40.4% (227/562) of HCWs in the medical mask arm and 42.6% (242/568) in the cloth mask arm (p value 0.450). General discomfort (35.1%, 397/1130) and breathing problems (18.3%, 207/1130) were the most frequently reported adverse events.

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Table 2 Intention-to-treat analysis

	CRI N (%)	RR (95% CI)	ILI N (%)	RR (95% CI)	Laboratory-confirmed viruses N (%)	RR (95% CI)
Medical mask*	28/580 (4.83)	Ref	1/580 (0.17)	Ref	19/580 (3.28)	Ref
Cloth masks†	43/569 (7.56)	1.57 (0.99 to 2.48)	13/569 (2.28)	**13.25 (1.74 to 100.97)**	31/569 (5.45)	1.66 (0.95 to 2.91)
Control‡	32/458 (6.99)	1.45 (0.88 to 2.37)	3/458 (0.66)	3.80 (0.40 to 36.40)	18/458 (3.94)	1.20 (0.64 to 2.26)

Bold typeface indicates statistically significant.
*p Value from cluster adjusted χ^2 tests is 0.510 and intracluster correlation coefficients is 0.065.
†p Value from cluster adjusted χ^2 tests is 0.028 and intracluster correlation coefficients is 0.029.
‡p Value from cluster adjusted χ^2 tests is 0.561 and intracluster correlation coefficients is 0.068.
CRI, clinical respiratory illness; ILI, influenza-like illness; RR, relative risk.

Laboratory tests showed the penetration of particles through the cloth masks to be very high (97%) compared with medical masks (44%) (used in trial) and 3M 9320 N95 (<0.01%), 3M Vflex 9105 N95 (0.1%).

DISCUSSION

We have provided the first clinical efficacy data of cloth masks, which suggest HCWs should not use cloth masks as protection against respiratory infection. Cloth masks resulted in significantly higher rates of infection than medical masks, and also performed worse than the control arm. The controls were HCWs who observed standard practice, which involved mask use in the majority, albeit with lower compliance than in the intervention arms. The control HCWs also used medical masks more often than cloth masks. When we analysed all mask-wearers including controls, the higher risk of cloth masks was seen for laboratory-confirmed respiratory viral infection.

The trend for all outcomes showed the lowest rates of infection in the medical mask group and the highest rates in the cloth mask arm. The study design does not allow us to determine whether medical masks had efficacy or whether cloth masks were detrimental to HCWs by causing an increase in infection risk. Either possibility, or a combination of both effects, could explain our results. It is also unknown whether the rates of infection observed in the cloth mask arm are the same or higher than in HCWs who do not wear a mask, as almost all participants in the control arm used a mask. The physical properties of a cloth mask, reuse, the frequency and effectiveness of cleaning, and increased moisture retention, may potentially increase the infection risk for HCWs. The virus may survive on the surface of the facemasks,[29] and modelling studies have quantified the contamination levels of masks.[30] Self-contamination through repeated use and improper doffing is possible. For example, a contaminated cloth mask may transfer pathogen from the mask to the bare hands of the wearer. We also showed that filtration was extremely poor (almost 0%) for the cloth masks. Observations during SARS suggested double-masking and other practices increased the risk of infection because of moisture, liquid diffusion and pathogen retention.[31] These effects may be associated with cloth masks.

We have previously shown that N95 respirators provide superior efficacy to medical masks,[8 9] but need to be worn continuously in high-risk settings to protect HCWs.[9] Although efficacy for medical masks was not shown, efficacy of a magnitude that was too small to be detected is possible.[8 9] The magnitude of difference between cloth masks and medical masks in the current study, if explained by efficacy of medical masks alone, translates to an efficacy of 92% against ILI, which is possible, but not consistent with the lack of efficacy in the two previous RCTs.[8 9] Further, we found no significant difference in rates of virus isolation in medical mask users between the three trials, suggesting that the results of this study could be interpreted as partly being explained by a detrimental effect of cloth masks. This is further supported by the fact that the rate of virus isolation in the no-mask control group in the first Chinese RCT was 3.1%, which was not significantly different to the rates of virus isolation in the medical mask arms in any of the three trials including this one. Unlike the previous RCTs, circulating influenza and RSV were almost completely absent during this study,

Table 3 Type of virus isolated

Study arm	hMPV	Rhino	Influenza B virus	hMPV & rhino	Influenza B virus & rhino	Total
Medical masks arm	1	16	1	1	0	19
Cloth mask arm	4	26	0	0	1	31
Control arm	2	16	0	0	0	18
Total	7	58	1	1	1	68

hMPV, human metapneumovirus; Rhino, rhinoviruses.

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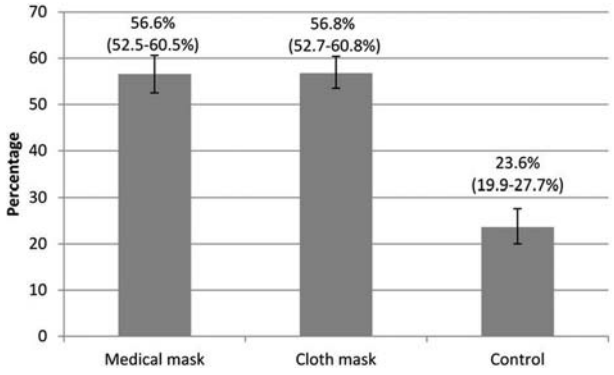


Figure 3 Compliance with the mask wearing—mask wearing more than 70% of working hours.

with rhinoviruses comprising 85% of isolated pathogens, which means the measured efficacy is against a different range of circulating respiratory pathogens. Influenza and RSV predominantly transmit through droplet and contact routes, while Rhinovirus transmits through multiple routes, including airborne and droplet routes.[32 33] The data also show that the clinical case definition of ILI is non-specific, and captures a range of pathogens other than influenza. The study suggests medical masks may be protective, but the magnitude of difference raises the possibility that cloth masks cause an increase in infection risk in HCWs. Further, the filtration of the medical mask used in this trial was poor, making extremely high efficacy of medical masks unlikely, particularly given the predominant pathogen was rhinovirus, which spreads by the airborne route. Given the obligations to HCW occupational health and safety, it is important to consider the potential risk of using cloth masks.

In many parts of the world, cloth masks and medical masks may be the only options available for HCWs. Cloth masks have been used in West Africa during the Ebola outbreak in 2014, due to shortages of PPE, (personal communication, M Jalloh). The use of cloth masks is recommended by some health organisations, with caveats.[34–36] In light of our study, and the obligation to ensure occupational health and safety of HCWs, cloth masks should not be recommended for HCWs, particularly during AGPs and in high-risk settings such as emergency, infectious/respiratory disease and intensive care wards. Infection control guidelines need to acknowledge the widespread real-world practice of cloth masks and should comprehensively address their use. In addition, other important infection control measure such as hand hygiene should not be compromised. We confirmed the protective effects of hand hygiene against laboratory-confirmed viral infection in this study, but mask type was an independent predictor of clinical illness, even adjusted for hand hygiene.

A limitation of this study is that we did not measure compliance with hand hygiene, and the results reflect self-reported compliance, which may be subject to recall or other types of bias. Another limitation of this study is the lack of a no-mask control group and the high use of masks in the controls, which makes interpretation of the results more difficult. In addition, the quality of paper and cloth masks varies widely around the world, so the results may not be generalisable to all settings. The lack of influenza and RSV (or asymptomatic infections) during the study is also a limitation, although the predominance of rhinovirus is informative about pathogens transmitted by the droplet and airborne routes in this setting. As in previous studies, exposure to infection outside the workplace could not be estimated, but we would assume it to be equally distributed between trial arms. The major strength of the randomised trial study design is in ensuring equal distribution of confounders and effect modifiers (such as exposure outside the workplace) between trial arms.

Cloth masks are used in resource-poor settings because of the reduced cost of a reusable option. Various types of cloth masks (made of cotton, gauze and other fibres) have been tested in vitro in the past and show lower filtration capacity compared with disposable masks.[7] The protection afforded by gauze masks increases with the fineness of the cloth and the number of layers,[37] indicating potential to develop a more effective cloth mask, for example, with finer weave, more layers and a better fit.

Cloth masks are generally retained long term and reused multiple times, with a variety of cleaning methods and widely different intervals of cleaning.[34] Further studies are required to determine if variations in frequency and type of cleaning affect the efficacy of cloth masks.

Table 4 Multivariable cluster-adjusted log-binomial model to calculate RR for study outcomes

	CRI RR (95% CI)	ILI RR (95% CI)	Laboratory-confirmed viruses RR (95% CI)
Medical masks arm	Ref	Ref	Ref
Cloth mask arm	1.56 (0.97 to 2.48)	**13.00 (1.69 to 100.07)**	1.54 (0.88 to 2.70)
Control arm	1.51 (0.90 to 2.52)	4.64 (0.47 to 45.97)	1.09 (0.57 to 2.09)
Male	0.67 (0.41 to 1.12)	1.03 (0.34 to 3.13)	0.65 (0.34 to 1.22)
Vaccination	0.83 (0.27 to 2.52)	1.74 (0.24 to 12.56)	1.27 (0.41 to 3.92)
Hand washing	0.91 (0.66 to 1.26)	0.94 (0.40 to 2.20)	**0.66 (0.44 to 0.97)**
Compliance	1.14 (0.77 to 1.69)	1.86 (0.67 to 5.21)	0.86 (0.53 to 1.40)

Bold typeface indicates statistically significant.
CRI, clinical respiratory illness; ILI, influenza-like illness; RR, relative risk.

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Table 5 Univariate and adjusted analysis comparing participants who used medical masks and cloth masks*

	Univariate RR (95% CI)	Adjusted RR (95% CI)
CRI		
Medical mask (35/750, 4.67%)	Ref	Ref
Cloth mask (46/607, 7.58%)	**1.62 (1.06 to 2.49)**	1.51 (0.97 to 2.32)
Male	0.60 (0.32 to 1.12)	0.58 (0.31 to 1.08)
Vaccination	0.66 (0.17 to 2.62)	0.68 (0.17 to 2.67)
Hand washing	0.81 (0.58 to 1.15)	0.84 (0.59 to 1.20)
Compliance	1.01 (1.00 to 1.03)	1.01 (1.00 to 1.02)
ILI		
Medical mask (2/750, 0.27%)	Ref	Ref
Cloth mask (13/607, 2.14%)	**8.03 (1.82 to 35.45)**	**6.64 (1.45 to 28.65)**
Male	0.95 (0.27 to 3.35)	0.92 (0.26 to 3.22)
Vaccination	1.87 (0.25 to 13.92)	1.97 (0.27 to 14.45)
Hand washing	0.56 (0.24 to 1.27)	0.61 (0.23 to 1.57)
Compliance	1.04 (1.01 to 1.08)	1.04 (1.00 to 1.08)
Laboratory-confirmed viruses		
Medical mask (22/750, 2.93%)	Ref	Ref
Cloth mask (34/607, 5.60%)	**1.91 (1.13 to 3.23)**	**1.72 (1.01 to 2.94)**
Male	0.64 (0.30 to 1.33)	0.61 (0.29 to 1.27)
Vaccination	0.97 (0.24 to 3.86)	1.03 (0.26 to 4.08)
Hand washing	0.61 (0.41 to 0.93)	0.65 (0.42 to 1.00)
Compliance	1.00 (0.99 to 1.02)	1.0 (0.99 to 1.02)

Bold typeface indicates statistically significant.
*The majority (456/458) of HCWs in the control arm used a mask. Controls who exclusively used a medical mask were categorised and analysed with the medical mask arm participants; and controls who exclusively wore a cloth mask were categorised and analysed with the cloth mask arm.
CRI, clinical respiratory illness; HCWs, healthcare workers; ILI, influenza-like illness; RR, relative risk.

Table 6 A comparison of outcome data for the medical mask arm with medical mask outcomes in previously published RCTs

	CRI N (%)	RR (95% CI)	ILI N (%)	RR (95% CI)	Laboratory-confirmed viruses N (%)	RR (95% CI)
Vietnam trial	28/580 (4.83)	Ref	1/580 (0.17)	Ref	19/580 (3.28)	Ref
Published RCT China 1[8]	33/492 (6.70)	1.40 (0.85 to 2.26)	3/492 (0.61)	3.53 (0.37 to 33.89)	13/492 (2.64)	0.80 (0.40 to 1.62)
Published RCT China 2[9]	98/572 (17.13)	**3.54 (2.37 to 5.31)**	4/572 (0.70)	4.06 (0.45 to 36.18)	19/572 (3.32)	1.01 (0.54 to 1.89)

Bold typeface indicates statistically significant.
CRI, Clinical respiratory illness; ILI, influenza-like illness; RCT, randomised clinical trial; RR, relative risk.

Pandemics and emerging infections are more likely to arise in low-income or middle-income settings than in wealthy countries. In the interests of global public health, adequate attention should be paid to cloth mask use in such settings. The data from this study provide some reassurance about medical masks, and are the first data to show potential clinical efficacy of medical masks. Medical masks are used to provide protection against droplet spread, splash and spray of blood and body fluids. Medical masks or respirators are recommended by different organisations to prevent transmission of Ebola virus, yet shortages of PPE may result in HCWs being forced to use cloth masks.[38–40] In the interest of providing safe, low-cost options in low income countries, there is scope for research into more effectively designed cloth masks, but until such research is carried out, cloth masks should not be recommended. We also recommend that infection control guidelines be updated about cloth mask use to protect the occupational health and safety of HCWs.

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grant; however they were not involved in study design, data collection or analysis. The 3M products were not used in this study.

Contributors CRM was the lead investigator, and responsible for the conception and design of the trial, obtaining the grant funding, overseeing the whole study, analysing the data and writing of the report. HS contributed to overseeing the study, staff training, form/database development and drafting of the manuscript. TCD was responsible for overseeing the study, database management, recruitment, training and revision of the manuscript. NTH was responsible for the implementation of research and revision of the manuscript. PTN was responsible for the laboratory testing in Vietnam. AAC contributed to the statistical analysis and drafting of the manuscript. BR was responsible for the statistical analysis and revision of the manuscript. DED contributed to the laboratory technical assistance and revision of the manuscript. QW assisted in comparing the rates of infection from two previous RCTs conducted in China and revision of the manuscript.

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Competing interests CRM has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator-driven research. 3M has also contributed masks and respirators for investigator-driven clinical trials. CRM has received research grants and laboratory testing as in-kind support from Pfizer, GSK and Bio-CSL for investigator-driven research. HS had a NHMRC Australian-based Public Health Training Fellowship at the time of the study (1012631). She has also received funding from vaccine manufacturers GSK, bio-CSL and Sanofi Pasteur for investigator-driven research and presentations. AAC used filtration testing of masks for his PhD thesis conducted by 3M Australia.

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Research Square

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Corona children studies "Co-Ki": First results of a Germany-wide registry on mouth and nose covering (mask) in children

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EDITORIAL NOTE:

This study is based on a survey regarding the adverse effects of mask wearing in children. **Due to multiple limitations, this study cannot demonstrate a causal relationship between mask wearing and the reported adverse effects in children.** Most of the respondents were parents, and the survey was distributed preferentially in social media forums that, according to the authors, “criticize the

government's corona protection measures in principle". The limitations of the study include sampling bias, reporting bias, and confounding bias as well as lack of a control group. The use of masks, together with other precautionary measures, significantly reduces the spread of COVID-19 and is considered safe for children over the age of two years old.

Abstract

Background: Narratives about complaints in children and adolescents caused by wearing a mask are accumulating. There is, to date, no registry for side effects of masks.

Methods: At the University of Witten/Herdecke an online registry has been set up where parents, doctors, pedagogues and others can enter their observations. On 20.10.2020, 363 doctors were asked to make entries and to make parents and teachers aware of the registry.

Results: By 26.10.2020 the registry had been used by 20,353 people. In this publication we report the results from the parents, who entered data on a total of 25,930 children. The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%).

Discussion: This world's first registry for recording the effects of wearing masks in children is dedicated to a new research question. The frequency of the registry's use and the spectrum of symptoms registryed indicate the importance of the topic and call for representative surveys, randomized controlled trials with various masks and a renewed risk-benefit assessment for the vulnerable group of children: adults need to collecticely reflect the circumstances under which they would be willing to take a residual risk upon themselves in favor of enabling children to have a higher quality of life without having to wear a mask.

Background And Questions

The question of a certificate of exemption from the obligation to wear a mouth and nose cover (hereinafter referred to as "mask") is a new phenomenon in pediatric practice. Parents, educators and doctors are increasingly reporting problems and health complaints in children in connection with wearing a mask. There are no manufacturer-independent studies on the use of masks for children and adolescents that are certified as medical products for occupational safety in professional applications. In addition, due to the unknown materials used, there are no findings on the potential protective effects or side effects of the often home-made "everyday masks" worn by the majority of children. In view of the ongoing measures to contain the COVID-19 pandemic, and in particular the varying obligations for children and adolescents to wear masks in school over a longer period of time, there is an urgent need for research.

Study Design And Research Methods

Based on the registry of adverse drug reactions at the Paul Ehrlich Institute (www.nebenwirkungen.pei.de), an online registry has been set up where parents, doctors, educators and others can enter their observations on the effects of wearing a mask on children and adolescents. On 20.10.2020, 363 doctors on the Co-Ki study distribution list were informed about the possibility of making entries there themselves and to communicate the registry to their patients and colleagues. The registry and the questionnaire can

be found online at www.co-ki-masken.de (Figure in Online Supplement S1) as part of the Co-Ki study complex (figure in Online Supplement S2). The data entered in the registry includes information regarding the role of the registrant, demographic data, previous illnesses, situation and duration of mask wearing, type of mask, existence of complaints from the child about an impairment via the mask, symptoms, behavioral problems, personal attitude to corona protection measures of the government and the possibility to leave name and e-mail address. A positive ethics vote from the University of Witten/Herdecke was obtained.

Results

By the evening of 26.10.2020, one week after the registry went online, 20,353 people had already taken part in the survey, with 48,657 entries. Of the survey participants, 17,854 (87.7%) were parents, 736 (3.6%) were teachers, 352 (1.7%) were doctors, and 1,411 (6.9%) were "others" (Figure S3 in the Online Supplement shows the analysis set of the entries of the first week). This article reports on the 17,854 entering parents with a total of 25,930 children and youth. The data of the entering doctors, teachers and other roles are published separately.

Of the 17,854 entering parents, 6,877 (38.5%) stated that they had a university degree (bachelor, master, master's degree, diploma, state examination, doctorate), 671 (3.8%) had a master craftsman, 3,704 (20.7%) had completed an apprenticeship and 3,040 (17.0%) had a high school diploma (general qualification for university entrance) or subject-related higher education entrance qualification or technical college entrance qualification. 2,509 (14.1%) of the participants stated that their highest educational level was a secondary school leaving certificate (In Germany: *Mittlere Reife, Fachoberschulereife* or similar), 327 participants (1.8%) had a secondary modern school leaving certificate, and 31 participants (0.2%) stated that they had no school or training qualification. The remaining did not enter an education. The participation of contributors per state corresponds to the distribution of the population (Figure 1).

The demographic situation of the children and previous illnesses among the children from the parents' point of view are shown in Table 1: the genders are equally represented with a slight trend towards boys; and 55.6% of the children were between 7-12 years of age. In 79.4% of the children it was stated that they had no previous illnesses, 5.9% had asthma and 1.8% had another lung disease. Furthermore, there was the possibility of free text entries on other previous illnesses, which was used by 8.6%.

Table 1: *Demography and pre-existing conditions of children*

		Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
	Age group n (%)	25 926* (100%)	4 002 (15.4%)	14 407 (55.6%)	7 517 (29.0%)	
Gender	Male	12 589 (48.5%)	1 880 (47.0%)	7 027 (48.8%)	3 682 (49.0%)	p = 0.0002
	Female	12 248 (47.2%)	1 899 (47.5%)	6 790 (47.1%)	3 559 (47.3%)	
	Divers	62 (0.2%)	13 (0.3%)	32 (0.2%)	17 (0.2%)	
	Without specification	1 031* (4.0%)	210 (5.2%)	558 (3.9%)	259 (3.4%)	
Pre-existing conditions	No previous illnesses	20 586 (79.4%)	3 400 (85.0%)	11 606 (80.6%)	5 580 (74.2%)	p < 0.0001
	Asthma	1 541 (5.9%)	123 (3.1%)	801 (5.6%)	617 (8.2%)	
	Other lung diseases	458 (1.8%)	50 (1.2%)	251 (1.7%)	157 (2.1%)	
	Other previous illnesses (free text input)	2 232 (8.6%)	233 (5.8%)	1 178 (8.2%)	821 (10.9%)	
	Not specified	1 110 (4.3%)	196 (4.9%)	571 (4.0%)	343 (4.5%)	
* for four children the age specification is missing.						

Table 2 presents the situation of wearing masks with the children and whether any form of impairment from parents view was present. When asked about the situations in which the children wear a mask, 81.1% of the survey participants answered that the child wears the mask at school outside of class, i.e. during breaks and in the corridors, 48.6% also stated that the child also wears the mask in class at the seat during lessons. 68.5% of the children recorded wearing the mask in stores and 39% on the way to school 4.6% of the children never wear a mask.A mask exemption certificate had been granted to 6.7% of the registered children and youth. The average length of time the mask was worn varies greatly with age; it averaged 4.5 hours per day, and was much higher, especially among youth (13-18 years), averaging 6 hours (Table 2). In 16 913 children (65.2%) it was reported that fabric masks were worn, followed by surgical masks. FPP masks are hardly worn by children.

Regarding the question as to whether children themselves complain about impairments caused by wearing the mask, 67.7% of the respondents answered yes for their children; 26% answered no. The question as to whether the respondents themselves observed an impairment of the child by wearing the mask was answered yes in 66.1% (Table 2). The assessment of the health impairment is shown in Table 3. Four percent had no opinion when asked about their personal attitude to the government's corona protection measures, 11.7% of the participants thought that the measures should be more stringent,

11.0% considered the current measures appropriate and good and 41.7% were in favor of milder measures. A further 31.6% expressed a different opinion than the setting option specified in the selection option. In general, they described the policy measures as inappropriate, incomprehensible and undifferentiated.

Table 2: *Wearing situation of the mask and impairment*

	Wearing situation (Total Age group)		Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)	Wearing situation (Total Age group)
	Wearing time in minutes (IQR)**		270 (120;390)	90 (30;240)	240 (120;370)	360 (240; 450)	p < 0.0001
Type of Mask	Fabric mask		16 913 (65.2%)	2 501 (62,5%)	10 311 (71,6%)	4 101 (54,6%)	p < 0.0001
	Surgical Mask		5 542 (21.4%)	271 (6,8%)	2 619 (18,2%)	2 652 (35,3%)	
	FFP mask		536 (2.1%)	51 (1,3%)	273 (1,9%)	212 (2,8%)	
	Not specified		2 935 (11.3%)	1 179 (29.5%)	1 204 (8.4%)	552 (7.3%)	
Impairments	Impairment by mask according to child	Yes	17 550 (67.7%)	1 607 (40.2%)	10 244 (71.1%)	5 699 (75.8%)	p < 0.0001
		No	6 801 (26.2%)	1 431 (35.8%)	3 744 (26.0%)	1 626 (21.6%)	p < 0.0001
		Not specified	1.575 (6.1%)	964 (24.1%)	419 (2.9%)	192 (2.6%)	p < 0.0001
	Have you observed any adverse effects of a mask on your child?	Yes	17.125 (66.1%)	1.640 (41.0%)	9.980 (69.3%)	5.505 (73.2%)	p < 0.0001
		No	6.841 (26.4%)	1.367 (34,2%)	3.810 (26.4%)	1.664 (22.1%)	p < 0.0001
		Not specified	1.960 (7.6%)	995 (24.9%)	617 (4.3%)	348 (4.6%)	p < 0.0001
The child must wear a mask...	on the way to school		10.105 (39.0%)	668 (16.7%)	5.704 (39.6%)	3.733 (49.7%)	p < 0.0001
	in school outside the classroom (corridor, playground)		20.124 (81.1%)	1.834 (45.8%)	12.682 (88.0%)	5.608 (86.6%)	p < 0.0001
	at school in class		12 593 (48.6%)	713 (17.8%)	6 880 (47.8%)	5 000 (66.5%)	p < 0.0001
	in kindergarten		361 (1.4%)	295 (7.4%)	53 (0.4%)	13 (0.2%)	p < 0.0001
	in stores		17 763 (68.5%)	2 060 (51.5%)	10 237 (71.1%)	5 466 (72.7%)	p < 0.0001
	never		1.198 (4.6%)	933 (24.8%)	155 (1.1%)	50 (0.7%)	p < 0.0001
	has a certificate of mask release		1.732 (6.7%)	144 (3.6%)	1.045 (7.3%)	543 (7.2%)	p < 0.0001
	** IQR (interquartile range) n = 4427 (17.1%) missing.						

The frequency distribution of the above-mentioned side effects associated with masks is similar in the different age groups, with headaches, concentration difficulties, discomfort, learning difficulties and drowsiness / tiredness being the most common (Table 3). Other complaints were described in the free text. First of all: 269 entries on worsened skin, especially increased pimples, rashes and allergic phenomena around the mouth area up to fungal diseases in and around the mouth. There were 151 entries on nosebleeds, 122 entries on school displeasure up to school anxiety / refusal to attend school, 64 entries on increased sweating, 52 entries on pressure points and wounds behind the ears, 46 entries on sore or cracked and partly bloody lips, 31 entries on increased migraine attacks in frequency and severity, 23 entries on impaired vision, 13 entries on aphthae. Table 3 shows the classification of a possible health impairment of the children, as assessed by the parents. Table 4 shows further behavioral problems in the children, above all with 60.4% an increased irritability, 49.3% less happy children, 44% children who do not want to go to school anymore, in each case children in the age category 7-12 years are affected most. In 25.3% of the children it was stated that they have developed new anxieties (Table 4). In addition, 2,672 entries in this question alone mention explicit specifications of anxiety or the reappearance of several anxieties in free text entries. In addition to a general fear of the future, the fear of suffocation even with a mask, as well as the fear of death of relatives through corona, is most frequently represented. In addition, there is the fear of stigmatization both by wearing and not wearing a mask in the social environment. Many parents also report nightmares and anxiety disorders that relate to masked people whose facial expressions and identity are not recognizable to the children. A detailed evaluation and publication of the free text entries is planned.

Table 3: *Symptoms in children in parental report*

	Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
Headaches	13.811 (53.3%)	960 (24.0%)	7.863 (54.6%)	4.988 (66.4%)	p < 0.0001
Concentration difficulties	12.824 (49.5%)	961 (24.0%)	7.313 (50.8%)	4.550 (60.5%)	p < 0.0001
Discomfort	10.907 (42.1%)	1.040 (26.0%)	6.369 (44.2%)	3.498 (46.5%)	p < 0.0001
Impairment in learning	9.845 (38.0%)	621 (15.5%)	5.604 (38.9%)	3.620 (48.2%)	p < 0.0001
drowsiness / tiredness	9.460 (36.5%)	729 (18.2%)	5.163 (35.8%)	3.568 (47.5%)	p < 0.0001
Tightness under the mask	9.232 (35.6%)	968 (24.2%)	5.427 (37.7%)	2.837 (37.7%)	p < 0.0001
Feeling of shortness of breath	7.700 (29.7%)	677 (16.9%)	4.440 (30.8%)	2.583 (34.4%)	p < 0.0001
Dizziness	6.848 (26.4%)	427 (10.7%)	3.814 (26.5%)	2.607 (34.7%)	p < 0.0001
Dry neck	5.883 (22.7%)	516 (12.9%)	3.313 (23.0%)	2.054 (27.3%)	p < 0.0001
Syncope	5.365 (20.7%)	410 (10.2%)	2.881 (20.0%)	2.074 (27.6%)	p < 0.0001
Unwillingness to move, unwillingness to play	4.629 (17.9%)	456 (11.4%)	2.824 (19.6%)	1.349 (17.9%)	p < 0.0001
Itching in the nose	4.431 (17.1%)	513 (12.8%)	2550 (17.7%)	1.368 (18.2%)	p < 0.0001
Nausea	4.292 (16.6%)	310 (7.7%)	2.544 (17.7%)	1.438 (19.1%)	p < 0.0001
Feeling of weakness	3.820 (14.7%)	300 (7.5%)	2.020 (14.0%)	1.500 (20.0%)	p < 0.0001
Abdominal pain	3.492 (13.5%)	397 (9.9%)	2.292 (15.9%)	803 (10.7%)	p < 0.0001
Accelerated respiration	3.170 (12.2%)	417 (10.4%)	1.796 (12.5%)	957 (12.7%)	p < 0.0001
Disease feeling	2.503 (9.7%)	205 (5.1%)	1.328 (9.2%)	970 (12.9%)	p < 0.0001
Tightness in the chest	2.074 (8.0%)	161 (4.0%)	1.122 (7.8%)	791 (10.5%)	p < 0.0001
Flickering eyes	2.027 (7.8%)	149 (3.7%)	1.047 (7.3%)	831 (11.1%)	p < 0.0001
Loss of appetite	1.812 (%)	182 (4.5%)	1.099 (7.6%)	531 (7.1%)	p < 0.0001
tachycardia, stumbling heart stings	1.459 (5.6%)	118 (2.9%)	766 (5.3%)	575 (7.6%)	p < 0.0001
Noise in the ears	1.179	107	632	440	p < 0.0001

	(4.5%)	(2.7%)	(4.4%)	(5.9%)	
Short-term impairment of consciousness / fainting spells	565 (2.2%)	39 (1.0%)	274 (1.9%)	252 (3.4%)	p < 0.0001
Vomiting	480 (1.9%)	40 (1.0%)	296 (2.1%)	144 (1.9%)	p < 0.0001

Table 4: *Further behavior of the children, changed by wearing the mask, from parents' point of view*

	Total age group	Age group 0-6 years	Age group 7-12 years	Age group 13-18 years	Test for difference
The child is more often irritated than usual	11 364 (60.4%)	1 041 (40.0%)	6 566 (62.1%)	3 757 (66.5%)	p < 0.0001
The child is less cheerful	9 286 (49.3%)	959 (36.9%)	5 640 (53.3%)	2 687 (47.6%)	p < 0.0001
The child no longer wants to go to school/kindergarten	8 280 (44.0%)	824 (31.7%)	5 168 (48.9%)	2 288 (40.5%)	p < 0.0001
The child is more restless than usual	5 494 (29.2%)	773 (29.7%)	3 515 (33.2%)	1 206 (21.4%)	p < 0.0001
The child sleeps worse than usual	5 849 (31.1%)	633 (24.3%)	3 507 (33.2%)	1 709 (30.3%)	p < 0.0001
No other abnormalities	7 103 (27.4%)	1 400 (35.0%)	3 834 (26.6%)	1 869 (24.9%)	p < 0.0001
The child has developed new fears	4 762 (25.3%)	713 (27.4%)	2 935 (27.8%)	1 114 (19.7%)	p < 0.0001
The child sleeps more than usual	4 710 (25.0%)	319 (12.3%)	2 183 (20.6%)	2 208 (39.1%)	p < 0.0001
The child plays less	2 912 (15.5%)	400 (15.4%)	1.998 (18.9%)	514 (9.1%)	p < 0.0001
The child has a greater urge to move than usual	1 615 (8.6%)	253 (9.7%)	1.124 (10.6%)	238 (4.2%)	p < 0.0001

The optional possibility to leave name and e-mail address for possible questions was used by 27.1% (5 513) of the participants. A validation performed with the software *Bouncer* proved 4 710 (85.4%) of the mail addresses to be reachable.

Discussion

The explosiveness of the topic and the need for communication of the interviewees are made clear by the "viral" use of the registry within a few days after publication, leading within one week to 25 930 parental

entries for affected children in Germany (approx. 0.2% of the population). The fact that 23.1% of the participating parents used the optional possibility of leaving their name and valid e-mail address for possible questions shows the seriousness of the entries. According to the status report of the Robert Koch Institute (RKI) of October 25, 2020, there were a total of 429 181 reported infections in Germany, with an increasing trend, of which 8 764 (3.6% of the reported) were under 10 years of age and 16 548 (6.7% of the reported) were between 10 and 19 years of age [1]. This is less than the number of children reported in this registry within one week. It is still unclear whether children are less likely than adults to be infected with SARS-CoV-2 and transmit the infection to adults in such a way that the latter become seriously ill [2-5]. However, it has been shown that the majority of infected children, especially up to the age of 10, develop no or only mild symptoms [6-9]. In rare cases, children up to the age of 10 years develop severe courses of the disease. The one child and two adolescents who have died of COVID-19 (as of 25.10.2020, not yet described in detail by the RKI) had chronic pre-existing conditions [10, 11]. In Europe, children under 10 years of age rarely seem to be spreaders in this infection process, although data from India, a country with a different hygiene background, do ascribe a certain transmission role to children (although without differentiation between 5-year-olds and 17-year-olds) [12]. A Scottish study of 300 000 households found that the more children in the household, the less likely adults are to be hospitalized with COVID-19 [13]. A recent study suggests that children emit less aerosol when singing and talking than adults [14].

Based on our data, it can be said that the effects of compulsory masks on the quality of life and presumably also on the health of individual children should not be ignored by politics and society. While many children tolerate the mask relatively easily, there are clearly children who cannot be expected to wear a mask in good conscience, especially when the effectiveness of the mouth and nose protection in smaller children is questionable. Parents, teachers and doctors report stigmatization, exclusion and aggressive behavior towards children who do not wear a mask for psychological or medical reasons. Inappropriate use of masks, which tends to be the case in children, may increase the risk of pathogen spread and transmission through the increased tendency to put their fingers in their face, and may thus be worse than not wearing a mask at all in some cases [15]. Looking at the symptom spectrum of the complaints, 66.1% of the interviewees show a clear and broadly diversified burden of complaints, both in the physical (rashes, headaches, etc.), as well as in the mental (fears, irritability, etc.) and intellectual (concentration disorders) areas in the children of the interviewees. In addition to acute health impairments with, in individual cases, significantly experienced health impairments, the long-term effects on the various developmental areas that go beyond well-being, such as language, play, learning, communication, sensomotoric development and empathy of children are difficult to assess. The often mentioned headaches and concentration difficulties should be seriously explored in their importance for cognitive development. It is noticeable that the distribution of complaints fits well with the age of the children (Tables 3 and 4), which supports the plausibility of parental input.

Direct effects of indoor CO_2 concentration on cognitive functions have been demonstrated [16]. This is not directly transferable to the air breathed under the masks, but increased CO_2 concentrations could occur under some mask types. This may be particularly true in small children with large fabric masks,

which sometimes have a thicker material and which were used particularly frequently by the children in the registry (65.2%). Families are currently free to choose their children's mask type according to the thickness of the material and thus there is still a margin between breathable and multi-layer, rather airtight models, yet the problem remains that parents, regardless of whether or not they themselves approve of the corona protection measures, can overburden their children through ignorance or fear of infection by using masks that are inappropriate for their child. A benefit-risk analysis is therefore called for. However, this is complicated by the fact that the study situation is extremely weak both in terms of benefits and risks. Both the calculations of a benefit from masks and almost all studies of the risks of masks are based on adults. It must also be assumed that the SARS-CoV-2 protection standards for schools, such as those of the German statutory accident insurance, are not known everywhere [17]. In particular, they contain recommendations on recovery times when wearing masks for schoolchildren with short breaks and, at the latest after three hours of wearing, a subsequent recovery time of 15-30 minutes [17].

Limitation of the results: Even though the rapid development of the registry and the high number of participants within a few days is impressive, this first evaluation of the Co-Ki mask registry has limitations. The fact that 38.5% of the participants indicated a university degree could be an indication that the registry was not equally accessible to all groups of people as an online version and due to its complexity. All online registries have this problem. A reporting bias (also with regard to the preferential documentation of particularly severely affected children) cannot be ruled out. In addition, the link to the registry was also found in social media forums, among other places, which criticize the government's corona protection measures in principle, which is partly reflected in the results of the query on attitudes to the government's corona protection measures. At the same time, other participants reported that their children had no complaints.

Both the gender distribution and the distribution of participants according to federal states, as well as the distribution of symptoms according to age, speak in favor of the data being representative for the German population of children. With a few exceptions, the data sets in the free text entries reflect differentiated, sincere parents and, taken as a whole, provide a balanced overall picture with a plausible spectrum of symptoms and a comprehensive description of the impairments observed in children in connection with the mask. The hundreds of incoming e-mails to the study initiators, including questions about the existence of the registry, specification and completion of the entries made by participants, detailed case descriptions and suggestions for further research, are a further indication of the high relevance of the topic and the honesty with which many participants address the question. Naturally, an openly accessible registry can never provide a medical counter-validation of all submissions. The number of entries in the registry is continuing to increase daily. The registry questionnaire will be expanded and validated on the basis of the new symptoms entered by parents in the free text information.

Conclusion

Many children are subject to great challenges and families try to master these as best they can. While the proportion of people tested positive for SARS-CoV-2 and also the number of intensive care patients in

Germany is high in many places, we report here on a relatively small, unrepresentative problem: several thousand children who seem to suffer from wearing the mask or who may experience health problems from the mask. Our study provides the basis for a representative survey on which a precise benefit-risk analysis of mask wearing in children can be built.

" Conclusion For The Practice"

- A certain percentage of children and adolescents have non-negligible complaints when wearing the mask. These children should not be stigmatized.

- This worldwide first registry on side effects of the mask reflects the spectrum of symptoms in children and adolescents.

- A precise benefit-risk analysis is urgently required. The occurrence of reported side effects in children due to wearing the masks must be taken seriously and requires a precise clarification of the accompanying health circumstances, the situation of wearing the mask (duration, breaks and mask type) and the school situation.

- Furthermore, all parents, doctors, pedagogues and others are invited to participate in www.co-ki-masken.de to document their observations on effects that occur when wearing the mask. The registry will also be available in English from 15.12.2020.

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Supplemental Information

Supplemental Information is not available with this version.

Figures



Figure 1

Distribution of participants by federal state. First row: Name of the federal state, second line: Parents in the registry, as absolute and relative frequency (as of 26.10.2020). Third line: Population in Germany in

comparison, as absolute and relative frequency. The distribution of contributors corresponds approximately to the respective share of the population.

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ORIGINAL RESEARCH ARTICLE Open Access

The effect of adenoid hypertrophy on maxillofacial development: an objective photographic analysis

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Abstract

Background: Deformity in the dental arc and facial skeleton by adenoid hypertrophy due to chronic mouth breathing is a well-known process. Most of the related studies have been based on cephalometric analyses. The aim of this study is to detect the presence of skeletal deformities on the soft tissue by analyzing distances and angles on photographs.

Methods: Ninety-seven children having between 25 and 100 % of adenoids, ages 4–12 years (48 boys, 49 girls), and 90 cases having 0–25 % adenoid tissue, ages 4–12 years (54 boys, 36 girls), were studied by clinical history, physical examination (including endoscopy), and standardized clinical photographs. The children and parents were asked if any of the following were present in the children: snoring, sleep apnea, daytime sleepiness, poor school performance, mouth breathing during sleep, smoking parents, and restlessness during sleep.

Results: The assessment of linear and angular measurements on the clinical photographs showed, in the group having thicker adenoids compared with controls, a statistically significant increase in the distance between nasion and tip and nasion and subnasale and in the angle between Frankfort horizontal plane-gnathion-angulus mandible; there was also a statistically significant decrease in the distance between endocanthion and exocanthion and the angles between tragion-angulus mandible and gnathion and between nasion-angulus mandible and gnathion.

Conclusions: The analyses showed a significant increase in the anterior face height and increase in the angle between Frankfort horizontal plane-gnathion-angulus mandible and a retropositioned and posterior-rotated mandible due to thicker adenoids.

Trial registration: 2010/140 Date: 04 January 2010.

Keywords: Adenoid hypertrophy, Mouth breathing, Photographic analysis, Facial morphology

Background

Adenoid hypertrophy is the most common pathology causing upper airway obstruction in childhood [1]. Adenoid hypertrophy causes upper airway obstruction and may affect both dental and maxillofacial development [2]. Nasal breathing is partially obstructed due to large adenoids, and this leads to mouth breathing and typical "adenoid face" [3]. Adenoid face is characterized as having upper lip incompetence, a retropositioned hyoid bone, a narrow upper dental arch, retropositioned mandibular incisors, increased anterior face height, a narrow or "V"-shaped maxillary arch, increased mandibular plane angle, and a posterior-rotated mandible in comparison with healthy controls [2]. The positioning of the tongue is downward due to mouth breathing, and the balance between the tongue and mandible is different in comparison with healthy children. This leads to the lower positioning of the mandible. In this situation, a number of postural changes can occur, such as open mandible posture and extension of the head. Intraorally, a narrow maxillary arch, high palatal arch, and class 2 or 3 dental malocclusion may be seen. Cephalometrically, a large anterior face height and increased mandibular

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plane angle can be noted [3]. Timing of the removal of excessive adenoid tissue is important for the recovery of the craniofacial growth pattern [2]. After adenoidectomy and facilitation of nasal breathing, accelerated mandibular growth and closure of the mandibular plane angle have been reported. Nasal airway obstruction may lead to some problems, such as night discomfort, behavioral issues, poor school performance, and daytime sleepiness [3].

Methods

Ethics consent and permissions

We studied 97 children having between 25 and 100 % of adenoids, ages 4–12 (48 boys, 49 girls), and 90 cases having 0–25 % adenoid tissue, ages 4–12 (54 boys, 36 girls), who consulted the Department of Otolaryngology Head and Neck Surgery, Inonu University, between November 2010 and March 2011. We started the study after approval of Human Ethics Committee of Inonu University (2010).

After defining the process in detail to the parents, the children (whose parents approved) were included in the study. A detailed, complete otolaryngological examination was performed. The information of all children was registered by a previously prepared anamnesis form.

The exclusion criteria

The exclusion criteria were maxillofacial surgery, dysmorphism and craniofacial syndromes, septal deviation, chronic illnesses, decongestant use, upper airway obstruction causes other than adenoid hypertrophy, acute upper airway infection, thumb sucking, and tonsillar hypertrophy.

Patients, clinical and instrumental evaluations

The children having 0–25 % adenoids were declared as Group 1 (controls: 90 children). The children having between 25 and 100 % of adenoids (97 children) were declared as Group 2 and were divided into three subgroups according to the degree of their adenoid tissue obstruction in choana. Group 2a: 25–50 % adenoid tissue (50 children), Group 2b: 50–75 % adenoid tissue (35 children), and Group 2c: 75–100 % adenoid tissue (12 children). Flexible fiberoptic nasopharyngolaryngoscopy (FNFL) was used to evaluate the degree of obstruction of the adenoid tissue for each child. We saved all flexible fiberoptic nasopharyngolaryngoscopic images of all children (Fig. 1).

Both the children and their parents were asked if any of the following were present in the children: snoring, sleep apnea, daytime sleepiness, poor school performance, mouth breathing during sleep, smoking parents, and restlessness during sleep. We compared whether the children had these complaints, and each complaint was scored by the visual analog scale (VAS). We included the children having these complaints lasting at least for 6 months. The average period was 1.06 years (6 months to 4 years).

Photographs of Groups 1 and 2 were taken using a point-and-shoot or SLR-like digital camera with a 90-mm lens (Fujifilm finepix s2500 HD 12.2 megapixels Fujinon 18× optical zoom lens) for standardized facial plastic measurements from a 150-cm distance. Children were instructed to position their heads in a natural head position as much as possible. The lateral photographs were taken with the Frankfort horizontal plane parallel to the ground. In both photographs, the ruler was held in equal distance between the facial plane and photograph machine. Anterior and lateral photographs of children in both groups were taken with a ruler, and maxillofacial measurements were performed on the standardized clinical photographs. Data of both groups were registered and compared. The Scion Image (Beta 4.02 Win version; Scion Corporation, Frederick, MD, USA.) software program was used for measurements of the distances between reference points by referring to the 1 cm shown on the ruler in anteroposterior photographs. The measurements of the angles between points given were performed on the lateral view photographs. This method was previously used in two facial analysis studies performed in our clinic [4, 5].

The reference points

The reference points used for the measurements included the vertex (v; the top of the head), trichion (tr; midpoint of the anterior hairline), glabella (g; the most forward-projecting point of the forehead in the midline of the supraorbital ridges), nasion (n; midpoint of the nasofrontal suture), tip (t: the junction of the inferior margin of the nasal ridge and the columella), subnasale (sn; the middle point of the inferior border of the nasal columella), right and left ala nasi (ala; the most lateral point of nasal alar wall), gnathion (gn; in the midline, the lowest point on the lower border of the chin), endocanthion (en; the point at which the inner ends of the upper and the lower eyelid meet), exocanthion (ex; the point at which the outer ends of the upper and the lower eyelid meet), zygion (zy; zygomatic process), angulus oris (an: the lateral limit of the oral fissure), stomion (st: the median point of the oral slit when the lips are closed), superaurale (sa; top of the auricular helix), subaurale (sba; the lowest point of the ear), pogonion (pg: the most forward-projecting point on the anterior surface of the chin), infraorbitale (io: the point below the orbit; it is a guide point for the Frankfort horizontal plane), angulus of mandible (anm: the angle formed by the

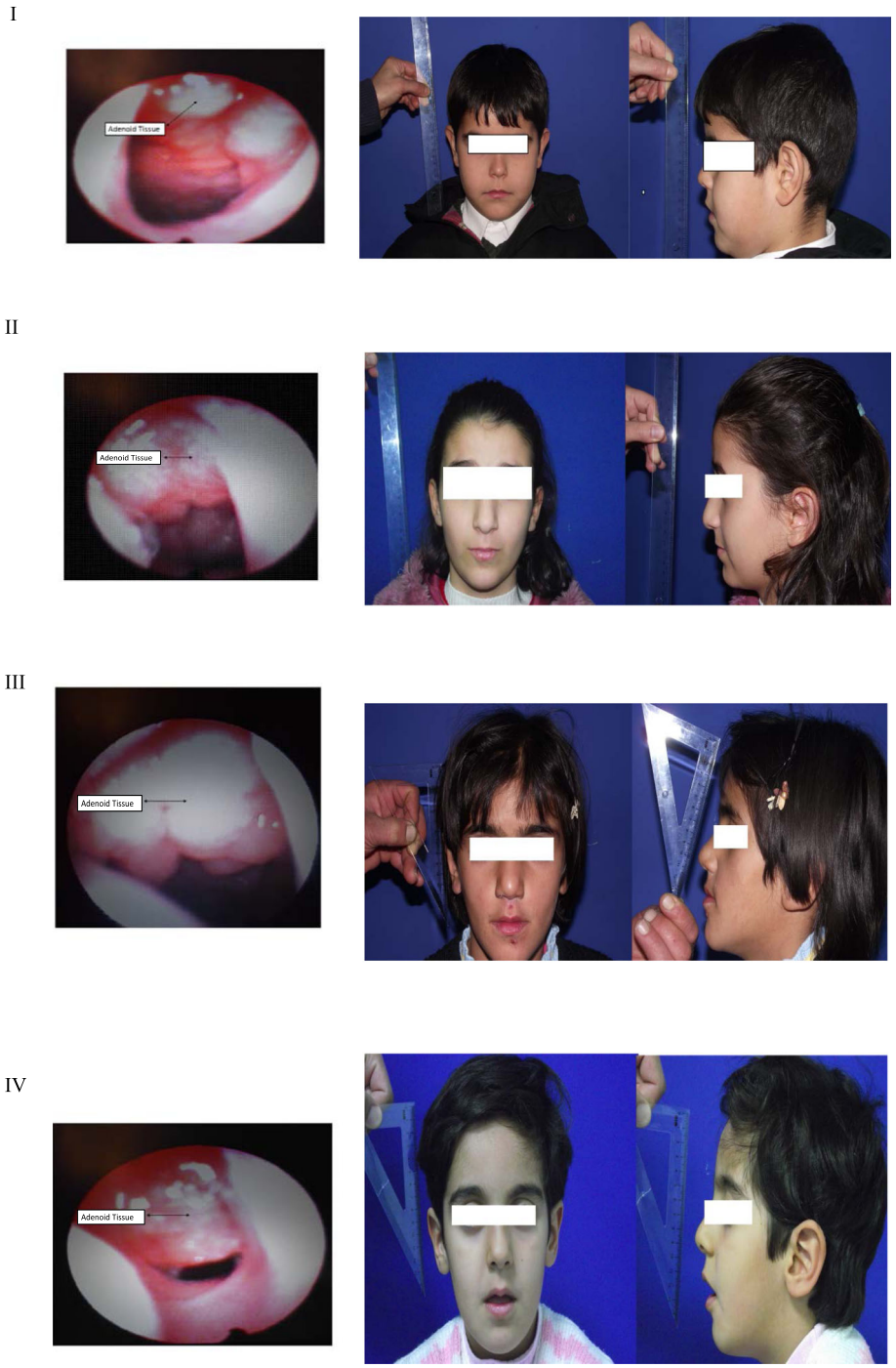


Fig. 1 I: 0–25 % adenoid tissue (Group 1: controls). II: 25–50 % adenoid tissue (Group 2a). III: 50–75 % adenoid tissue (Group 2b). IV: 75–100 % adenoid tissue (Group 2c) and the actual representative pictures of each group

inferior border of the mandible and the posterior edge of the ramus of the lower jaw), and tragion (tra: the superior margin of the tragus of the ear). Distances between those reference points were measured in millimeters.

Distances and angles

We measured the distances between vertex and trichion (v-tr), vertex and glabella (v-g), vertex and nasion (v-n), trichion and glabella (tr-g), trichion and nasion (tr-n), nasion and tip (n-t), nasion and subnasale (n-sn; the

nose length), subnasale and stomion (sn-st), subnasale and gnathion (sn-gn; the height of the lower third of the face), endocanthion and exocanthion (en-ex; eye fissure width), right and left ala nasi (ala-ala; width of the nose), angulus oris and angulus oris (an-an; width of the mouth), zygion and zygion (zy-zy; width of the face), superaurale and subaurale (sa-sba; ear length), glabella and subnasale (g-sn; the length of the middle third of the face), tip and ala (t-ala), and tragion and angulus mandible (tra-anm) and the angles between tragion, nasion, and pogonion (tra-n-pg), tragion, nasion, and subnasale (tra-n-sn), tragion, angulus mandible, and gnathion (tra-anm-gn), Frankfort horizontal plane (a line extending from the most inferior point of the orbital margin to the left tragion), gnathion, and angulus mandible (frank-gn-anm), nasion, angulus mandible, and gnathion (n-anm-gn), and nasolabial and nasofrontal angles (Figs. 2 and 3).

Statistical analyses

The statistical analyses were performed with SPSS version 16 for Windows. Measurable variables were defined as average ± standard deviation (SD), and discontinuous data were defined as numbers and percentages. The normal distribution of measurable variables was carried out by Shapiro–Wilk normality test. We used Pearson's chi-squared test and Fisher's exact test for discontinuous data and unpaired *T*-test, one way variance analysis (ANOVA) test, and least significant difference method (LSD) for measurable variables. Pearson correlation test was used to evaluate the relation between variables. The significance level $p < 0.05$ was chosen.

Results

The average values of the distances (v-tr), (v-g), (v-n), (tr-g), (tr-n), (n-t), (n-sn), (sn-st), (sn-gn), (en-ex), (ala-ala), (an-an), (zy-zy), (sa-sba), (g-sn), (t-ala), and (tra-anm) and the angles (tra-n-pg), (tra-n-sn), (tra-anm-gn), (frank-gn-anm), and (n-anm-gn), SDs, *t*-test values, and *p* values are given in Tables 1 and 2.

There was a statistically significant increase in the distance between nasion-tip ($p = 0.035$) and the angle between Frankfort horizontal plane-gnathion-angulus mandible ($p = 0.043$) and statistically significant decrease in the distance between endocanthion-exocanthion ($p = 0.036$) and the angles between tragion-angulus mandible-gnathion (p value: 0.035), nasion-angulus mandible-gnathion ($p = 0.011$), in the group having thicker adenoids compared with controls.

There was a statistically significant increase in the distance between nasion-subnasale (n-sn) in the children having higher adenoids (Group 2) than in controls (Group 1). The average length was 48.7 mm (±6.6 mm) in Group 2 and 46.8 mm (±5.9 mm) in the control group ($p = 0.038$, $p < 0.05$). In the evaluation between the four groups (Group 1: 0–25 % adenoid tissue (control group), Group 2a: 25–50 % adenoid tissue, Group 2b: 50–75 % adenoid tissue, and Group 2c: 75–100 % adenoid tissue), the distance between nasion-subnasale was longer in the groups having thicker adenoids compared with controls, but there was no statistical difference ($p = 0.101$)($p > 0.05$). Statistically, there was no difference in age and gender between groups. The mean age was 7.9 ± 2.4 in Group 2 and 8.0 ± 2.5 in control Group 1. There was no significant difference in gender between groups, according to chi-Squared statistical test ($p > 0.05$).



Fig. 2 Facial-analyzing points. V:Vertex, Tr:Trichion, G:Glabella, N:Nasion, T:Tip, Sn:Subnasale, St:Stomion, Gn:Gnathion, En: Endocanthion, Ex: Exocanthion, Zy: Zygion, An: Angulus oris, Sa: Superaurale, Sba: Subaurale, Ala: Ala nasi and distances measured on anterior photographs

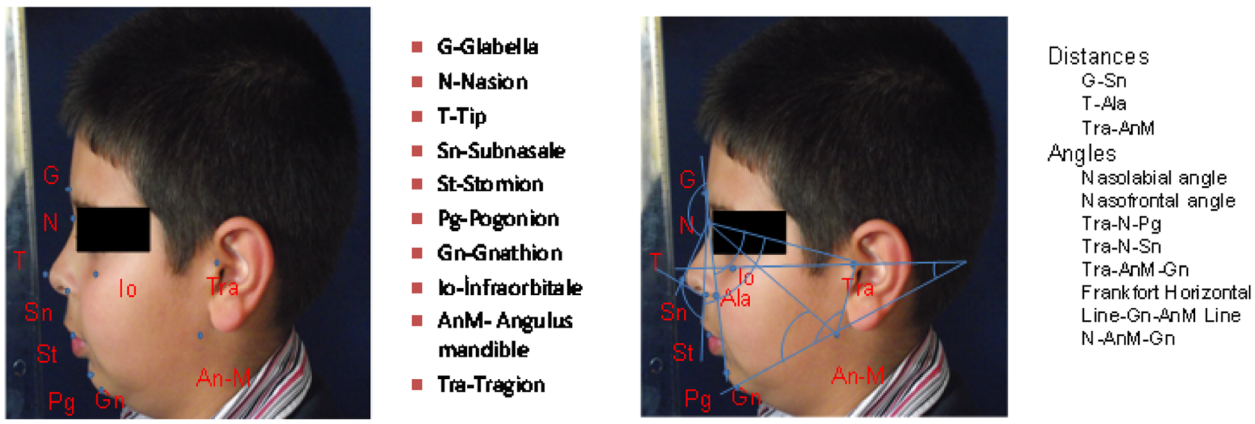


Fig. 3 Lateral photographs and facial-analyzing points, angles, and distances

There were statistically significant differences in vas1 (vas score of snoring; $p = 0.0001$), vas2 (vas score of mouth breathing in sleep; $p = 0.0001$), vas3 (vas score of sleep apnea; $p = 0.006$), vas6 (vas score of poor school performance; $p = 0.001$) between groups. In Group 2, the complaints of the degree of snoring, sleep apnea, and mouth breathing was greater than in the control group. In addition, there was poor school performance in Group 2 (Table 3). We compared the smoking ratio in parents for children between Groups 1 and 2 (Table 4).

Discussion

Adenoid hypertrophy is the most common pathology causing upper airway obstruction in childhood [1]. Patients experience mouth breathing as a result of nasal obstruction. Therefore, incisors, which have large dental pulp, are exposed to moisture and get cold by the effect of evaporation. The cold causes pain, and this triggers the tongue-pushing reflex in an effort to warm the incisors. If the mouth breathing continues, tongue pushing and anterior positioning of the tongue also continue, which this leads to an anterior open-bite deformity [6]. An increase in the anterior face height may be seen due to nasal obstruction caused by chronic mouth breathing [7, 8].

Woodside and Linder-Aronson reported the increase in anterior face height in nasal-obstructed individuals by aging. They also pointed out that the anterior face height is independent from other skeletal units, and it depends

Table 1 Distance measurements between groups (*$p < 0.05$) (*n*: number of children in each group)

Distances (mean ± SD) (mm)	Group 1 (*n* = 90)	Group 2a (*n* = 50)	Group 2b (*n* = 35)	Group 2c (*n* = 12)	*P* value
vertex and trichion (v-tr)	*49.9* ± 9.9	48,7 ± 11,1	52,5 ± 12,4	51,2 ± 10,3	0.435
vertex and glabella (v-g)	106 ± 14	105,8 ± 16	110,2 ± 15	103,8 ± 9,9	0.421
vertex and nasion (v-n)	123.1 ± 14.1	120,3 ± 15,2	124,8 ± 16,4	118,9 ± 9,2	0.415
trichion and glabella (tr-g)	56,9 ± 8,5	57,5 ± 8,3	58,3 ± 9,4	53,7 ± 6,1	0.431
trichion and nasion (tr-n)	73,4 ± 10,1	72,4 ± 8,6	71,3 ± 11,6	68,8 ± 6,7	0.421
nasion and tip (n-t)	36,7 ± 5,8	39,4 ± 6,6	39,7 ± 7,6	37,9 ± 5,4	0.035*
nasion and subnasale (n-sn)	*46,8* ± 5,9	49,5 ± 6,4	48,2 ± 7,1	46,9 ± 5,8	0.101
subnasale and stomion (sn-st)	23,8 ± 2,1	21,6 ± 3,1	21,5 ± 3,3	20,2 ± 2,8	0.741
subnasale and gnathion (sn-gn)	59,2 ± 8,2	60,3 ± 8,9	58,9 ± 8,3	55,4 ± 10,6	0.373
endocanthion and exocanthion (en-ex)	31 ± 3,1	30,9 ± 3,2	30,3 ± 3,3	28,3 ± 2,5	0.036*
ala and ala (ala-ala)	36,7 ± 4,2	36,4 ± 4,3	35,9 ± 3,9	33,8 ± 3,1	0.137
angulus oris and angulus oris (an-an)	48 ± 6,2	48,1 ± 7	46,7 ± 7,3	43,5 ± 5,6	0.116
zygion and zygion (zy-zy)	100,1 ± 13,2	101,5 ± 8,1	100,5 ± 9,4	96,7 ± 6,1	0.590
superaurale and subaurale (sa-sba)	56,4 ± 5,6	54,4 ± 9,2	56,5 ± 6,6	53 ± 5,4	0.174
glabella and subnasale (g-sn)	57,3 ± 6,3	59 ± 5,8	56,2 ± 6	58,2 ± 5	0.196
tip and ala (t-ala)	23 ± 2,7	23,5 ± 3,1	23,7 ± 2,4	21,6 ± 2,9	0.121
tragion and angulus mandible (tra-anm)	53,5 ± 7,1	52,5 ± 6,1	51 ± 7,2	50,7 ± 7,6	0.237

Table 2 Angle measurements between groups (*$p < 0.05$)

Angles (mean ± SD)	Group 1 ($n = 90$)	Group 2a ($n = 50$)	Group 2b ($n = 35$)	Group 2c ($n = 12$)	*P* value
tragion, nasion and pogonion (tra-n-pg)^0,	65,8 ± 5,1	68,1 ± 5,2	67,1 ± 4,8	65,9 ± 3,1	0.074
and tragion, nasion and subnasale (tra-n-sn)^0	75,7 ± 5,4	77,4 ± 4,7	77,1 ± 5,5	74,7 ± 3,4	0.150
tragion, angulus mandible and gnathion (tra-anm-gn)^0	136,8 ± 7,7	135,1 ± 5,6	134 ± 8,9	131,1 ± 5,2	0.035*
Frankfort horizontal plane, gnathion and angulus mandible (frank-gn-anm)^0	28 ± 4	28 ± 2,8	28,9 ± 3,5	31 ± 3,9	0.043*
nasion, angulus mandible and gnathion (n-anm-gn)^0	67,1 ± 5,4	64,3 ± 5,7	64,1 ± 6,1	63,9 ± 9,2	0.011*

on only factors that affect mandibular posture, such as mouth breathing [9]. Fields and colleagues identified a relation between dentofacial morphology and nasal airway capacity [10]. Yamada and colleagues found inferior and posterior mandible, superior and posterior development of the condil, and anterior crossbite deformity due to nasopharyngeal obstruction [11]. In our study, we measured 17 distances and 7 angles on the anterior and lateral standardized clinical photographs of normal children and those with thicker adenoids. There was a statistically significant increase in the distance between nasion-tip ($p = 0.035$) and the angle between Frankfort horizontal plane-gnathion-angulus mandible ($p = 0.043$) and a statistically significant decrease in the distance between endocanthion-exocanthion ($p = 0.036$) and the angles between tragion-angulus mandible-gnathion ($p = 0.035$) and nasion-angulus mandible-gnathion ($p = 0.011$) in the group having thicker adenoids compared with controls. There was a statistically significant increase in the distance between nasion-subnasale (n-sn) in Group 2 compared with Group 1. In children with adenoid hypertrophy, the positioning of the tongue is downward due to mouth breathing and the balance between the tongue and mandible is different in comparison with healthy children. This leads to the lower positioning of the mandible. In this situation, a number of postural changes can occur, including open mandible posture and extension of the head. Cephalometrically, a large anterior face height and increased mandibular plane angle can be observed [3].

Table 3 Statistical analyses of age and vas between groups 1 and 2

	Group (*n*)	mean	Std. Deviation	*t*-test value	*p*- value
Age	1.00 (90)	8.0000	2.59645	−0.249	0.804
	2.00 (97)	7.9072	2.49617		**$p > 0.05$**
vas1	1.00 (90)	1.5000	2.63618	4.400	0.0001
	2.00 (97)	3.5258	3.55344		**$p < 0.05$**
vas2	1.00 (90)	1.4444	2.63985	5.341	0.0001
	2.00 (97)	3.8969	3.53696		**$p < 0.05$**
vas3	1.00 (90)	0.2333	0.98357	2.767	0.006
	2.00 (97)	0.9072	2.10695		**$p < 0.05$**
vas4	1.00 (90)	0.1444	0.78699	1.084	0.280
	2.00 (97)	0.3093	1.22781		$p > 0.05$
vas5	1.00 (90)	0.5889	1.85360	3.525	0.273
	2.00 (97)	1.9588	3.22722		$p > 0.05$
vas6	1.00 (90)	0.4778	1.55229	3.719	**0.001**
	2.00 (97)	1.7526	2.88686		**$p < 0.05$**

vas1: vas score of snoring, vas2: vas score of mouth breathing while sleeping, vas3: vas score of sleep apnea, vas4: vas score of daytime sleepiness, vas5: vas score of restless sleep, and vas6: vas score of poor school performance

In our study, the increase of the distance between the nasion-tip and the nasion subnasale (anterior face height) and an increase in the angle between the Frankfort horizontal plane and the angulus-gnathion mandible (craniomandibular angle) was similar to the findings presented in previous cephalometric studies [2, 3, 6–8, 12–14].

In our study, children were evaluated according to their school performance. School performance was scored according to the VAS. A statistically poorer school performance was observed in the group having thicker adenoids compared with controls ($p < 0.05$). This result was parallel to the literature. The failure in school performance may result from the relation between chronic nocturnal hypoxia and neurocognitive functioning. How the interruption of sleep causes neurobehavioral difficulties is unknown. It is probable that sleep interruption and episodic hypoxia cause propulsive functional failures due to changes in the neurochemical structure of the prefrontal cortex. Poor performance in linguistic skills and visual–spatial functions and poor academic performance confirm that children with adenoid hypertrophy have problems with their prefrontal cortical functions. A significant increase in school performance has been observed after adenoidectomy [15, 16].

Smoking status was asked of the parents of both groups. There were three results: no smoking, only one parent smoking, and both parents smoking. An increased smoking ratio was observed in Group 2 compared with Group 1. The results were statistically significant ($p < 0.05$). The relationship between cigarette smoke exposure and adenoid hypertrophy has been reported by many studies. The increase of nitric oxide concentration may cause cytotoxic effects. Cigarette smoke exposure increases the synthesis of heat shock proteins in tissues. Heat shock proteins are synthesized

Table 4 Smoking ratio of parents between groups 1 and 2

GROUP		No smoking	1 Parent smoking	2 Parents smoking	Total	Chi-squared test value	*p* value
1	number	50	18	22	90	10.564	0.005*
	Within group %	55.6 %	20.0 %	24.4 %	100.0 %		
2	number	32	23	42	97		
	Within group %	33.0 %	23.7 %	43.3 %	100.0 %		

In statistical analyses, the smoking ratio of parents in Group 2 was higher than in control Group 1 ($p = 0.005$)
*: p value for the smoking ratio of parents in Group 2

in tissues in response to environmental stressors. Cigarette smoke causes its destructive effects in adenoid tissue by reagent oxygen and nitrogen products. Heat shock protein 70 is responsible for adenoid hypertrophy in children exposed to cigarette smoke. Heat shock protein 70 prevents adenoid regression by preventing apoptosis in hypertrophied adenoid tissue [17].

Our analyses showed a significant increase in the anterior face height and an increase in the angle between the Frankfort horizontal plane and the angulus-gnathion mandible, as well as a retropositioned and posteriorrotated mandible, due to increased thickness in the adenoids. Treatment of nasal obstruction in growing children results in normal dentofacial development. For this reason, it is important to address the direct relation between nasal airway obstruction and dentofacial development, and early treatment should be administered to help to ensure normal development. We must familiarize ourselves with dentofacial development. Earlier detection is necessary to prevent adenoid face. Normalization of the breathing pattern has a favorable effect on dentofacial development. Pediatricians, orthodontists, and otolaryngologist should cooperate to ensure proper evaluation of nasal obstruction and dental abnormalities.

Conclusions

In conclusion, the effects of adenoid hypertrophy on maxillofacial development have been analyzed by cephalometric studies up to now. However, the effects of adenoid hypertrophy on maxillofacial development have not been analyzed by a photographic method; in this respect, this is the first reported study. The analyses on clinical photographs were parallel to the cephalometric analyses reported in the literature, and our study also observed the reflection of skeletal deformities on soft tissue distances and angles.

Abbreviations

ala: Right and left ala nasi; an: Angulus oris; anm: Angulus of mandible; en: Endocanthion; ex: Exocanthion; FNFL: Flexible fiberoptic nasopharyngolaryngoscopy; frank: Frankfort horizontal plane; g: Glabella; gn: Gnathion; io: Infraorbitale; n: Nasion; pg: Pogonion; sa: Superaurale; SA: Standard deviation; sba: Subaurale; sn: Subnasale; st: Stomion; t: Tip; tr: Trichion; tra: Tragion; v: Vertex; VAS: Visual analog scale; VAS: Visual analog scale; zy: Zygion

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Availability of data and materials

http://scion-image.software.informer.com/versions/.

Authors' contributions

TE participated in the design of the study and performed the statistical analysis. ÇFK and TB conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

We obtained consent to publish from the parents. we will send to you a copy at any stage of the publication.

Ethics approval and consent to participate

We started the study after approval of Human Ethics Committee of Inonu University Malatya/Turkey. (committee's reference number 2010/140).

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Review

Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?

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Abstract: Many countries introduced the requirement to wear masks in public spaces for containing SARS-CoV-2 making it commonplace in 2020. Up until now, there has been no comprehensive investigation as to the adverse health effects masks can cause. The aim was to find, test, evaluate and compile scientifically proven related side effects of wearing masks. For a quantitative evaluation, 44 mostly experimental studies were referenced, and for a substantive evaluation, 65 publications were found. The literature revealed relevant adverse effects of masks in numerous disciplines. In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES). We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.

Keywords: personal protective equipment; masks; N95 face mask; surgical mask; risk; adverse effects; long-term adverse effects; contraindications; health risk assessment; hypercapnia; hypoxia; headache; dyspnea; physical exertion; MIES syndrome

1. Introduction

At the beginning of the spread of the novel pathogen SARS-CoV-2, it was necessary to make far-reaching decisions even without available explicit scientific data. The initial assumption was that the pandemic emergency measures were set in place to reduce the acute threat of the public health system effectively and swiftly.

In April 2020, the World Health Organization (WHO) recommended the use of masks only for symptomatic, ill individuals and health care workers and did not recommend its widespread use.

In June 2020, they changed this recommendation to endorse the general use of masks in, e.g., crowded places [1,2]. In a meta-analysis study commissioned by the WHO (evidence level Ia), no clear, scientifically graspable benefit of moderate or strong evidence was derived from wearing masks [3].

While maintaining a distance of at least one meter showed moderate evidence with regard to the spreading of SARS-CoV-2, only weak evidence at best could be found for masks alone in everyday use (non-medical setting) [3]. Another meta-analysis conducted in the same year confirmed the weak scientific evidence for masks [4].

Accordingly, the WHO did not recommend general or uncritical use of masks for the general population and expanded its risk and hazard list within just two months. While the April 2020 guideline highlighted the dangers of self-contamination, possible breathing difficulties and false sense of security, the June 2020 guideline found additional potential adverse effects such as headache, development of facial skin lesions, irritant dermatitis, acne or increased risk of contamination in public spaces due to improper mask disposal [1,2].

However, under pressure from increasing absolute numbers of positive SARS-CoV-2 tests, many prescribers further extended mask-wearing according to certain times and situations, always justified by the desire to limit the spread of the virus [5]. The media, numerous institutions and most of the population supported this approach.

Among the medical profession and scientists, the users and observers of medical devices, there have been simultaneous calls for a more nuanced approach [6–8]. While there has been a controversial scientific discussion worldwide about the benefits and risks of masks in public spaces, they became the new social appearance in everyday life in many countries at the same time.

Although there seems to be a consensus among the decision makers who have introduced mandatory masks that medical exemptions are warranted, it is ultimately the responsibility of individual clinicians to weigh up when to recommend exemption from mandatory masks. Physicians are in a conflict of interest concerning this matter. On the one hand, doctors have a leading role in supporting the authorities in the fight against a pandemic. On the other hand, doctors must, in accordance with the medical ethos, protect the interests, welfare and rights of their patient's third parties with the necessary care and in accordance with the recognized state of medical knowledge [9–11].

A careful risk–benefit analysis is becoming increasingly relevant for patients and their practitioners regarding the potential long-term effects of masks. The lack of knowledge of legal legitimacy on the one hand and of the medical scientific facts on the other is a reason for uncertainty among clinically active colleagues.

The aim of this paper is to provide a first, rapid, scientific presentation of the risks of general mandatory mask use by focusing on the possible adverse medical effects of masks, especially in certain diagnostic, patient and user groups.

2. Materials and Methods

The objective was to search for documented adverse effects and risks of different types of mouth–nose-covering masks. Of interest here were, on the one hand, readymade and self-manufactured fabric masks, including so-called community masks and, on the other hand medical, surgical and N95 masks (FFP2 masks).

Our approach of limiting the focus to negative effects seems surprising at first glance. However, such an approach helps toprovide us with more information. This methodology is in line with the strategy of Villalonga-Olives and Kawachi, who also conducted a review exclusively on the negative effects [12].

For an analysis of the literature, we defined the risk of mouth–nose protection as the description of symptoms or the negative effects of masks. Reviews and expert presentations from which no measurable values could be extracted, but which clearly present the research situation and describe negative effects, also fulfill this criterion.

Additionally, we defined the quantifiable, negative effect of masks as the presentation of a measured, statistically significant change in a physiological parameter in a pathological direction ($p < 0.05$), a statistically significant detection of symptoms ($p < 0.05$) or the occurrence of symptoms in at least 50% of those examined in a sample ($n \geq 50\%$).

Up to and including 31 October 2020, we conducted a database search in PubMed/MEDLINE on scientific studies and publications on adverse effects and risks of different types of mouth–nose-covering masks according to the criteria mentioned above (see Figure 1: Review flowchart). Terms searched were "face masks", "surgical mask" and "N95" in combination with the terms "risk" and "adverse effects" as well as "side effects". The selection criteria of the papers were based on our above definition of risk and adverse effect of masks. Mainly English- and German-language publications of evidence levels I to III according to the recommendations of the Agency for Healthcare Research and Quality (AHQR) that were not older than 20 years at the time of the review were considered. The evaluation also excluded level IV evidence, such as case reports and irrelevant letters to the editor that exclusively reflect opinions without scientific evidence.

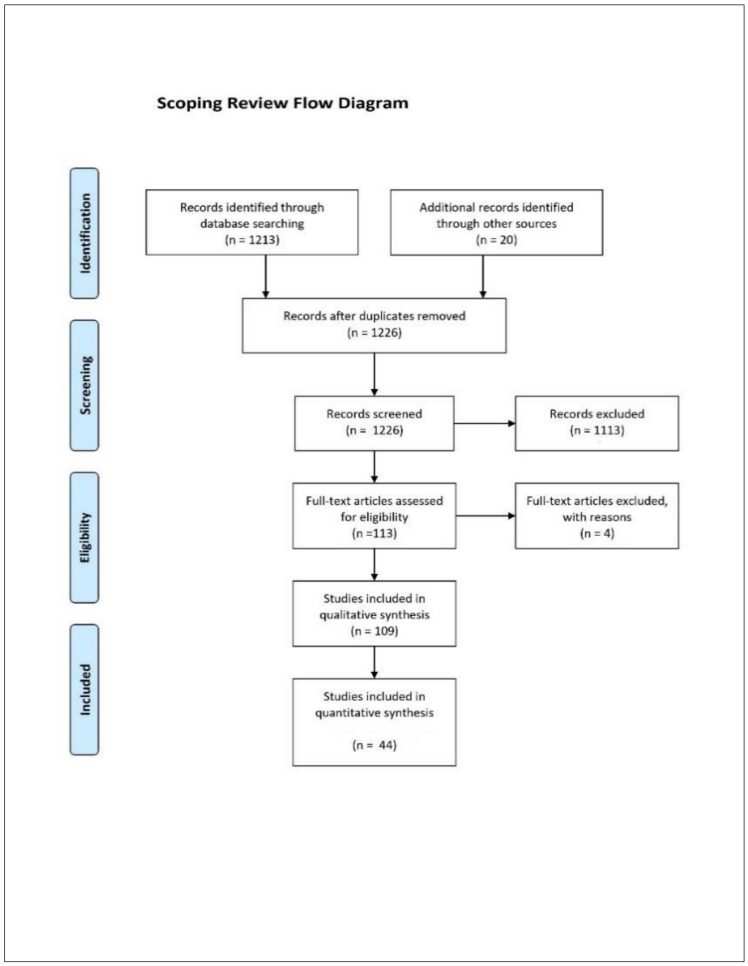


Figure 1. Scoping review flow diagram according to the PRISMA scheme.

After excluding 1113 papers that were irrelevant to the research question and did not meet the criteria mentioned (quantifiable, negative effects of masks, description of symptoms or the negative effects of masks), a total of 109 relevant publications were found for evaluation in the context of our scoping review (see Figure 1: Flow chart).

Sixty-five relevant publications concerning masks were considered being within the scope of the content-related evaluation. These included 14 reviews and 2 meta-analyses from the primary research. For the quantitative evaluation, 44 presentations of nega-

tive effects from the years 2004 to 2020 were eligible. Thirty-one of these studies were experimental (70%), and 13 studies were data collection studies in the sense of simple observational studies, especially in the dermatological field (30%). The observed study parameters and significant results from these 44 publications ($p < 0.05$ or $n \geq 50\%$) were compiled in an overall display (Figure 2). Based on this data, a correlation analysis of the observed mask effects was performed. This included a correlation calculation of the recorded symptoms and physiological changes (for nominally scaled, dichotomous variables according to Fisher using R, R Foundation for Statistical Computing, Vienna, Austria, version 4.0.2).

significantly measured mask-induced changes in scientific studies 2004-2020: • = p<0.05 ■ = n≥50 %	Fabric Mask	Surgical Mask	N95-Mask	O2↓	CO2↑	Humidity↑	Temperature↑	Breathing Resistance↑	Respiratory Rate↑	Blood Pressure↑	Cerebral Vasodilation	Heart Rate↑	Respiratory Impairment	Exhaustion & Fatigue	Drowsiness	Dizziness	Headache	Psycho-vegetative Effect	Decrease in Empathy	Itch	Skin Irritation	Acne	Rhinitis	Voice Disorder	False Sense of Security	Bacterial Contamination	Fungal Contamination	Viral Contamination
Beder 2008		X		•								•																
Bharatendu 2020			X		•						•						•											
Butz 2005		X			•																							
Chughtai 2019		X																										•
Epstein 2020		X	X		•																							
Fikenzer 2020		X	X	•		•	•	•					•	•						•								
Foo 2006			X																	■	■	■						
Georgi 2020	X	X	X	•	•				•				•	•														
Goh 2019			X		■																							
Heider 2020		X	X																					•				
Hua 2020		X	X			•														■	•							
Jacobs 2009		X															•											
Jagim 2018	X			•										•	•													
Kao 2004			X	•					•				•	•														
Klimek 2020																							•					
Kyung 2020			X	•	•				•			•	•															
Lan 2020			X																	■	•							
Lee 2011			X					•																				
Li 2005		X	X			•	•	•		•		•	•	•						•								
Lim 2006			X														•											
Liu 2020	X	X	X	•		•	•					•	•	•	•	•					•							
Luckman 2020	X	X	X																						•			
Luksamijarulkul 2014		X																								•	•	
Matusiak 2020	X	X	X			•	•						•							•	•			•				
Mo 2020		X			•					•			•															
Monalisa 2017		X																								•	•	
Ong 2020			X														•											
Person 2018		X											•															
Pifarre 2020		X	X	•	•																							
Porcari 2016	X			•										•														
Prousa 2020	X	X	X															•										
Ramirez 2020		X	X														•											
Rebmann 2013		X	X	•	•							•	•	•	•		•											
Roberge 2012		X			•	•	•		•			•	•															
Roberge 2014			X		•		•																					
Rosner 2020		X	X														■				■	■						
Scarano 2020		X	X			•	•						•								•							
Shenal 2012	X	X	X											•														
Smart 2020		X	X				•						•															
Szepietkowski 2020	X	X	X																	•								
Techasatian 2020	X	X	X																		■							
Tong 2015			X	•	•																							
Wong 2013		X																	•									
Zhiqing 2018		X																								•		

Figure 2. Overview including all 44 considered studies with quantified, significant adverse effects of masks (black dots and black rectangles). Not all studies examined each mentioned parameter, as focused or subject-related questions were often in the foreground. Gray fields correspond to a lack of coverage in the primary studies, white fields represent measured effects. We found an often combination of significant chemical, physical, physiological parameters and complaints. Drowsiness summarizes the symptom for any qualitative neurological deficits described in the scientific literature examined.

In addition, another 64 publications with a neighboring range of topics were consulted in connection with the mask effects we found. These included declarations, guidelines

and legal principles. In order to expand the amount of data for the discussion, we proceeded according to the "snowball principle" by locating citations of selected papers in the bibliographies and including them where appropriate.

Since the findings from the topics presented for discussion were to an unexpected degree subject-related, we decided to divide the results according to the fields of medicine. Of course, there are overlaps between the respective fields, which we point out in detail.

3. Results

A total of 65 scientific papers on masks qualified for a purely content-based evaluation. These included 14 reviews and two meta-analyses.

Of the mathematically evaluable, groundbreaking 44 papers with significant negative mask effects ($p < 0.05$ or $n \geq 50\%$), 22 were published in 2020 (50%), and 22 were published before the COVID-19 pandemic. Of these 44 publications, 31 (70%) were of experimental nature, and the remainder were observational studies (30%). Most of the publications in question were English (98%). Thirty papers referred to surgical masks (68%), 30 publications related to N95 masks (68%), and only 10 studies pertained to fabric masks (23%).

Despite the differences between the primary studies, we were able to demonstrate a statistically significant correlation in the quantitative analysis between the negative side effects of blood-oxygen depletion and fatigue in mask wearers with $p = 0.0454$.

In addition, we found a mathematically grouped common appearance of statistically significant confirmed effects of masks in the primary studies ($p < 0.05$ and $n \geq 50\%$) as shown in Figure 2. In nine of the 11 scientific papers (82%), we found a combined onset of N95 respiratory protection and carbon dioxide rise when wearing a mask. We found a similar result for the decrease in oxygen saturation and respiratory impairment with synchronous evidence in six of the nine relevant studies (67%). N95 masks were associated with headaches in six of the 10 studies (60%). For oxygen deprivation under N95 respiratory protectors, we found a common occurrence in eight of 11 primary studies (72%). Skin temperature rise under masks was associated with fatigue in 50% (three out of six primary studies). The dual occurrence of the physical parameter temperature rise and respiratory impairment was found in seven of the eight studies (88%). A combined occurrence of the physical parameters temperature rise and humidity/moisture under the mask was found in 100% within six of six studies, with significant readings of these parameters (Figure 2).

The literature review confirms that relevant, undesired medical, organ and organ system-related phenomena accompanied by wearing masks occur in the fields of internal medicine (at least 11 publications, Section 3.2). The list covers neurology (seven publications, Section 3.3), psychology (more than 10 publications, Section 3.4), psychiatry (three publications, Section 3.5), gynecology (three publications, Section 3.6), dermatology (at least 10 publications, Section 3.7), ENT medicine (four publications, Section 3.8), dentistry (one publication, Section 3.8), sports medicine (four publications, Section 3.9), sociology (more than five publications, Section 3.10), occupational medicine (more than 14 publications, Section 3.11), microbiology (at least four publications, Section 3.12), epidemiology (more than 16 publications, Section 3.13), and pediatrics (four publications, Section 3.14) as well as environmental medicine (four publications, Section 3.15).

We will present the general physiological effects as a basis for all disciplines. This will be followed by a description of the results from the different medical fields of expertise and closing off with pediatrics the final paragraph.

3.1. General Physiological and Pathophysiological Effects for the Wearer

As early as 2005, an experimental dissertation (randomized crossover study) demonstrated that wearing surgical masks in healthy medical personnel (15 subjects, 18–40 years old) leads to measurable physical effects with elevated transcutaneous carbon dioxide values after 30 min [13]. The role of dead space volume and CO_2 retention as a cause of the significant change ($p < 0.05$) in blood gases on the way to hypercapnia, which was still

within the limits, was discussed in this article. Masks expand the natural dead space (nose, throat, trachea, bronchi) outwards and beyond the mouth and nose.

An experimental increase in the dead space volume during breathing increases carbon dioxide (CO_2) retention at rest and under exertion and correspondingly the carbon dioxide partial pressure pCO_2 in the blood ($p < 0.05$) [14].

As well as addressing the increased rebreathing of carbon dioxide (CO_2) due to the dead space, scientists also debate the influence of the increased breathing resistance when using masks [15–17].

According to the scientific data, mask wearers as a whole show a striking frequency of typical, measurable, physiological changes associated with masks.

In a recent intervention study conducted on eight subjects, measurements of the gas content for oxygen (measured in O_2 Vol%) and carbon dioxide (measured in CO_2 ppm) in the air under a mask showed a lower oxygen availability even at rest than without a mask. A Multi-Rae gas analyzer was used for the measurements (RaeSystems®) (Sunnyvale, California CA, United States). At the time of the study, the device was the most advanced portable multivariant real-time gas analyzer. It is also used in rescue medicine and operational emergencies. The absolute concentration of oxygen (O_2 Vol%) in the air under the masks was significantly lower (minus 12.4 Vol% O_2 in absolute terms, statistically significant with $p < 0.001$) at 18.3% compared to 20.9% room air concentration. Simultaneously, a health-critical value of carbon dioxide concentration (CO_2 Vol%) increased by a factor of 30 compared to normal room air was measured (ppm with mask versus 464 ppm without mask, statistically significant with $p < 0.001$) [18].

These phenomena are responsible for a statistically significant increase in carbon dioxide (CO_2) blood content in mask wearers [19,20], on the one hand, measured transcutaneously via an increased $PtcCO_2$ value [15,17,19,21,22], on the other hand, via end-expiratory partial pressure of carbon dioxide ($PETCO_2$) [23,24] or, respectively, the arterial partial pressure of carbon dioxide ($PaCO_2$) [25].

In addition to the increase in the wearer's blood carbon dioxide (CO_2) levels ($p < 0.05$) [13,15,17,19,21–28], another consequence of masks that has often been experimentally proven is a statistically significant drop in blood oxygen saturation (SpO_2) ($p < 0.05$) [18,19,21,23,29–34]. A drop in blood oxygen partial pressure (PaO_2) with the effect of an accompanying increase in heart rate ($p < 0.05$) [15,23,29,30,34] as well as an increase in respiratory rate ($p < 0.05$) [15,21,23,35,36] have been proven.

A statistically significant measurable increase in pulse rate ($p < 0.05$) and decrease in oxygen saturation SpO_2 after the first ($p < 0.01$) and second hour ($p < 0.0001$) under a disposable mask (surgical mask) were reported by researchers in a mask intervention study they conducted on 53 employed neurosurgeons [30].

In another experimental study (comparative study), surgical and N95 masks caused a significant increase in heart rate ($p < 0.01$) as well as a corresponding feeling of exhaustion ($p < 0.05$). These symptoms were accompanied by a sensation of heat ($p < 0.0001$) and itching ($p < 0.01$) due to moisture penetration of the masks ($p < 0.0001$) in 10 healthy volunteers of both sexes after only 90 min of physical activity [35]. Moisture penetration was determined via sensors by evaluating logs (SCXI-1461, National Instruments, Austin, TX, USA).

These phenomena were reproduced in another experiment on 20 healthy subjects wearing surgical masks. The masked subjects showed statistically significant increases in heart rate ($p < 0.001$) and respiratory rate ($p < 0.02$) accompanied by a significant measurable increase in transcutaneous carbon dioxide $PtcCO_2$ ($p < 0.0006$). They also complained of breathing difficulties during the exercise [15].

The increased rebreathing of carbon dioxide (CO_2) from the enlarged dead space volume in mask wearers can reflectively trigger increased respiratory activity with increased muscular work as well as the resulting additional oxygen demand and oxygen consumption [17]. This is a reaction to pathological changes in the sense of an adaptation effect. A mask-induced drop in blood oxygen saturation value (SpO_2) [30] or the blood

oxygen partial pressure (PaO_2) [34] can in turn additionally intensify subjective chest complaints [25,34].

The documented mask-induced changes in blood gases towards hypercapnia (increased carbon dioxide/CO_2 blood levels) and hypoxia (decreased oxygen/O_2 blood levels) may result in additional nonphysical effects such as confusion, decreased thinking ability and disorientation [23,36–39], including overall impaired cognitive abilities and decrease in psychomotoric abilities [19,32,38–41]. This highlights the importance of changes in blood gas parameters (O_2 and CO_2) as a cause of clinically relevant psychological and neurological effects. The above parameters and effects (oxygen saturation, carbon dioxide content, cognitive abilities) were measured in a study on saturation sensors (Semi-Tec AG, Therwil, Switzerland), using a Borg Rating Scale, Frank Scale, Roberge Respirator Comfort Scale and Roberge Subjective Symptoms-during-Work Scale, as well as with a Likert scale [19]. In the other main study, conventional ECG, capnography and symptom questionnaires were used in measuring carbon dioxide levels, pulse and cognitive abilities [23]. Other physiological data collection was done with pulse oximeters (Allegiance, MCGaw, USA), subjective complaints were assessed with a 5-point Likert scale and motoric speed was recorded with linear-position transducers (Tendo-Fitrodyne, Sport Machins, Trencin, Slovakia) [32]. Some researchers used standardized, anonymized questionnaires to collect data on subjective complaints associated with masks [37].

In an experimental setting with different mask types (community, surgical, N95) a significant increase in heart rate ($p < 0.04$), a decrease in oxygen saturation SpO_2 ($p < 0.05$) with an increase in skin temperature under the mask (face) and difficulty of breathing ($p < 0.002$) were recorded in 12 healthy young subjects (students). In addition, the investigators observed dizziness ($p < 0.03$), listlessness ($p < 0.05$), impaired thinking ($p < 0.03$) and concentration problems ($p < 0.02$), which were also statistically significant when wearing masks [29].

According to other researchers and their publications, masks also interfere with temperature regulation, impair the field of vision and of non-verbal and verbal communication [15,17,19,36,37,42–45].

The above-mentioned measurable and qualitative physiological effects of masks can have implications in various areas of expertise in medicine.

It is known from pathology that not only supra-threshold stimuli exceeding normal limits have disease-relevant consequences. Subthreshold stimuli are also capable of causing pathological changes if the exposure time is long enough. Examples occur from the slightest air pollution by hydrogen sulfide resulting in respiratory problems (throat irritation, coughing, reduced absorption of oxygen) and neurological diseases (headaches, dizziness) [46]. Furthermore, subthreshold but prolonged exposure to nitrogen oxides and particulate matter is associated with an increased risk of asthma, hospitalization and higher overall mortality [47,48]. Low concentrations of pesticides are also associated with disease-relevant consequences for humans such as mutations, development of cancer and neurological disorders [49]. Likewise, the chronic subthreshold intake of arsenic is associated with an increased risk of cancer [50], subthreshold intake of cadmium with the promotion of heart failure [51], subthreshold intake of lead is associated with hypertension, renal metabolic disorders and cognitive impairment [52] or subthreshold intake of mercury with immune deficiency and neurological disorders [53]. Subliminal UV radiation exposure over long periods is also known to cause mutation-promoting carcinogenic effects (especially white skin cancer) [54].

The mask-induced adverse changes are relatively minor at first glance, but repeated exposure over longer periods in accordance with the above-mentioned pathogenetic principle is relevant. Long-term disease-relevant consequences of masks are to be expected. Insofar, the statistically significant results found in the studies with mathematically tangible differences between mask wearers and people without masks are clinically relevant. They give an indication that with correspondingly repeated and prolonged exposure to physical, chemical, biological, physiological and psychological conditions, some of which are

subliminal, but which are significantly shifted towards pathological areas, health-reducing changes and clinical pictures can develop such as high blood pressure and arteriosclerosis, including coronary heart disease (metabolic syndrome) as well as neurological diseases. For small increases in carbon dioxide in the inhaled air, this disease-promoting effect has been proven with the creation of headaches, irritation of the respiratory tract up to asthma as well as an increase in blood pressure and heart rate with vascular damage and, finally, neuropathological and cardiovascular consequences [38]. Even slightly but persistently increased heart rates encourage oxidative stress with endothelial dysfunction, via increased inflammatory messengers, and finally, the stimulation of arteriosclerosis of the blood vessels has been proven [55]. A similar effect with the stimulation of high blood pressure, cardiac dysfunction and damage to blood vessels supplying the brain is suggested for slightly increased breathing rates over long periods [56,57]. Masks are responsible for the aforementioned physiological changes with rises in inhaled carbon dioxide [18–28], small sustained increases in heart rate [15,23,29,30,35] and mild but sustained increases in respiratory rates [15,21,23,34,36].

For a better understanding of the side effects and dangers of masks presented in this literature review, it is possible to refer to well-known principles of respiratory physiology (Figure 3).

The average dead space volume during breathing in adults is approximately 150–180 mL and is significantly increased when wearing a mask covering the mouth and nose [58]. With an N95 mask, for example, the dead space volume of approximately 98–168 mL was determined in an experimental study [59]. This corresponds to a mask-related dead space increase of approximately 65 to 112% for adults and, thus, almost a doubling. At a respiratory rate of 12 per minute, the pendulum volume respiration with such a mask would, thus, be at least 2.9–3.8 L per minute. Therefore, the dead space amassed by the mask causes a relative reduction in the gas exchange volume available to the lungs per breath by 37% [60]. This largely explains the impairment of respiratory physiology reported in our work and the resulting side effects of all types of masks in everyday use in healthy and sick people (increase in respiratory rate, increase in heart rate, decrease in oxygen saturation, increase in carbon dioxide partial pressure, fatigue, headaches, dizziness, impaired thinking, etc.) [36,58].

In addition to the effect of increased dead space volume breathing, however, mask-related breathing resistance is also of exceptional importance (Figure 3) [23,36].

Experiments show an increase in airway resistance by a remarkable 126% on inhalation and 122% on exhalation with an N95 mask [60]. Experimental studies have also shown that moisturization of the mask (N95) increases the breathing resistance by a further 3% [61] and can, thus, increase the airway resistance up to 2.3 times the normal value.

This clearly shows the importance of the airway resistance of a mask. Here, the mask acts as a disturbance factor in breathing and makes the observed compensatory reactions with an increase in breathing frequency and simultaneous feeling of breathlessness plausible (increased work of the respiratory muscles). This extra strain due to the amplified work of breathing against bigger resistance caused by the masks also leads to intensified exhaustion with a rise in heart rate and increased CO_2 production. Fittingly, in our review of the studies on side effects of masks (Figure 2), we also found a percentage clustering of significant respiratory impairment and a significant drop in oxygen saturation (in about 75% of all study results).

In the evaluation of the primary papers, we also determined a statically significant correlation of the drop in oxygen saturation (SpO_2) and fatigue with a common occurrence in 58% of the mask use studies with significant results (Figure 2, $p < 0.05$).

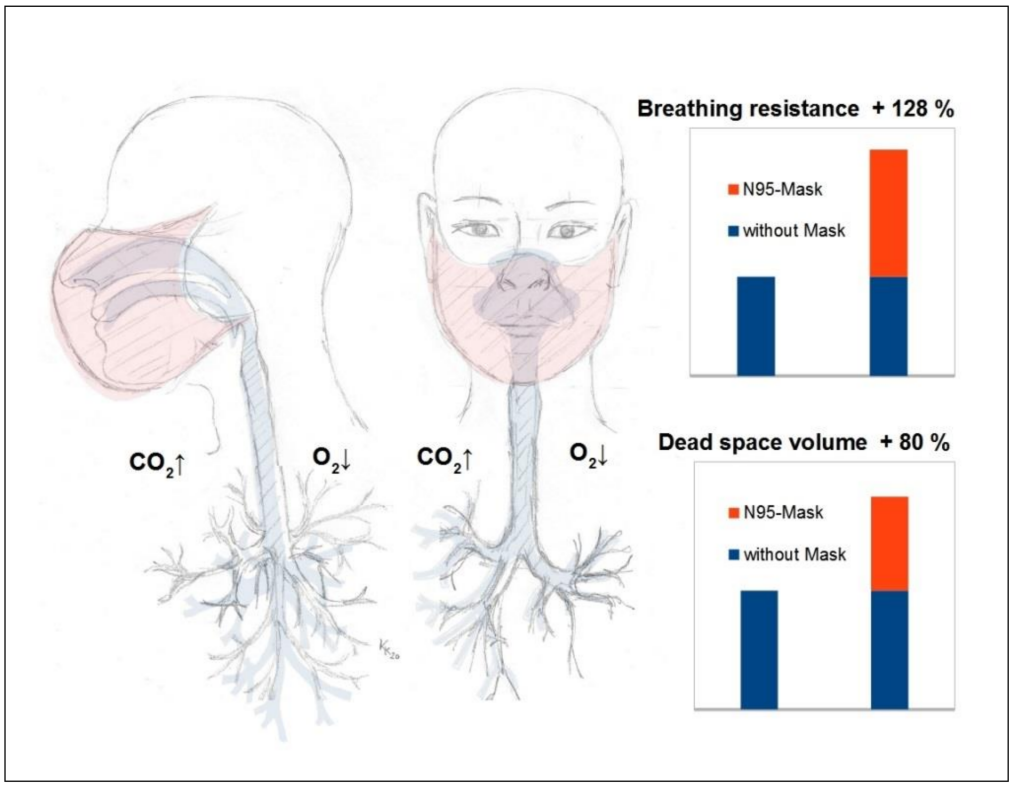


Figure 3. Pathophysiology of the mask (important physical and chemical effects): Illustration of the breathing resistance* and of the dead space volume of an N95 mask in an adult. When breathing, there is an overall significantly reduced possible gas exchange volume of the lungs of minus 37% caused by the mask (Lee 2011) [60] according to a decrease in breathing depth and volume due to the greater breathing resistance of plus128%* (exertion when inhaling greater than when exhaling) and due to the increased dead space volume of plus80%**, which does not participate directly in the gas exchange and is being only partially mixed with the environment. (* = averaged inspiration and expiration according to Lee 2011 [60] including moisture penetration according to Roberge 2010 [61], ** = averaged values according to Xu 2015 [59]).

3.2. Internistic Side Effects and Dangers

As early as 2012, an experiment showed that walking in the 20 masked subjects compared to the identical activity without masks significantly increased heart rates (average +9.4 beats per minute, $p < 0.001$) and breathing rates ($p < 0.02$). These physiological changes were accompanied by transcutaneous significantly measurable increased transcutaneous carbon dioxide ($PtcCO_2$) levels ($p < 0.0006$) as well as respiratory difficulties in the mask wearers compared to the control group [15].

In a recent experimental comparative study from 2020, 12 healthy volunteers under surgical masks as well as under N95 masks experienced measurable impairments in the measured lung function parameters as well as cardiopulmonary capacity (lower maximum blood lactate response) during moderate to heavy physical exertion compared to exertion without masks ($p < 0.001$) [31]. The mask-induced increased airway resistance led to increased respiratory work with increased oxygen consumption and demand, both of the respiratory muscles and the heart. Breathing was significantly impeded ($p < 0.001$) and participants reported mild pain. The scientists concluded from their results that the cardiac compensation of the pulmonary, mask-induced restrictions, which still functioned in healthy people, was probably no longer possible in patients with reduced cardiac output [31].

In another recent study, researchers tested fabric masks (community masks), surgical masks and FFP2/N95 masks in 26 healthy people during exercise on a cycle ergometer. All

masks also showed a measurable carbon dioxide (CO_2) retention ($PtcCO_2$) (statistically significant with $p < 0.001$) and, for N95 masks, a decrease in the oxygen saturation value SpO_2 (statistically significant at 75 and 100 W with $p < 0.02$ and $p < 0.005$, respectively). The clinical relevance of these changes was shown in an increase in breathing frequency with fabric masks ($p < 0.04$) as well as in the occurrence of the previously described mask-specific complaints such as a feeling of heat, shortness of breath and headaches. The stress perception was recorded on a Borg scale from 1 to 20. During physical exertion under an N95 mask, the group with masks showed a significant increase in the feeling of exhaustion compared to the group without with 14.6 versus 11.9 on the scale of 20. During the exposure, 14 of the 24 subjects wearing masks complained of shortness of breath (58%), four of headaches and two of a feeling of heat. Most of the complaints concerned FFP2 masks (72%) [21].

The aforementioned physiological and subjective physical effects of masks on healthy people at rest and under exertion [21,31] give an indication of the effect of masks on sick and elderly people even without exertion.

In an observational study of ten 20 to 50 year-old nurses wearing N95 masks during their shift work, side effects such as breathing difficulties ("I can't breathe"), feelings of exhaustion, headache ($p < 0.001$), drowsiness ($p < 0.001$) and a decrease in oxygen saturation SpO_2 ($p < 0.05$) as well as an increase in heart rate ($p < 0.001$) were statistically significant in association with an increase in obesity (BMI) [19]. The occurrence of symptoms under masks was also associated with older age (statistically significant correlation of fatigue and drowsiness with $p < 0.01$ each, nausea with $p < 0.05$, an increase in blood pressure with $p < 0.01$, headache with $p < 0.05$, breathing difficulties with $p < 0.001$) [19].

In an intervention study involving 97 patients with advanced chronic obstructive pulmonary disease (COPD) the respiratory rate, oxygen saturation and exhaled carbon dioxide equivalents (capnometry) changed unfavorably and significantly after the use of N95 masks (FFP2 equivalent) with an initial 10-minute rest and subsequent 6-minute walking. Seven patients discontinued the experiment due to serious complaints with a decrease in the oxygen saturation value SpO_2 and a pathological carbon dioxide (CO_2) retention as well as increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) [23]. In two patients, the $PETCO_2$ exceeded the normal limits and reached values of >50 mmHg. An FEV1 < 30% and a modified Medical Research Council (mMRC) Dyspnea Scale Score of $\geq$3, both indicators of advanced COPD, correlated with mask intolerance overall in this study. The most common symptom under mask was breathlessness at 86%. In the dropouts of the study, dizziness (57%) and headaches were also often recorded. In the mask-tolerant COPD patients, significant increases in heart rate, respiratory rate and end-expiratory carbon dioxide partial pressure $PETCO_2$ could be objectified even at rest, after only 10 min of mask-wearing ($p < 0.001$), accompanied by a decrease in oxygen saturation SpO_2 ($p < 0.001$) [23]. The results of this study with an evidence level IIa are indicative for COPD mask wearers.

In another retrospective comparative study on COPD and surgical masks, examiners were able to demonstrate statistically an increase in arterial partial pressure of carbon dioxide ($PaCO_2$) of approximately +8 mmHg ($p < 0.005$) and a concomitant mask-related increase in systolic blood pressure of +11 mmHg ($p < 0.02$) [25]. This increase is relevant in hypertensive patients, but also in healthy people with borderline blood pressure values as pathological value range triggered by mask-wearing can be induced.

In 39 hemodialysis patients with end-stage renal disease, a type N95 mask (FFP2 equivalent) caused a significant drop in blood oxygen partial pressure (PaO_2) in 70% of patients at rest (on hemodialysis) within only 4 h ($p = 0.006$). Despite a compensatory increased respiratory rate ($p < 0.001$), malaise with chest pain occurred ($p < 0.001$) and even resulted in hypoxemia (drop in oxygen below the normal limit) in 19% of the subjects [34]. The researchers concluded from their findings that elderly or patients with reduced cardiopulmonary function have a higher risk of developing a severe respiratory failure while wearing a mask [34].

In a review paper on the risks and benefits of masks worn during the COVID-19 crisis, other authors provide an equally critical assessment of mandatory mask use for patients with pneumonia, both with and without COVID-19 pneumonia disease [16].

3.3. Neurological Side Effects and Dangers

In a scientific evaluation of syncope in the operating theatre, 36 of 77 affected persons (47%) were associated with wearing a mask [62]. However, other factors could not be ruled out as contributory causes.

In their level III evidence review, neurologists from Israel, the UK and the USA state that a mask is unsuitable for epileptics because it can trigger hyperventilation [63]. The use of a mask significantly increases the respiratory rate by about plus 15 to 20% [15,21,23,34,64]. However, an increase in breathing frequency leading to hyperventilation is known to be used for provocation in the diagnosis of epilepsy and causes seizure-equivalent EEG changes in 80% of patients with generalized epilepsy and in up to 28% of focal epileptics [65].

Physicians from New York studied the effects of wearing masks of the surgical-type mask and N95 among medical personnel in a sample of 343 participants (surveyed using standardized, anonymized questionnaires). Wearing the masks caused detectable physical adverse effects such as impaired cognition (24% of wearers) and headaches in 71.4% of the participants. Of these, 28% persisted and required medication. Headache occurred in 15.2% under 1 h of wear, in 30.6% after 1 h of wear and in 29.7% after 3 h of wear. Thus, the effect intensified with increasing wearing time [37].

Confusion, disorientation and even drowsiness (Likert scale questionnaire) and reduced motoric abilities (measured with a linear position transducer) with reduced reactivity and overall impaired performance (measured with the Roberge Subjective Symptoms-during-Work Scale) as a result of mask use have also been documented in other studies [19,23,29,32,36,37].

The scientists explain these neurological impairments with a mask-induced latent drop in blood gas oxygen levels O_2 (towards hypoxia) or a latent increase in blood gas carbon dioxide levels CO_2 (towards hypercapnia) [36]. In view of the scientific data, this connection also appears to be indisputable [38–41].

In a mask experiment from 2020, significant impaired thinking ($p < 0.03$) and impaired concentration ($p < 0.02$) were found for all mask types used (fabric, surgical and N95 masks) after only 100 min of wearing the mask [29]. The thought disorders correlated significantly with a drop in oxygen saturation ($p < 0.001$) during mask use.

Initial headaches ($p < 0.05$) were experienced by up to 82% of 158, 21–35 year-old mask wearers in another study of N95 respiratory protection with one third (34%) experiencing headaches up to four times daily. Participants wore the mask for 18.3 days over a 30-day period with a mean of 5.9 h per day [66].

Significantly increased headache ($p < 0.05$) could be observed not only for N95 but also for surgical masks in participants of another observational study of health care workers [67].

In another study, the researchers classified 306 users with an average age of 43 years and wearing different types of masks, of whom 51% had an initial headache as a specific symptom related exclusively to increased surgical and N95 mask use (1 to 4 h, $p = 0.008$) [68].

Researchers from Singapore were able to demonstrate in a trial involving 154 healthy N95 health service mask wearers that a significant increase in mask-induced blood carbon dioxide levels (measured by end-expiratory partial pressure of carbon dioxide $PETCO_2$) and a measurably greater vasodilatation with an increase in cerebral artery flow in the cerebri media resulted. This was associated with headaches in the trial group ($p < 0.001$) [27].

According to the researchers, the aforementioned changes also contribute to headaches during the prolonged use of masks with a shift towards hypoxia and hypercapnia. Furthermore, stress and mechanical factors such as the irritation of cervical nerves in the neck and head area caused by the tight mask straps pressuring the nerve strands also contribute to headaches [66].

In the analysis of the primary studies, we were able to detect an association between the N95 mask and headaches. In six out of 10 studies, the significant headache appeared in conjunction with the N95 mask (60% of all studies, Figure 2).

3.4. Psychological Side Effects and Dangers

According to an experimental study, wearing surgical masks and N95 masks can also lead to a reduced quality of life owing to reduced cardiopulmonary capacity [31]. Masks, along with causing physiological changes and discomfort with progressive length of use, can also lead to significant discomfort ($p < 0.03$ to $p < 0.0001$) and a feeling of exhaustion ($p < 0.05$ to 0.0001) [69].

Besides the shift in blood gases towards hypercapnia (increase in CO_2) and hypoxia (decrease in O_2), detailed under general physiological effects (Section 3.1), masks also restrict the cognitive abilities of the individual (measured using a Likert scale survey) accompanied by a decline in psycho-motoric abilities and consequently a reduced responsiveness (measured using a linear position transducer) as well as an overall reduced performance capability (measured with the Roberge Subjective Symptoms-during-Work Scale) [29,32,38,39,41].

The mask also causes an impaired field of vision (especially affecting the ground and obstacles on the ground) and also presents an inhibition to habitual actions such as eating, drinking, touching, scratching and cleaning the otherwise uncovered part of the face, which is consciously and subconsciously perceived as a permanent disturbance, obstruction and restriction [36]. Wearing masks, thus, entails a feeling of deprivation of freedom and loss of autonomy and self-determination, which can lead to suppressed anger and subconscious constant distraction, especially as the wearing of masks is mostly dictated and ordered by others [70,71]. These perceived interferences of integrity, self-determination and autonomy, coupled with discomfort, often contribute to substantial distraction and may ultimately be combined with the physiologically mask-related decline in psychomotoric abilities, reduced responsiveness and an overall impaired cognitive performance. It leads to misjudging situations as well as delayed, incorrect and inappropriate behavior and a decline in the effectiveness of the mask wearer [36,37,39–41].

The use of masks for several hours often causes further detectable adverse effects such as headaches, local acne, mask-associated skin irritation, itching, sensations of heat and dampness, impairments and discomfort predominantly affecting the head and face [19,29,35–37,71–73]. However, the head and face are significant for well-being due to their large representation in the sensitive cerebral cortex (homunculus) [36].

According to a questionnaire survey, masks also frequently cause anxiety and psychovegetative stress reactions in children—as well as in adults—with an increase in psychosomatic and stress-related illnesses and depressive self-experience, reduced participation, social withdrawal and lowered health-related self-care [74]. Over 50% of the mask wearers studied had at least mild depressive feelings [74]. Additional fear-inducing and often exaggerated media coverage can further intensify this. A recent retrospective analysis of the general media in the context of the 2014 Ebola epidemic showed a scientific truth content of only 38% of all publicly published information [75]. Researchers classified a total of 28% of the information as provocative and polarizing and 42% as exaggerating risks. In addition, 72% of the media content aimed to stir up health-related negative feelings. The feeling of fear, combined with insecurity and the primal human need to belong [76], causes a social dynamic that seems partly unfounded from a medical and scientific point of view.

The mask, which originally served purely hygienic purpose, has been transformed into a symbol of conformity and pseudo-solidarity. The WHO, for example, lists the advantages of the use of masks by healthy people in public to include a potentially reduced stigmatization of mask wearers, a sense of contribution to preventing the spread of the virus and a reminder to comply with other measures [2].

3.5. Psychiatric Side Effects and Dangers

As explained earlier, masks can cause increased rebreathing with an accumulation of carbon dioxide in the wearer due to increased dead space volume [16–18,20] (Figure 3), with often statistically significant measurable elevated blood carbon dioxide (CO2) levels in sufferers [13,15,17,19–28] (Figure 2). However, changes that lead to hypercapnia are known to trigger panic attacks [77,78]. This makes the significantly measurable increase in CO_2 caused by wearing a mask clinically relevant.

Interestingly, breath provocation tests by inhaling CO_2 are used to differentiate anxiety states in panic disorders and premenstrual dysphoria from other psychiatric clinical pictures. Here, absolute concentrations of 5% CO_2 already suffice to trigger panic reactions within 15–16 min [77]. The normal exhaled air content of CO_2 is about 4%.

It is obvious from experimental studies on masked subjects that concentration changes in the respiratory gases in the above-mentioned range with values above 4% could occur during rebreathing with prolonged mask use [18,23].

The activation of the locus coeruleus by CO_2 is used to generate panic reactions via respiratory gases [78,79]. This is because the locus coeruleus is an important part of the system of vegetative noradrenergic neurons, a control center in the brainstem, which reacts to an appropriate stimulus and changes in the gas concentrations in the blood by releasing the stress hormone noradrenaline [78].

From the physiological, neurological and psychological side effects and dangers described above (Sections 3.1, 3.3 and 3.4), additional problems can be derived for the use of masks in psychiatric cases. People undergoing treatment for dementia, paranoid schizophrenia, personality disorders with anxiety and panic attacks, but also panic disorders with claustrophobic components, are difficult to reconcile with a mask requirement, because even small increases in CO_2 can cause and intensify panic attacks [44,77–79].

According to a psychiatric study, patients with moderate to severe dementia have no understanding of COVID-19 protection measures and have to be persuaded to wear masks constantly [80].

According to a comparative study, patients with schizophrenia have a lower acceptance of mask-wearing (54.9% agreement) than ordinary practice patients (61.6%) [81]. The extent to which mask-wearing can lead to an exacerbation of schizophrenia symptoms has not yet been researched in detail.

When wearing masks, confusion, impaired thinking, disorientation (standardized recording via special rating and Likert scales, $p < 0.05$) and in some cases a decrease in maximum speed and reaction time (measured with the linear-position transducer, $p < 0.05$) were observed [19,32,36,38–41]. Psychotropic drugs reduce psycho-motoric functions in psychiatric patients. This can become clinically relevant especially with regard to the further reduced ability to react and the additional increased susceptibility to accidents of such patients when wearing masks.

In order to avoid an unintentional CO_2-triggered anesthesia [39], fixed and medically sedated patients, without the possibility of continuous monitoring, should not be masked according to the criteria of the Centers for Disease Control and Prevention, USA (CDC). This is because of the possible CO_2 retention described above, as there is a risk of unconsciousness, aspiration and asphyxia [16,17,20,38,82,83].

3.6. Gynaecological Side Effects and Dangers

As a critical variable, a low blood carbon dioxide level in pregnant women is maintained via an increased respiratory minute volume, stimulated by progesterone [22]. For a pregnant woman and her unborn child, there is a metabolic need for a fetal–maternal carbon dioxide (CO_2) gradient. The mother's blood carbon dioxide level should always be lower than that of the unborn child in order to ensure the diffusion of CO_2 from the fetal blood into the maternal circulation via the placenta.

Therefore, mask-related phenomena described above (Sections 3.1 and 3.2), such as the measurable changes in respiratory physiology with increased breathing resistance,

increased dead space volume (Figure 3) and the retention of exhaled carbon dioxide (CO_2) are of importance. If CO_2 is increasingly rebreathed under masks, this manifestation could, even with subliminal carbon dioxide increases, act as a disturbing variable of the fetal–maternal CO_2 gradient increasing over time of exposure and, thus, develop clinical relevance, also with regard to a reduced compensation reserve of the expectant mothers [20,22,28].

In a comparative study, 22 pregnant women wearing N95 masks during 20 min of exercise showed significantly higher percutaneous CO_2 values, with average $PtcCO_2$ values of 33.3 mmHg compared to 31.3 mmHg than in 22 pregnant women without masks ($p = 0.04$) [22]. The heat sensation of the expectant mothers was also significantly increased with masks, with $p < 0.001$ [22].

Accordingly, in another intervention study, researchers demonstrated that breathing through an N95 mask (FFP2 equivalent) impeded gas exchange in 20 pregnant women at rest and during exercise, causing additional stress on their metabolic system [28]. Thus, under an N95 mask, 20 pregnant women showed a decrease in oxygen uptake capacity VO_2 of about 14% (statistically significant, $p = 0.013$) and a decrease in carbon dioxide output capacity VCO_2 of about 18% (statistically significant, $p = 0.001$). Corresponding significant changes in exhaled oxygen and carbon dioxide equivalents were also documented with increases in exhaled carbon dioxide ($FeCO_2$) ($p < 0.001$) and decreases in exhaled oxygen (FeO_2) ($p < 0.001$), which were explained by an altered metabolism due to respiratory mask obstruction [28].

In experiments with predominantly short mask application times, neither the mothers nor the fetuses showed statistically significant increases in heart rates or changes in respiratory rates and oxygen saturation values. However, the exact effects of prolonged mask use in pregnant women remain unclear overall. Therefore, in pregnant women, extended use of surgical and N95 masks is viewed critically [20].

In addition, it is unclear whether the substances contained in industrially manufactured masks that can be inhaled over longer periods of time (e.g., formaldehyde as an ingredient of the textile and thiram as an ingredient of the ear bands) are teratogenic [20,84].

3.7. Dermatological Side Effects and Dangers

Unlike garments worn over closed skin, masks cover body areas close to the mouth and nose, i.e., body parts that are involved with respiration.

Inevitably, this leads not only to a measurable temperature rise [15,44,85], but also to a severe increase in humidity due to condensation of the exhaled air, which in turn changes the natural skin milieu considerably of perioral and perinasal areas [36,61,82]. It also increases the redness, pH-value, fluid loss through the skin epithelium, increased hydration and sebum production measurably [73]. Preexisting skin diseases are not only perpetuated by these changes, but also exacerbated. In general, the skin becomes more susceptible to infections and acne.

The authors of an experimental study were able to prove a disturbed barrier function of the skin after only 4 h of wearing a mask in 20 healthy volunteers, both for surgical masks and for N95 masks [73]. In addition, germs (bacteria, fungi and viruses) accumulate on the outside and inside of the masks due to the warm and moist environment [86–89]. They can cause clinically relevant fungal, bacterial or viral infections. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German Robert Koch Institute (RKI) from 2020 [90] could be another indication of this phenomenon.

In addition, a region of the skin that is not evolutionarily adapted to such stimuli is subjected to increased mechanical stress. All in all, the above-mentioned facts cause the unfavorable dermatological effects with mask related adverse skin reactions like acne, rashes on the face and itch symptoms [91].

A Chinese research group reported skin irritation and itching when using N95 masks among 542 test participants and also a correlation between the skin damage that occurred and the time of exposure (68.9% at $\leq$6 h/day and 81.7% at >6 h/day) [92].

A New York study evaluated in a random sample of 343 participants the effects of frequent wearing of surgical mask type and N95 masks among healthcare workers during the COVID-19 pandemic. Wearing the masks caused headache in 71.4% of participants, in addition to drowsiness in 23.6%, detectable skin damage in 51% and acne in 53% of mask users [37].

On the one hand, direct mechanical skin lesions occur on the nose and cheekbones due to shear force, especially when masks are frequently put on and taken off [37,92].

On the other hand, masks create an unnaturally moist and warm local skin environment [29,36,82]. In fact, scientists were able to demonstrate a significant increase in humidity and temperature in the covered facial area in another study in which the test individuals wore masks for one hour [85]. The relative humidity under the masks was measured with a sensor (Atmo-Tube, San Francisco, CA, USA). The sensation of humidity and temperature in the facial area is more crucial for well-being than other body regions [36,44]. This can increase discomfort under the masks. In addition, the increase in temperature favors bacterial optimization.

The pressure of the masks also causes an obstruction of the flow physiology of lymph and blood vessels in the face, with the consequence of increased disturbance of skin function [73] and ultimately also contributing to acne in up to 53% of all wearers and other skin irritations in up to 51% of all wearers [36,37,82].

Other researchers examined 322 participants with N95 masks in an observational study and detected acne in up to 59.6% of them, itching in 51.4% and redness in 35.8% as side effects [72].

In up to 19.6% (273) of the 1393 wearers of different masks (community masks, surgical, N95 masks), itching could be objectified in one study, in 9% even severely. An atopic predisposition (allergy tendency) correlated with the risk of itching. The length of use was significantly related to the risk of itching ($p < 0.0001$) [93].

In another dermatological study from 2020, 96.9% of 876 users of all mask types (community masks, surgical masks, N95 masks) confirmed adverse problems with a significant increase in itching (7.7%), accompanied by fogging-up of glasses (21.3%), flushing (21.3%), slurred speech (12.3%) and difficulty breathing (35.9%) ($p < 0.01$) [71].

Apart from an increased incidence of acne [37,72,91] under masks, contact eczema and urticaria [94] are generally described in connection with hypersensitivities to ingredients of the industrially manufactured masks (surgical mask and N95) such as formaldehyde (ingredient of the textile) and thiram (ingredient of the ear bands) [73,84]. The hazardous substance thiram, originally a pesticide and corrosive, is used in the rubber industry as a optimization accelerator. Formaldehyde is a biocide and carcinogen and is used as a disinfectant in the industry.

Even isolated permanent hyperpigmentation as a result of post-inflammatory or pigmented contact dermatitis has been described by dermatologists after prolonged mask use [72,91].

3.8. ENT and Dental Side Effects and Dangers

There are reports from dental communities about negative effects of masks and are accordingly titled “mask mouth” [95]. Provocation of gingivitis (inflammation of the gums), halitosis (bad breath), candidiasis (fungal infestation of the mucous membranes with Candida albicans) and cheilitis (inflammation of the lips), especially of the corners of the mouth, and even plaque and caries are attributed to the excessive and improper use of masks. The main trigger of the oral diseases mentioned is an increased dry mouth due to a reduced saliva flow and increased breathing through the open mouth under the mask. Mouth breathing causes surface dehydration and reduced salivary flow rate (SFR) [95]. Dry mouth is scientifically proven due to mask wear [29]. The bad habit of breathing through the open mouth while wearing a mask seems plausible because such breathing pattern compensates for the increased breathing resistance, especially when inhaling through the masks [60,61]. In turn, the outer skin moisture [71,73,85] with altered

skin flora, which has already been described under dermatological side effects (Section 3.7), is held responsible as an explanation for the inflammation of the lips and corners of the mouth (cheilitis) [95]. This clearly shows the disease-promoting reversal of the natural conditions caused by masks. The physiological internal moisture with external dryness in the oral cavity converts into internal dryness with external moisture.

ENT physicians recently discovered a new form of irritant rhinitis due to N95 mask use in 46 patients. They performed endoscopies and nasal irrigations on mask wearers, which were subsequently assessed pathologically. Clinical problems were recorded with standardized questionnaires. They found statistically significant evidence of mask-induced rhinitis and itching and swelling of the mucous membranes as well as increased sneezing ($p < 0.01$). Endoscopically, it showed an increased secretion and evidence of inhaled mask polypropylene fibers as the trigger of mucosal irritation [96].

In a study of 221 health care workers, ENT physicians objectified a voice disorder in 33% of mask users. The VHI-10 score of 1 to 10, which measures voice disorders, was on average 5.72 higher in these mask users (statistically significant with $p < 0.001$). The mask not only acted as an acoustic filter, provoking excessively loud speech, it also seems to trigger impaired vocal cord coordination because the mask compromises the pressure gradients required for undisturbed speech [43]. The researchers concluded from their findings that masks could pose a potential risk of triggering new voice disorders as well as exacerbating existing ones.

3.9. Sports Medicine Side Effects and Dangers

According to the literature, performance-enhancing effects of masks regarding cardiovascular optimization and improvement of oxygen uptake capacity cannot be proven.

For example, in an experimental reference study (12 subjects per group), the training mask that supposedly mimics altitude training (ETM: elevation training mask) only had training effects on the respiratory muscles. However, mask wearers showed significantly lower oxygen saturation values (SpO_2%) during exercise (SpO_2 of 94% for mask wearers versus 96% for mask-less, $p < 0.05$) [33], which can be explained by an increased dead space volume and increased resistance during breathing. The measured oxygen saturation values were significantly lower than the normal values in the group of mask wearers, which indicates a clinical relevance.

The proven adaptation effect of the respiratory muscles in healthy athletes [33] clearly suggests that masks have a disruptive effect on respiratory physiology.

In another intervention study on mask use in weightlifters, researchers documented statistically significant effects of reduced attention (questionnaire recording, Likert scale) and a slowed maximum speed of movement detectable by means of sensors (both significant at $p < 0.001$), leading the researchers to conclude that mask use in sport is not without risks. As a secondary finding, they also detected a significant decrease in oxygen saturation SpO_2 when performing special weight-lifting exercises ("back squats") in the mask group after only 1 min of exercise compared to the mask-free group ($p < 0.001$) [32]. The proven tendency of the masks to shift the chemical parameter oxygen saturation SpO_2 in a pathological direction (lower limit value 95%) may well have clinical relevance in untrained or sick individuals.

Sports medicine confirmed an increase in carbon dioxide (CO_2) retention, with an elevation in CO_2 partial pressure in the blood with larger respiratory dead space volumes [14].

In fact, dead space-induced CO_2 retention while wearing a mask during exercise was also experimentally proven. The effects of a short aerobic exercise under N95 masks were tested on 16 healthy volunteers. A significantly increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) with plus 8 mmHg ($p < 0.001$) was found [24]. The increase in blood carbon dioxide (CO_2) in the mask wearers under maximum load was plus 14% CO_2 for surgical masks and plus 23% CO_2 for N95 masks, an effect that may well have clinical relevance in the pre-diseased, elderly and children, as these values strongly approached the pathological range [24].

In an interesting endurance study with eight middle-aged subjects (19–66), the gas content for O_2 and CO_2 under the masks was determined before and after exercise. Even at rest, the oxygen availability under the masks was 13% lower than without the masks and the carbon dioxide (CO_2) concentration was 30 times higher. Under stress (Ruffier test), the oxygen concentration (% O_2) below the mask dropped significantly by a further 3.7%, while the carbon dioxide concentration (% CO_2) increased significantly by a further 20% (statistically significant with $p < 0.001$). Correspondingly, the oxygen saturation of the blood (SpO_2) of the test persons also decreased significantly from 97.6 to 92.1% ($p < 0.02$) [18]. The drop in the oxygen saturation value (SpO_2) to 92%, clearly below the normal limit of 95%, is to be classified as clinically relevant and detrimental to health.

These facts are an indication that the use of masks also triggers the effects described above leading to hypoxia and hypercapnia in sports. Accordingly, the WHO and Centers for Disease Control and Prevention, GA, USA (CDC) advise against wearing masks during physical exercise [82,97].

3.10. Social and Sociological Side Effects and Dangers

The results of a Chilean study with health care workers show that masks act like an acoustic filter and provoke excessively loud speech. This causes a voice disorder [43]. The increased volume of speech also contributes to increased aerosol production by the mask wearer [98]. These experimental data measured with the Aerodynamic Particle Sizer (APS, TSI, model 332, TSI Incorporated, Minnesota, MI, USA) are highly relevant.

Moreover, mask wearers are prevented from interacting normally in everyday life due to impaired clarity of speech [45], which tempts them to get closer to each other.

This results in a distorted prioritization in the general public, which counteracts the recommended measures associated with the COVID-19 pandemic. The WHO prioritizes social distancing and hand hygiene with moderate evidence and recommends wearing a mask with weak evidence, especially in situations where individuals are unable to maintain a physical distance of at least 1 m [3].

The disruption of non-verbal communication due to the loss of facial expression recognition under the mask can increase feelings of insecurity, discouragement and numbness as well as isolation, which can be extremely stressful for the mentally and hearing-impaired [16].

Experts point out that masks disrupt the basics of human communication (verbal and nonverbal). The limited facial recognition caused by masks leads to a suppression of emotional signals. Masks, therefore, disrupt social interaction, erasing the positive effect of smiles and laughter but at the same time greatly increasing the likelihood of misunderstandings because negative emotions are also less evident under masks [42].

A decrease in empathy perception through mask use with disruption of the doctor–patient relationship has already been scientifically proven on the basis of a randomized study (statistically significant, with $p = 0.04$) [99]. In this study, the Consultation Empathy Care Measury, the Patient Enablement Instrument (PEI) Score and a Satisfaction Rating Scale were assessed in 1030 patients. The 516 doctors, who wore masks throughout, conveyed reduced empathy towards the patients and, thus, nullified the positive health-promoting effects of a dynamic relationship. These results demonstrate a disruption of interpersonal interaction and relationship dynamics caused by masks.

The WHO guidance on the use of masks in children in the community, published in August 2020, points out that the benefits of mask use in children must be weighed up against the potential harms, including social and communicational concerns [100].

Fears that widespread pandemic measures will lead to dysfunctional social life with degraded social, cultural and psychological interactions have also been expressed by other experts [6–8,42].

3.11. Social and Occupational Medicine Side Effects and Hazards

In addition to mask-specific complaints such as a feeling of heat, dampness, shortness of breath and headache, various physiological phenomena were documented, such as the significant increase in heart and respiratory rate, the impairment of lung function parameters, the decrease in cardiopulmonary capacity (e.g., lower maximum blood lactate response) [15,19,21,23,29–31], as well as the changes in oxygen and carbon dioxide both in the end-expiratory and the air under the mask that was measured in the blood of the individuals [13,15,18,19,21–25,27–34]. The significant changes were measurable after only a few minutes of wearing a mask and in some cases reached magnitudes of minus 13% reduced O_2 concentration and 30-fold increased CO_2 concentration of the inhaled air under masks ($p < 0.001$) [18]. The changes observed were not only statistically significant, but also clinically relevant; the subjects also showed pathological oxygen saturation after exposure to masks ($p < 0.02$) [18].

Shortness of breath during light exertion (6 min walking) under surgical masks has been recorded with statistical significance in 44 healthy subjects in a prospective experimental intervention study ($p < 0.001$) [101]. Here, the complaints were assessed using a subjective, visual analogue scale.

In another study from 2011, all tested masks caused a significantly measurable increase in discomfort and a feeling of exhaustion in the 27 subjects during prolonged usage ($p < 0.0001$) [69].

These symptoms lead to additional stress for the occupational mask wearer and, thus, in relation to the feeling of exhaustion, contribute to the self-perpetuating vicious circle caused by the vegetative sympathetic activation, which further increases the respiratory and heart rate, blood pressure and increased sense of exhaustion [16,20,35,83].

Other studies showed that the psychological and physical effects of the masks can lead to an additional reduction in work performance (measured with the Roberge Subjective Symptoms-during-Work Scale, a Likert scale of 1–5) via increased feelings of fatigue, dissatisfaction and anxiety [58,102,103].

Wearing masks over a longer period of time also led to physiological and psychological impairments in other studies and, thus, reduced work performance [19,36,58,69]. In experiments on respiratory-protective equipment, an increase in the dead space volume by 350 mL leads to a reduction in the possible performance time by approx. −19%, furthermore to a decrease in breathing comfort by −18% (measured via a subjective rating scale) [58]. In addition, the time spent working and the flow of work is interrupted and reduced by putting on and taking off the masks and changing them. The reduced work performance has been recorded in the literature found as described above (especially in Sections 3.1 and 3.2) but has not been quantified further in detail [36,58].

Surgical mask type and N95 protective equipment frequently caused adverse effects in medical personnel such as headaches, breathing difficulties, acne, skin irritation, itching, decreased alertness, decreased mental performance and feelings of dampness and heat [19,29,37,71,85]. Subjective, work performance-reducing, mask-related impairments in users, measured with special survey scores and Likert scales, have also been described in other studies [15,21,27,32,35,43,66–68,72,96,99].

In Section 3.7 on dermatology, we already mentioned a paper that demonstrated a significant temperature increase of 1.9 °C on average (to over 34.5 °C) in the mask-covered facial area ($p < 0.05$) [85]. Due to the relatively larger representation in the sensitive cerebral cortex (homunculus), the temperature sensation in the face is more decisive for the feeling of well-being than other body regions [36,44]. The perception of discomfort when wearing a mask can, thus, be intensified. Interestingly, in our analysis, we found a combined occurrence of the physical variable temperature rise under the mask and the symptom respiratory impairment in seven of eight studies concerned, with a mutual significantly measured occurrence in 88%. We also detected a combined occurrence of significantly measured temperature rise under the mask and significantly measured fatigue in 50% of the relevant primary studies (three of six papers, Figure 2). These clustered associations of

temperature rise with symptoms of respiratory impairment and fatigue suggest a clinical relevance of the detected temperature rise under masks. In the worst case scenario, the effects mentioned can reinforce each other and lead to decompensation, especially in the presence of COPD, heart failure and respiratory insufficiency.

The sum of the disturbances and discomforts that can be caused by a mask also contributes to distraction (see also psychological impairment). These, in conjunction with a decrease in psycho-motoric skills, reduced responsiveness and overall impaired cognitive performance (all of which are pathophysiological effects of wearing a mask) [19,29,32,39–41] can lead to a failure to recognize hazards and, thus, to accidents or avoidable errors at work [19,36,37]. Of particular note here are mask-induced listlessness ($p < 0.05$), impaired thinking ($p < 0.05$) and concentration problems ($p < 0.02$) as measured by a Likert scale (1–5) [29]. Accordingly, occupational health regulations take action against such scenarios. The German Industrial Accident Insurance (DGUV) has precise and extensive regulations for respiratory protective equipment where they document the limitation of wearing time, levels of work intensity and defined instruction obligation [104].

The standards and norms prescribed in many countries regarding different types of masks to protect their workers are also significant from an occupational health point of view [105]. In Germany, for example, there are very strict safety specifications for masks from other international countries. These specify the requirements for the protection of the wearer [106]. All these standards and the accompanying certification procedures were increasingly relaxed with the introduction of mandatory masks for the general public. This meant that non-certified masks such as community masks were also used on a large scale in the work and school sectors for longer periods during the pandemic measures [107]. Most recently, in October 2020, the German Social Accident Insurance (DGUV) recommended the same usage time limits for community masks as for filtering half masks, namely, a maximum of three shifts of 120 min per day with recovery breaks of 30 min in between. In Germany, FFP2 (N95) masks must be worn for 75 min, followed by a 30-minute break. An additional suitability examination by specialized physicians is also obligatory and stipulated for occupationally used respirators [104].

3.12. Microbiological Consequences for Wearer and Environment: Foreign/Self-Contamination

Masks cause retention of moisture [61]. Poor filtration performance and incorrect use of surgical masks and community masks, as well as their frequent reuse, imply an increased risk of infection [108–110]. The warm and humid environment created by and in masks without the presence of protective mechanisms such as antibodies, the complement system, defense cells and pathogen-inhibiting and on a mucous membrane paves the way for unimpeded growth and, thus, an ideal growth and breeding ground for various pathogens such as bacteria and fungi [88] and also allows viruses to accumulate [87]. The warm and humid mask microclimate favors the accumulation of various germs on and underneath the masks [86], and the germ density is measurably proportional to the length of time the mask is worn. After only 2 h of wearing the mask, the pathogen density increases almost tenfold in experimental observation studies [87,89].

From a microbiological and epidemiological point of view, masks in everyday use pose a risk of contamination. This can occur as foreign contamination but also as self-contamination. On the one hand, germs are sucked in or attach themselves to the masks through convection currents. On the other hand, potential infectious agents from the nasopharynx accumulate excessively on both the outside and inside of the mask during breathing [5,88]. This is compounded by contact with contaminated hands. Since masks are constantly penetrated by germ-containing breath and the pathogen reproduction rate is higher outside mucous membranes, potential infectious pathogens accumulate excessively on the outside and inside of masks. On and in the masks, there are quite serious, potentially disease-causing bacteria and fungi such as *E. coli* (54% of all germs detected), Staphylococcus aureus (25% of all germs detected), Candida (6%), Klebsiella (5%), Enterococci (4%),

Pseudomonads (3%), Enterobacter (2%) and Micrococcus (1%) even detectable in large quantities [88].

In another microbiological study, the bacterium Staphylococcus aureus (57% of all bacteria detected) and the fungus Aspergillus (31% of all fungi detected) were found to be the dominant germs on 230 surgical masks examined [86].

After more than six hours of use, the following viruses were found in descending order on 148 masks worn by medical personnel: adenovirus, bocavirus, respiratory syncytial virus and influenza viruses [87].

From this aspect, it is also problematic that moisture distributes these potential pathogens in the form of tiny droplets via capillary action on and in the mask, whereby further proliferation in the sense of self- and foreign contamination by the aerosols can then occur internally and externally with every breath [35]. In this regard, it is also known from the literature that masks are responsible for a proportionally disproportionate production of fine particles in the environment and, surprisingly, much more so than in people without masks [98].

It was shown that all mask-wearing subjects released significantly more smaller particles of size 0.3–0.5 µm into the air than mask-less people, both when breathing, speaking and coughing (fabric, surgical, N95 masks, measured with the Aerodynamic Particle Sizer, APS, TS, model 3329) [98]. The increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be a further indication of this phenomenon, as masks were consistently used by the general population in public spaces in that year.

3.13. Epidemiological Consequences

The possible side effects and dangers of masks described in this paper are based on studies of different types of masks. These include the professional masks of the surgical mask type and N95/KN95 (FFP2 equivalent) that are commonly used in everyday life, but also the community fabric masks that were initially used. In the case of N95, the N stands for National Institute for Occupational Safety and Health of the United States (NIOSH), and 95 indicates the 95 per cent filtering capacity for fine particles up to at least 0.3 µm [82].

A major risk of mask use in the general public is the creation of a false sense of security with regard to protection against viral infections, especially in the sense of a falsely assumed strong self-protection. Disregarding infection risks may not only neglect aspects of source control, but also result in other disadvantages. Although there are quite a few professional positive accounts of the widespread use of masks in the general populace [111], most of the serious and evident scientific reports conclude that the general obligation to wear masks conveys a false sense of security [4,5]. However, this leads to a neglect of those measures that, according to the WHO, have a higher level of effectiveness than mask-wearing: social distancing and hand hygiene [2,112]. Researchers were able to provide statistically significant evidence of a false sense of security and more risky behavior when wearing masks in an experimental setting [112].

Decision makers in many countries informed their citizens early on in the pandemic in March 2020 that people without symptoms should not use a medical mask, as this created a false sense of security [113]. The recommendation was ultimately changed in many countries. At least Germany pointed out that wearers of certain types of masks such as the common fabric masks (community masks) cannot rely on them to protect them or others from transmission of SARS-CoV-2 [114].

However, scientists not only complain about the lack of evidence for fabric masks in the scope of a pandemic [16,110], but also about the high permeability of fabric masks with particles and the potential risk of infection they pose [108,109]. Ordinary fabric masks with a 97% penetration for particle dimensions of $\geq$0.3 µm are in stark contrast to medical-type surgical masks with a 44% penetration. In contrast, the N95 mask has a penetration rate of less than 0.01% for particles $\geq$ 0.3 µm in the laboratory experiment [108,115].

For the clinical setting in hospitals and outpatient clinics, the WHO guidelines recommend only surgical masks for influenza viruses for the entire patient treatment except for the strongly aerosol-generating measures, for which finer filtering masks of the type N95 are suggested. However, the WHO's endorsement of specific mask types is not entirely evidence-based due to the lack of high-quality studies in the health sector [108,109,116,117].

In a laboratory experiment (evidence level IIa study), it was demonstrated that both surgical masks and N95 masks have deficits in protection against SARS-CoV-2 and influenza viruses using virus-free aerosols [118]. In this study, the FFP2-equivalent N95 mask performed significantly better in protection (8–12 times more effective) than the surgical mask, but neither mask type established reliable, hypothesis-generated protection against corona and influenza viruses. Both mask types could be penetrated unhindered by aerosol particles with a diameter of 0.08 to 0.2 µm. Both the SARS-CoV-2 pathogens with a size of 0.06 to 0.14 µm [119] and the influenza viruses with 0.08 to 0.12 µm are unfortunately well below the mask pore sizes [118].

The filtering capacity of the N95 mask up to 0.3 µm [82] is usually not achieved by surgical masks and community masks. However, aerosol droplets, which have a diameter of 0.09 to 3 µm in size, are supposed to serve as a transport medium for viruses. These also penetrate the medical masks by 40%. Often, there is also a poor fit between the face and the mask, which further impairs their function and safety [120]. The accumulation of aerosol droplets on the mask is problematic. Not only do they absorb nanoparticles such as viruses [6], but they also follow the airflow when inhaling and exhaling, causing them to be carried further. In addition, a physical decay process has been described for aerosol droplets at increasing temperatures, as also occurs under a mask [15,44,85]. This process can lead to a decrease in size of the fine water droplets up to the diameter of a virus [121,122]. The masks filter larger aerosol droplets but cannot retain viruses themselves and such smaller, potentially virus-containing aerosol droplets of less than 0.2 µm and hence cannot stop the spread of virus [123].

Similarly, in an in vivo comparative studies of N95 and surgical masks, there were no significant differences in influenza virus infection rates [124,125]. Although this contrasts with encouraging in vitro laboratory results with virus-free aerosols under non-natural conditions, even with fabric masks [126], it should be noted that under natural in-vivo conditions, the promising filtration functions of fabric masks based on electrostatic effects also rapidly diminish under increasing humidity [127]. A Swiss textile lab test of various masks available on the market to the general public recently confirmed that most mask types filter aerosols insufficiently. For all but one of the eight reusable fabric mask types tested, the filtration efficacy according to EN149 was always less than 70% for particles of 1 µm in size. For disposable masks, only half of all eight mask types tested were efficient enough at filtering to retain 70% of particles 1 µm in size [128].

A recent experimental study even demonstrated that all mask-wearing people (surgical, N95, fabric masks) release significantly and proportionately smaller particles of size 0.3 to 0.5 µm into the air than mask-less people, both when breathing, speaking and coughing [98]. According to this, the masks act like nebulizers and contribute to the production of very fine aerosols. Smaller particles, however, spread faster and further than large ones for physical reasons. Of particular interest in this experimental reference study was the finding that a test subject wearing a single-layer fabric mask was also able to release a total of 384% more particles (of various sizes) when breathing than a person without [98].

It is not only the aforementioned functional weaknesses of the masks themselves that lead to problems, but also their use. This increases the risk of a false sense of security. According to the literature, mistakes are made by both healthcare workers and lay people when using masks as hygienically correct mask use is by no means intuitive. Overall, 65% of healthcare professionals and as many as 78% of the general population, use masks incorrectly [116]. With both surgical masks and N95 masks, adherence to the rules of use is impaired and not adequately followed due to reduced wearability with heat discomfort and skin irritation [29,35,116,129]. This is exacerbated by the accumulation of carbon dioxide

due to the dead space (especially under the N95 masks) with the resulting headaches described [19,27,37,66–68,83]. Increased heart rate, itching and feelings of dampness [15,29,30,35,71] also lead to reduced safety and quality during use (see also social and occupational health side effects and hazards). For this reason, (everyday) masks are even considered a general risk for infection in the general population, which does not come close to imitating the strict hygiene rules of hospitals and doctors' offices: the supposed safety, thus, becomes a safety risk itself [5].

In a meta-analysis of evidence level Ia commissioned by the WHO, no effect of masks in the context of influenza virus pandemic prevention could be demonstrated [130]. In 14 randomized controlled trials, no reduction in the transmission of laboratory-confirmed influenza infections was shown. Due to the similar size and distribution pathways of the virus species (influenza and Corona, see above), the data can also be transferred to SARS-CoV-2 [118]. Nevertheless, a combination of occasional mask-wearing with adequate hand-washing caused a slight reduction in infections for influenza in one study [131]. However, since no separation of hand hygiene and masks was achieved in this study, the protective effect can rather be attributed to hand hygiene in view of the aforementioned data [131].

A recently published large prospective Danish comparative study comparing mask wearers and non-mask wearers in terms of their infection rates with SARS-CoV2 could not demonstrate any statistically significant differences between the groups [132].

3.14. Paediatric Side Effects and Hazards

Children are particularly vulnerable and may be more likely to receive inappropriate treatment or additional harm. It can be assumed that the potential adverse mask effects described for adults are all the more valid for children (see Section 3.1 to Section 3.13: physiological internal, neurological, psychological, psychiatric, dermatological, ENT, dental, sociological, occupational and social medical, microbiological and epidemiological impairments and also Figures 2 and 3).

Special attention must be paid to the respiration of children, which represents a critical and vulnerable physiological variable due to higher oxygen demand, increased hypoxia susceptibility of the CNS, lower respiratory reserve, smaller airways with a stronger increase in resistance when the lumen is narrowed. The diving reflex caused by stimulating the nose and upper lip can cause respiratory arrest to bradycardia in the event of oxygen deficiency.

The masks currently used for children are exclusively adult masks manufactured in smaller geometric dimensions and had neither been specially tested nor approved for this purpose [133].

In an experimental British research study, the masks frequently led to feelings of heat ($p < 0.0001$) and breathing problems ($p < 0.03$) in 100 school children between 8 and 11 years of age especially during physical exertion, which is why the protective equipment was taken off by 24% of the children during physical activity [133]. The exclusion criteria for this mask experiment were lung disease, cardiovascular impairment and claustrophobia [133].

Scientists from Singapore were able to demonstrate in their level Ib study published in the renowned journal "nature" that 106 children aged between 7 and 14 years who wore FFP2 masks for only 5 min showed an increase in the inspiratory and expiratory CO_2 levels, indicating disturbed respiratory physiology [26].

However, a disturbed respiratory physiology in children can have long-term disease-relevant consequences. Slightly elevated CO_2 levels are known to increase heart rate, blood pressure, headache, fatigue and concentration disorders [38].

Accordingly, the following conditions were listed as exclusion criteria for mask use [26]: any cardiopulmonary disease including but not limited to: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema; any condition that may be aggravated by physical exertion, including but not limited to: exercise-induced asthma; lower respiratory tract infections (pneumonia, bronchitis within the last 2 weeks), anxiety disorders,

diabetes, hypertension or epilepsy/attack disorder; any physical disability due to medical, orthopedic or neuromuscular disease; any acute upper respiratory illness or symptomatic rhinitis (nasal obstruction, runny nose or sneezing); any condition with deformity that affects the fit of the mask (e.g., increased facial hair, craniofacial deformities, etc.).

It is also important to emphasize the possible effects of masks in neurological diseases, as described earlier (Section 3.3).

Both masks and face shields caused fear in 46% of children (37 out of 80) in a scientific study. If children are given the choice of whether the doctor examining them should wear a mask they reject this in 49% of the cases. Along with their parents, the children prefer the practitioner to wear a face visor (statistically significant with $p < 0.0001$) [134].

A recent observational study of tens of thousands of mask-wearing children in Germany helped the investigators objectify complaints of headaches (53%), difficulty concentrating (50%), joylessness (49%), learning difficulties (38%) and fatigue in 37% of the 25,930 children evaluated. Of the children observed, 25% had new onset anxiety and even nightmares [135]. In children, the threat scenarios generated by the environment are further maintained via masks, in some cases, even further intensified, and in this way, existing stress is intensified (presence of subconscious fears) [16,35,136,137].

This can in turn lead to an increase in psychosomatic and stress-related illnesses [74,75]. For example, according to an evaluation, 60% of mask wearers showed stress levels of the highest grade 10 on a scale of 1 to a maximum of 10. Less than 10% of the mask wearers surveyed had a stress level lower than 8 out of a possible 10 [74].

As children are considered a special group, the WHO also issued a separate guideline on the use of masks in children in the community in August 2020, explicitly advising policy makers and national authorities, given the limited evidence, that the benefits of mask use in children must be weighed up against the potential harms associated with mask use. This includes feasibility and discomfort, as well as social and communication concerns [100].

According to experts, masks block the foundation of human communication and the exchange of emotions and not only hinder learning but deprive children of the positive effects of smiling, laughing and emotional mimicry [42]. The effectiveness of masks in children as a viral protection is controversial, and there is a lack of evidence for their widespread use in children; this is also addressed in more detail by the scientists of the German University of Bremen in their thesis paper 2.0 and 3.0 [138].

3.15. Effects on the Environment

According to WHO estimates of a demand of 89 million masks per month, their global production will continue to increase under the Corona pandemic [139]. Due to the composition of, e.g., disposable surgical masks with polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester [140], an increasing global challenge, also from an environmental point of view, can be expected, especially outside Europe, in the absence of recycling and disposal strategies [139]. The aforementioned single use polymers have been identified as a significant source of plastic and plastic particles for the pollution of all water cycles up to the marine environment [141].

A significant health hazard factor is contributed by mask waste in the form of microplastics after decomposition into the food chain. Likewise, contaminated macroscopic disposable mask waste—especially before microscopic decay—represents a widespread medium for microbes (protozoa, bacteria, viruses, fungi) in terms of invasive pathogens [86–89,142]. Proper disposal of bio-contaminated everyday mask material is insufficiently regulated even in western countries.

4. Discussion

The potential drastic and undesirable effects found in multidisciplinary areas illustrate the general scope of global decisions on masks in general public in the light of combating the pandemic. According to the literature found, there are clear, scientifically recorded adverse effects for the mask wearer, both on a psychological and on a social and physical level.

Neither higher level institutions such as the WHO or the European Centre for Disease Prevention and Control (ECDC) nor national ones, such as the Centers for Disease Control and Prevention, GA, USA (CDC) or the German RKI, substantiate with sound scientific data a positive effect of masks in the public (in terms of a reduced rate of spread of COVID-19 in the population) [2,4,5].

Contrary to the scientifically established standard of evidence-based medicine, national and international health authorities have issued their theoretical assessments on the masks in public places, even though the compulsory wearing of masks gives a deceptive feeling of safety [5,112,143].

From an infection epidemiological point of view, masks in everyday use offer the risk of self-contamination by the wearer from both inside and outside, including via contaminated hands [5,16,88]. In addition, masks are soaked by exhaled air, which potentially accumulates infectious agents from the nasopharynx and also from the ambient air on the outside and inside of the mask. In particular, serious infection-causing bacteria and fungi should be mentioned here [86,88,89], but also viruses [87]. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be an indication of this phenomenon. Clarification through further investigations would therefore be desirable.

Masks, when used by the general public, are considered by scientists to pose a risk of infection because the standardized hygiene rules of hospitals cannot be followed by the general public [5]. On top of that, mask wearers (surgical, N95, fabric masks) exhale relatively smaller particles (size 0.3 to 0.5 µm) than mask-less people and the louder speech under masks further amplifies this increased fine aerosol production by the mask wearer (nebulizer effect) [98].

The history of modern times shows that already in the influenza pandemics of 1918–1919, 1957–58, 1968, 2002, in SARS 2004–2005 as well as with the influenza in 2009, masks in everyday use could not achieve the hoped-for success in the fight against viral infection scenarios [67,144]. The experiences led to scientific studies describing as early as 2009 that masks do not show any significant effect with regard to viruses in an everyday scenario [129,145]. Even later, scientists and institutions rated the masks as unsuitable to protect the user safely from viral respiratory infections [137,146,147]. Even in hospital use, surgical masks lack strong evidence of protection against viruses [67].

Originally born out of the useful knowledge of protecting wounds from surgeons' breath and predominantly bacterial droplet contamination [144,148,149], the mask has been visibly misused with largely incorrect popular everyday use, particularly in Asia in recent years [150]. Significantly, the sociologist Beck described the mask as a cosmetic of risk as early as 1992 [151]. Unfortunately, the mask is inherent in a vicious circle: strictly speaking, it only protects symbolically and at the same time represents the fear of infection. This phenomenon is reinforced by the collective fear mongering, which is constantly nurtured by main stream media [137].

Nowadays, the mask represents a kind of psychological support for the general population during the virus pandemic, promising them additional anxiety-reduced freedom of movement. The recommendation to use masks in the sense of "source control" not out of self-protection but out of "altruism" [152] is also very popular with the regulators as well as the population of many countries. The WHO's recommendation of the mask in the current pandemic is not only a purely infectiological approach, but is also clear on the possible advantages for healthy people in the general public. In particular, a reduced potential stigmatization of mask wearers, the feeling of a contribution made to preventing the spread of the virus, as well as the reminder to adhere to other measures are mentioned [2].

It should not go unmentioned that very recent data suggest that the detection of SARS-CoV-2 infection does not seem to be directly related to popular mask use. The groups examined in a retrospective comparative study (infected with SARS-CoV-2 and not infected) did not differ in their habit of using masks: approximately 70% of the subjects in both groups always wore masks and another 14.4% of them frequently [143].

In a Danish prospective study on mask-wearing carried out on about 6000 participants and published in 2020, scientists found no statistically significant difference in the rates of SARS-CoV-2 infection when comparing the group of 3030 mask wearers with the 2994 maskless participants in the study ($p = 0.38$) [132].

Indeed, in the case of viral infections, masks appear to be not only less effective than expected, but also not free of undesirable biological, chemical, physical and psychological side effects [67]. Accordingly, some experts claim that well-intentioned unprofessionalism can be quite dangerous [6].

The dermatological colleagues were the first to describe common adverse effects of mask-wearing in larger collectives. Simple, direct physical, chemical and biological effects of the masks with increases in temperature, humidity and mechanical irritation caused acne in up to 60% of wearers [37,71–73,85]. Other significantly documented consequences were eczema, skin damage and overall impaired skin barrier function [37,72,73].

These direct effects of mask use are an important pointer to further detrimental effects affecting other organ systems.

In our work, we have identified scientifically validated and numerous statistically significant adverse effects of masks in various fields of medicine, especially with regard to a disruptive influence on the highly complex process of breathing and negative effects on the respiratory physiology and gas metabolism of the body (see Figures 2 and 3). The respiratory physiology and gas exchange play a key role in maintaining a health-sustaining balance in the human body [136,153]. According to the studies we found, a dead space volume that is almost doubled by wearing a mask and a more than doubled breathing resistance (Figure 3) [59–61] lead to a rebreathing of carbon dioxide with every breathing cycle [16–18,39,83] with—in healthy people mostly—a subthreshold but, in sick people, a partly pathological increase in the carbon dioxide partial pressure ($PaCO_2$) in the blood [25,34,58]. According to the primary studies found, these changes contribute reflexively to an increase in respiratory frequency and depth [21,23,34,36] with a corresponding increase in the work of the respiratory muscles via physiological feedback mechanisms [31,36]. Thus, it is not, as initially assumed, purely positive training through mask use. This often increases the subliminal drop in oxygen saturation SpO_2 in the blood [23,28–30,32], which is already reduced by increased dead space volume and increased breathing resistance [18,31].

The overall possible resulting measurable drop in oxygen saturation O_2 of the blood on the one hand [18,23,28–30,32] and the increase in carbon dioxide (CO_2) on the other [13,15,19,21–28] contribute to an increased noradrenergic stress response, with heart rate increase [29,30,35] and respiratory rate increase [15,21,23,34], in some cases also to a significant blood pressure increase [25,35].

In panic-prone individuals, stress-inducing noradrenergic sympathetic activation can be partly directly mediated via the carbon dioxide (CO_2) mechanism at the locus coeruleus in the brainstem [39,78,79,153], but also in the usual way via chemo-sensitive neurons of the nucleus solitarius in the medulla [136,154]. The nucleus solitarius [136] is located in the deepest part of the brainstem, a gateway to neuronal respiratory and circulatory control [154]. A decreased oxygen (O_2) blood level there causes the activation of the sympathetic axis via chemoreceptors in the carotids [155,156].

Even subthreshold changes in blood gases such as those provoked when wearing a mask cause reactions in these control centers in the central nervous system. Masks, therefore, trigger direct reactions in important control centers of the affected brain via the slightest changes in oxygen and carbon dioxide in the blood of the wearer [136,154,155].

A link between disturbed breathing and cardiorespiratory diseases such as hypertension, sleep apnea and metabolic syndrome has been scientifically proven [56,57]. Interestingly, decreased oxygen/O_2 blood levels and also increased carbon dioxide/CO_2 blood levels are considered the main triggers for the sympathetic stress response [38,136]. The aforementioned chemo-sensitive neurons of the nucleus solitarius in the medulla are considered to be the main responsible control centers [136,154,155]. Clinical effects of prolonged mask-wearing would, thus, be a conceivable intensification of chronic stress re-

actions and negative influences on the metabolism leading towards a metabolic syndrome. The mask studies we found show that such disease-relevant respiratory gas changes (O_2 and CO_2) [38,136] are already achieved by wearing a mask [13,15,18,19,21–34].

A connection between hypoxia, sympathetic reactions and leptin release is scientifically known [136].

Additionally important is the connection of breathing with the influence on other bodily functions [56,57], including the psyche with the generation of positive emotions and drive [153]. The latest findings from neuro-psychobiological research indicate that respiration is not only a function regulated by physical variables to control them (feedback mechanism), but rather independently influences higher-level brain centers and, thus, also helps to shape psychological and other bodily functions and reactions [153,157,158]. Since masks impede the wearer's breathing and accelerate it, they work completely against the principles of health-promoting breathing [56,57] used in holistic medicine and yoga. According to recent research, undisturbed breathing is essential for happiness and healthy drive [157,159], but masks work against this.

The result of significant changes in blood gases in the direction of hypoxia (drop in oxygen saturation) and hypercapnia (increase in carbon dioxide concentration) through masks, thus, has the potential to have a clinically relevant influence on the human organism even without exceeding normal limits.

According to the latest scientific findings, blood-gas shifts towards hypoxia and hypercapnia not only have an influence on the described immediate, psychological and physiological reactions on a macroscopic and microscopic level, but additionally on gene expression and metabolism on a molecular cellular level in many different body cells. Through this, the drastic disruptive intervention of masks in the physiology of the body also becomes clear down to the cellular level, e.g., in the activation of hypoxia-induced factor (HIF) through both hypercapnia and hypoxia-like effects [160]. HIF is a transcription factor that regulates cellular oxygen supply and activates signaling pathways relevant to adaptive responses. e.g., HIF inhibits stem cells, promotes tumor cell growth and inflammatory processes [160]. Based on the hypoxia- and hypercapnia-promoting effects of masks, which have been comprehensively described for the first time in our study, potential disruptive influences down to the intracellular level (HIF-a) can be assumed, especially through the prolonged and excessive use of masks. Thus, in addition to the vegetative chronic stress reaction in mask wearers, which is channeled via brain centers, there is also likely to be an adverse influence on metabolism at the cellular level. With the prospect of continued mask use in everyday life, this also opens up an interesting field of research for the future.

The fact that prolonged exposure to latently elevated CO_2 levels and unfavorable breathing air compositions has disease-promoting effects was recognized early on. As early as 1983, the WHO described "Sick Building Syndrome" (SBS) as a condition in which people living indoors experienced acute disease-relevant effects that increased with time of their stay, without specific causes or diseases [161,162]. The syndrome affects people who spend most of their time indoors, often with subliminally elevated CO_2 levels, and are prone to symptoms such as increased heart rate, rise in blood pressure, headaches, fatigue and difficulty concentrating [38,162]. Some of the complaints described in the mask studies we found (Figure 2) are surprisingly similar to those of Sick Building Syndrome [161]. Temperature, carbon dioxide content of the air, headaches, dizziness, drowsiness and itching also play a role in Sick Building Syndrome. On the one hand, masks could themselves be responsible for effects such as those described for Sick Building Syndrome when used for a longer period of time. On the other hand, they could additionally intensify these effects when worn in air-conditioned buildings, especially when masks are mandatory indoors. Nevertheless, there was a tendency towards higher systolic blood pressure values in mask wearers in some studies [21,31,34], but statistical significance was only found in two studies [25,35]. However, we found more relevant and significant evidence of heart

rate increase, headache, fatigue and concentration problems associated with mask wearers (Figure 2) indicating the clinical relevance of wearing masks.

According to the scientific results and findings, masks have measurably harmful effects not only on healthy people, but also on sick people and their relevance is likely to increase with the duration of use [69]. Further research is needed here to shed light on the long-term consequences of widespread mask use with subthreshold hypoxia and hypercapnia in the general population, also regarding possible exacerbating effects on cardiorespiratory lifestyle diseases such as hypertension, sleep apnea and metabolic syndrome. The already often elevated blood carbon dioxide (CO_2) levels in overweight people, sleep apnea patients and patients with overlap-COPD could possibly increase even further with everyday masks. Not only a high body mass index (BMI) but also sleep apnea are associated with hypercapnia during the day in these patients (even without masks) [19,163]. For such patients, hypercapnia means an increase in the risk of serious diseases with increased morbidity, which could then be further increased by excessive mask use [18,38].

The hypercapnia-induced effects of sympathetic stress activation are even cycle phase-dependent in women. Controlled by a progesterone mechanism, the sympathetic reaction, measured by increased blood pressure in the luteal phase, is considerably stronger [164]. This may also result in different sensitivities for healthy and sick women to undesirable effects masks have, which are related to an increase in carbon dioxide (CO_2).

In our review, negative physical and psychological changes caused by masks could be objectified even in younger and healthy individuals.

The physical and chemical parameters did not exceed the normal values in most cases but were statistically significantly measurable ($p < 0.05$) tending towards pathological ranges. They were accompanied by physical impairments (see Figure 2). It is well known that subthreshold stimuli are capable of causing pathological changes when exposed to them for a long time: not only a single high dose of a disturbance, but also a chronically persistent, subthreshold exposure to it often leads to illness [38,46–48,50–54]. The scientifically repeatedly measurable physical and chemical mask effects were often accompanied by typical subjective complaints and pathophysiological phenomena. The fact that these frequently occur simultaneously and together indicates a syndrome under masks.

Figure 2 sums up the significant mask-dependent physiological, psychological, somatic and general pathological changes and their frequent occurrence together is striking. Within the framework of the quantitative evaluation of the experimental studies, we were actually able to prove a statistically significant correlation of the observed side effects of fatigue and oxygen depletion under mask use with $p < 0.05$. In addition, we found a frequent, simultaneous and joint occurrence of further undesirable effects in the scientific studies (Figure 2). Statistically significant associations of such co-occurring, adverse effects have already been described in primary studies [21,29]. We detected a combined occurrence of the physical parameter temperature rise under the mask with the symptom respiratory impairment in seven of the nine studies concerned (88%). We found a similar result for the decrease in oxygen saturation under mask and the symptom respiratory impairment with a simultaneous detection in six of the eight studies concerned (67%). We detected a combined occurrence of carbon dioxide rise under N95 mask use in nine of the 11 scientific papers (82%). We found a similar result for oxygen drop under N95 mask use with simultaneous co-occurrence in eight of 11 primary papers (72%). The use of N95 masks was also associated with headache in six of the 10 primary studies concerned (60%). A combined occurrence of the physical parameters temperature rise and humidity under masks was even found 100% within six of the six studies with significant measurements of these parameters (Figure 2).

Since the symptoms were described in combination in mask wearers and were not observed in isolation in the majority of cases, we refer to them as general Mask-Induced Exhaustion Syndrome (MIES) because of the consistent presentation in numerous papers from different disciplines. These include the following, predominantly statistically significantly

($p < 0.05$) proven pathophysiological changes and subjective complaints, which often occur in combination as described above (see also Section 3.1 to Section 3.11, Figures 2–4):

- Increase in dead space volume [22,24,58,59] (Figure 3, Sections 3.1 and 3.2).
- Increase in breathing resistance [31,35,61,118] (Figure 3, Figure 2: Column 8).
- Increase in blood carbon dioxide [13,15,19,21–28] (Figure 2: Column 5).
- Decrease in blood oxygen saturation [18,19,21,23,28–34] (Figure 2: Column 4).
- Increase in heart rate [15,19,23,29,30,35] (Figure 2: Column 12).
- Decrease in cardiopulmonary capacity [31] (Section 3.2).
- Feeling of exhaustion [15,19,21,29,31–35,69] (Figure 2: Column 14).
- Increase in respiratory rate [15,21,23,34] (Figure 2: Column 9).
- Difficulty breathing and shortness of breath [15,19,21,23,25,29,31,34,35,71,85,101,133] (Figure 2: Column 13).
- Headache [19,27,37,66–68,83] (Figure 2: Column 17).
- Dizziness [23,29] (Figure 2: Column 16).
- Feeling of dampness and heat [15,16,22,29,31,35,85,133] (Figure 2: Column 7).
- Drowsiness (qualitative neurological deficits) [19,29,32,36,37] (Figure 2: Column 15).
- Decrease in empathy perception [99] (Figure 2: Column 19).
- Impaired skin barrier function with acne, itching and skin lesions [37,72,73] (Figure 2: Column 20–22).

It can be deduced from the results that the effects described in healthy people are all more pronounced in sick people, since their compensatory mechanisms, depending on the severity of the illness, are reduced or even exhausted. Some existing studies on and with patients with measurable pathological effects of the masks support this assumption [19,23,25,34]. In most scientific studies, the exposure time to masks in the context of the measurements/investigations was significantly less (in relation to the total wearing and duration of use) than is expected of the general public under the current pandemic regulations and ordinances.

The exposure time limits are little observed or knowingly disregarded in many areas today as already mentioned in Section 3.11 on occupational medicine. The above facts allow the conclusion that the described negative effects of masks, especially in some of our patients and the very elderly, may well be more severe and adverse with prolonged use than presented in some mask studies.

From a doctor's viewpoint, it may also be difficult to advise children and adults who, due to social pressure (to wear a mask) and the desire to feel they belong, suppress their own needs and concerns until the effects of masks have a noticeable negative impact on their health [76]. Nevertheless, the use of masks should be stopped immediately at the latest when shortness of breath, dizziness or vertigo occur [23,25]. From this aspect, it seems sensible for decision makers and authorities to provide information, to define instruction obligations and offer appropriate training for employers, teachers and other persons who have a supervisory or caregiving duty. Knowledge about first aid measures could also be refreshed and expanded accordingly in this regard.

Elderly, high-risk patients with lung disease, cardiac patients, pregnant women or stroke patients are advised to consult a physician to discuss the safety of an N95 mask as their lung volume or cardiopulmonary performance may be reduced [23]. A correlation between age and the occurrence of the aforementioned symptoms while wearing a mask has been statistically proven [19]. Patients with reduced cardiopulmonary function are at increased risk of developing serious respiratory failure with mask use according to the referenced literature [34]. Without the possibility of continuous medical monitoring, it can be concluded that they should not wear masks without close monitoring. The American Asthma and Allergy Society has already advised caution in the use of masks with regard to the COVID-19 pandemic for people with moderate and severe lung disease [165]. Since the severely overweight, sleep apnea patients and overlap-COPD sufferers are known to be prone to hypercapnia, they also represent a risk group for serious adverse health effects under extensive mask use [163]. This is because the potential of masks to produce additional

CO_2 retention may not only have a disruptive effect on the blood gases and respiratory physiology of sufferers, but may also lead to further serious adverse health effects in the long term. Interestingly, in an animal experiment an increase in CO_2 with hypercapnia leads to contraction of smooth airway muscles with constriction of bronchi [166]. This effect could explain the observed pulmonary decompensations of patients with lung disease under masks (Section 3.2) [23,34].

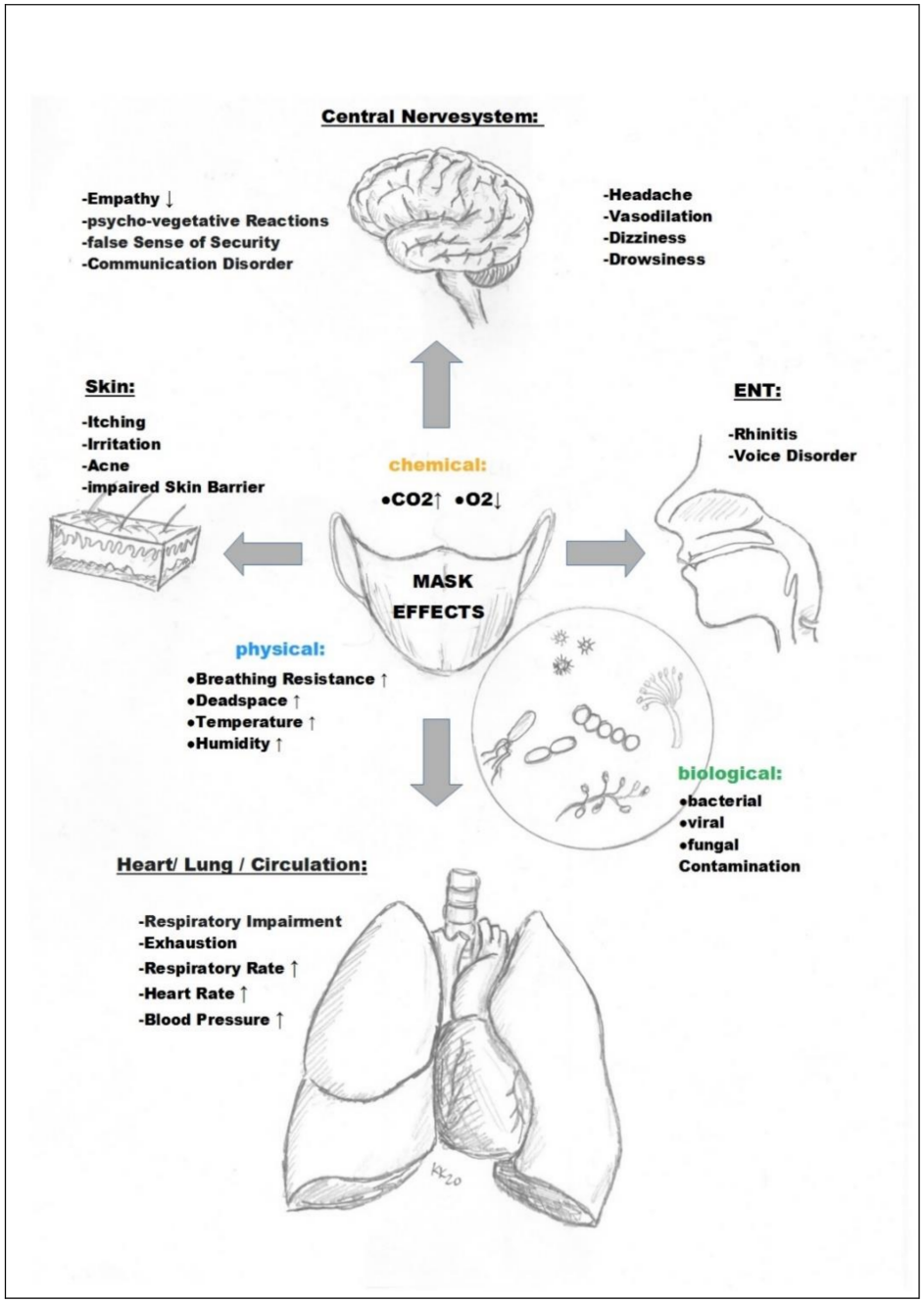


Figure 4. Unfavorable mask effects as components of Mask-Induced Exhaustion Syndrome (MIES). The chemical, physical and biological effects, as well as the organ system consequences mentioned, are all documented with statistically significant results in the scientific literature found (Figure 2). The term drowsiness is used here to summarize any qualitative neurological deficits described in the examined scientific literature.

Patients with renal insufficiency requiring dialysis are, according to the literature available, further candidates for a possible exemption from the mask requirement [34].

According to the criteria of the Centers for Disease Control and Prevention, GA, USA (CDC), sick and helpless people who cannot remove a mask on their own should be exempted from the mask requirement [82].

Since it can be assumed that children react even more sensitively to masks, the literature suggests that masks are a contraindication for children with epilepsies (hyperventilation as a trigger for seizures) [63]. In the field of pediatrics, special attention should also be paid to the mask symptoms described under psychological, psychiatric and sociological effects with possible triggering of panic attacks by CO_2 rebreathing in the case of predisposition and also reinforcement of claustrophobic fears [77–79,167]. The mask-related disturbance of verbal [43,45,71] and non-verbal communication and, thus, of social interaction is particularly serious for children. Masks restrict social interaction and block positive perceptions (smiling and laughing) and emotional mimicry [42]. The proven mask-induced mild to moderate cognitive impairment with impaired thinking, decreased attention and dizziness [19,23,29,32,36,37,39–41,69], as well as the psychological and neurological effects [135], should be additionally taken into account when masks are compulsory at school and in the vicinity of both public and non-public transport, also regarding the possibility of an increased risk of accidents (see also occupational health side effects and hazards) [19,29,32,36,37]. The exclusion criteria mentioned in pediatric studies on masks (see pediatric impairments, Section 3.14) [26,133] should also apply to an exclusion of these children from the general mask obligation in accordance with the scientific findings for the protection of the sick children concerned. The long-term sociological, psychological and educational consequences of a comprehensive masking requirement extended to schools are also unpredictable with regard to the psychological and physical development of healthy children [42,135]. Interestingly, according to the Corona Thesis Paper of the University of Bremen children "are infected less often, they become ill less often, the lethality is close to zero, and they also pass on the infection less often", according to the Thesis Paper 2.0 of the German University of Bremen on page 6 [138]. Studies conducted under real-life conditions with outcome endpoints showing hardly any infections, hardly any morbidity, hardly any mortality and only low contagiousness in children are clearly in the majority, according to Thesis Paper 3.0 of the German University of Bremen [138]. A recent German observational study (5600 reporting pediatricians) also showed a surprisingly low incidence of COVID-19 disease in children [168]. The infection of adults with SARS-CoV-2 by children has been considered in only one suspected case, but could not be proven with certainty, since the parents also had numerous contacts and exposure factors for viral infections due to their occupation. In this case, the circulating headlines in the public media that children contribute more to the incidence of infection are to be regarded as anecdotal.

In pregnant women, the use of masks during exertion or at rest over long periods of time is to be regarded as critical as little research has been done on this [20]. If there is clear scientific evidence of increased dead space ventilation with possible accumulation of CO_2 in the mother's blood, the use of masks by pregnant women for more than 1 h, as well as under physical stress, should be avoided in order to protect the unborn child [20,22]. The hypercapnia-promoting masks could act as a confounder of the fetal/maternal CO_2 gradient in this case (Section 3.6) [20,22,28].

According to the literature cited in the Section 3.5 on psychiatric side effects (personality disorders with anxiety and panic attacks, claustrophobia, dementia and schizophrenia), masking should only be done, if at all, with careful consideration of the advantages and disadvantages. Attention should be paid to possible provocation of the number and severity of panic attacks [77–79].

In patients with headaches, a worsening of symptoms can be expected with prolonged mask use (see also Section 3.3., neurological side effects) [27,66–68]. As a result of the increase in blood carbon dioxide (CO_2) when the mask is used, vasodilatation occurs in the central nervous system and the pulsation of the blood vessels decreases [27]. In this connection, it is also interesting to note radiological experiments that demonstrate an increase in brain volume under subthreshold, but still within normal limits of CO_2 increase

in the blood by means of structural MRI. The blood carbon dioxide increase was produced in seven subjects via rebreathing with resulting median carbon dioxide concentration of 42 mmHg and an interquartile range of 39.44 mmHg, corresponding to only a subthreshold increase given the normal values of 32–45 mmHg. In the experiment, there was a significant increase in brain parenchymal volume measurable under increased arterial CO_2 levels ($p < 0.02$), with a concomitant decrease in CSF spaces ($p < 0.04$), entirely in accordance with the Monroe–Kelly doctrine, according to which the total volume within the skull always remains the same. The authors interpreted the increase in brain volume as an expression of an increase in blood volume due to a CO_2 increase-induced dilation of the cerebral vessels [169]. The consequences of such equally subthreshold carbon dioxide (CO_2) increases even under masks [13,15,18,19,22,23,25] are unclear for people with pathological changes inside the skull (aneurysms, tumors, etc.) with associated vascular changes [27] and brain volume shifts [169] especially due to longer exposure while wearing a mask, but could be of great relevance due to the blood gas-related volume shifts that take place.

In view of the increased dead space volume, the long-term and increased accumulation and rebreathing of other respiratory air components apart from CO_2 is also unexplained, both in children and in old and sick people. Exhaled air contains over 250 substances, including irritant or toxic gases such as nitrogen oxides (NO), hydrogen sulfide (H2S), isoprene and acetone [170]. For nitrogen oxides [47] and hydrogen sulfide [46], pathological effects relevant to disease have been described in environmental medicine even at a low but chronic exposure [46–48]. Among the volatile organic compounds in exhaled air, acetone and isoprene dominate in terms of quantity, but allyl methyl sulfide, propionic acid and ethanol (some of bacterial origin) should also be mentioned [171]. Whether such substances also react chemically with each other underneath masks and in the dead space volume created by masks (Figure 3), and with the mask tissue itself, and in what quantities these and possible reaction products are rebreathed, has not yet been clarified. In addition to the blood gas changes described above (O_2 drop and CO_2 rise), these effects could also play a role with regard to undesirable mask effects. Further research is needed here and is of particular interest in the case of prolonged and ubiquitous use of masks.

The WHO sees the integration of individual companies and communities that produce their own fabric masks as a potential social and economic benefit. Due to the global shortage of surgical masks and personal protective equipment, it sees this as a source of income and points out that the reuse of fabric masks can reduce costs and waste and contribute to sustainability [2]. In addition to the question of certification procedures for such fabric masks, it should also be mentioned that due to the extensive mask obligation, textile (artificial) substances in the form of micro- and nanoparticles, some of which cannot be degraded in the body, are chronically absorbed into the body through inhalation to an unusual extent. In the case of medical masks, disposable polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester should be mentioned [140]. ENT physicians have already been able to detect such particles in the nasal mucosa of mask wearers with mucosal reactions in the sense of a foreign body reaction with rhinitis [96]. In the case of community masks, other substances from the textile industry are likely to be added to those mentioned above. The body will try to absorb these substances through macrophages and scavenger cells in the respiratory tract and alveoli as part of a foreign body reaction, whereby toxin release and corresponding local and generalized reactions may occur in an unsuccessful attempt to break them down [172]. Extensive respiratory protection in permanent long-term use (24/7), at least from a theoretical point of view, also potentially carries the risk of leading to a mask-related pulmonary [47] or even generalized disorder, as is already known from textile workers chronically exposed to organic dusts in the Third World (byssinosis) [172].

For the general public, from a scientific angle, it is necessary to draw on the long-standing knowledge of respiratory protection in occupational medicine in order to protect children in particular from harm caused by uncertified masks and improper use.

The universal undefined and extended mask requirement—without taking into account multiple predispositions and susceptibilities—contradicts the claim of an increasingly important individualized medicine with a focus on the unique characteristics of each individual [173].

A systematic review on the topic of masks is necessary according to the results of our scoping review. The primary studies often showed weaknesses in operationalization, especially in the evaluation of cognitive and neuropsychological parameters. Computerized test procedures will be useful here in the future. Mask research should also set itself the future goal of investigating and defining subgroups for whom respiratory protection use is particularly risky.

5. Limitations

Our approach with a focus on negative effects is in line with Villalonga-Olives and Kawachi [12]. With the help of such selective questioning in the sense of dialectics, new insights can be gained that might otherwise have remained hidden. Our literature search focused on adverse negative effects of masks, in particular to point out risks especially for certain patient groups. Therefore, publications presenting only positive effects of masks were not considered in this review.

For a compilation of studies with harmless results when using masks, reference must, therefore, be made to reviews with a different research objective, whereby attention must be paid to possible conflicts of interest there. Some of the studies excluded by us lacking negative effects have shown methodological weaknesses (small, non-uniform experimental groups, missing control group even without masks due to corona constraints, etc.) [174]. In other words, if no negative concomitant effects were described in publications, it does not necessarily mean that masks have exclusively positive effects. It is quite possible that negative effects were simply not mentioned in the literature and the number of negative effects may well be higher than our review suggests.

We only searched one database, so the number of papers on negative mask effects may be higher than we reported.

In order to be able to describe characteristic effects for each mask type even more extensively, we did not have enough scientific data on the respective special designs of the masks. There is still a great need for research in this area due to the current pandemic situation with extensive mandatory masking.

In addition, the experiments evaluated in this paper do not always have uniform measurement parameters and study variables and, depending on the study, take into account the effect of masks at rest or under stress with subjects having different health conditions. Figure 2, therefore, represents a compromise. The results of the primary studies on mask use partially showed no natural variation in parameters, but often showed such clear correlations between symptoms and physiological changes, so that a statistical correlation analysis was not always necessary. We found a statistically significant correlation of oxygen deprivation and fatigue in 58% of the studies ($p < 0.05$). A statistically significant correlation evidence for other parameters has been previously demonstrated in primary studies [21,29].

The most commonly used personal particulate matter protective equipment in the COVID-19 pandemic is the N95 mask [23]. Due to its characteristics (better filtering function, but greater airway resistance and more dead space volume than other masks), the N95 mask is able to highlight negative effects of such protective equipment more clearly than others (Figure 3). Therefore, a relatively frequent consideration and evaluation of N95 masks within the studies found (30 of the 44 quantitatively evaluated studies, 68%) is even advantageous within the framework of our research question. Nevertheless, it remains to be noted that the community masks sold on the market are increasingly similar to the protective equipment that has been better investigated in scientific studies, such as surgical masks and N95 masks, since numerous manufacturers and users of community masks are striving to approximate the professional standard (surgical mask, N95/FFP2). Recent

study results on community masks indicate similar effects for respiratory physiology as described for medical masks: in a recent publication, fabric masks (community masks) also provoked a measurable increase in carbon dioxide $PtcCO_2$ in wearers during exertion and came very close to surgical masks in this effect [21].

Most of the studies cited in our paper included only short observation and application periods (mask-wearing durations investigated ranged from 5 min [26] to 12 h [19]. In only one study, a maximum observation period of an estimated 2-month period was chosen [37]. Therefore, the actual negative effects of masks over a longer application period might be more pronounced than presented in our work.

6. Conclusions

On the one hand, the advocacy of an extended mask requirement remains predominantly theoretical and can only be sustained with individual case reports, plausibility arguments based on model calculations and promising in vitro laboratory tests. Moreover, recent studies on SARS-CoV-2 show both a significantly lower infectivity [175] and a significantly lower case mortality than previously assumed, as it could be calculated that the median corrected infection fatality rate (IFR) was 0.10% in locations with a lower than average global COVID-19 population mortality rate [176]. In early October 2020, the WHO also publicly announced that projections show COVID-19 to be fatal for approximately 0.14% of those who become ill—compared to 0.10% for endemic influenza—again a figure far lower than expected [177].

On the other hand, the side effects of masks are clinically relevant.

In our work, we focused exclusively on the undesirable and negative side effects that can be produced by masks. Valid significant evidence of combined mask-related changes were objectified ($p < 0.05$, $n \geq 50\%$), and we found a clustered and common occurrence of the different adverse effects within the respective studies with significantly measured effects (Figure 2). We were able to demonstrate a statistically significant correlation of the observed adverse effect of hypoxia and the symptom of fatigue with $p < 0.05$ in the quantitative evaluation of the primary studies. Our review of the literature shows that both healthy and sick people can experience Mask-Induced Exhaustion Syndrome (MIES), with typical changes and symptoms that are often observed in combination, such as an increase in breathing dead space volume [22,24,58,59], increase in breathing resistance [31,35,60,61], increase in blood carbon dioxide [13,15,17,19,21–30,35], decrease in blood oxygen saturation [18,19,21,23,28–34], increase in heart rate [23,29,30,35], increase in blood pressure [25,35], decrease in cardiopulmonary capacity [31], increase in respiratory rate [15,21,23,34,36], shortness of breath and difficulty breathing [15,17,19,21,23,25,29,31,34,35,60,71,85,101,133], headache [19,27,29,37,66–68,71,83], dizziness [23,29], feeling hot and clammy [17,22,29,31,35,44,71,85,133], decreased ability to concentrate [29], decreased ability to think [36,37], drowsiness [19,29,32,36,37], decrease in empathy perception [99], impaired skin barrier function [37,72,73] with itching [31,35,67,71–73,91–93], acne, skin lesions and irritation [37,72,73], overall perceived fatigue and exhaustion [15,19,21,29,31,32,34,35,69] (Figures 2–4).

Wearing masks does not consistently cause clinical deviations from the norm of physiological parameters, but according to the scientific literature, a long-term pathological consequence with clinical relevance is to be expected owing to a longer-lasting effect with a subliminal impact and significant shift in the pathological direction. For changes that do not exceed normal values, but are persistently recurring, such as an increase in blood carbon dioxide [38,160], an increase in heart rate [55] or an increase in respiratory rate [56,57], which have been documented while wearing a mask [13,15,17,19,21–30,34,35] (Figure 2), a long-term generation of high blood pressure [25,35], arteriosclerosis and coronary heart disease and of neurological diseases is scientifically obvious [38,55–57,160]. This pathogenetic damage principle with a chronic low-dose exposure with long-term effect, which leads to disease or disease-relevant conditions, has already been extensively studied and described in many areas of environmental medicine [38,46–54]. Extended

mask-wearing would have the potential, according to the facts and correlations we have found, to cause a chronic sympathetic stress response induced by blood gas modifications and controlled by brain centers. This in turn induces and triggers immune suppression and metabolic syndrome with cardiovascular and neurological diseases.

We not only found evidence in the reviewed mask literature of potential long-term effects, but also evidence of an increase in direct short-term effects with increased mask-wearing time in terms of cumulative effects for: carbon dioxide retention, drowsiness, headache, feeling of exhaustion, skin irritation (redness, itching) and microbiological contamination (germ colonization) [19,22,37,66,68,69,89,91,92].

Overall, the exact frequency of the described symptom constellation MIES in the mask-using populace remains unclear and cannot be estimated due to insufficient data.

Theoretically, the mask-induced effects of the drop in blood gas oxygen and increase in carbon dioxide extend to the cellular level with induction of the transcription factor HIF (hypoxia-induced factor) and increased inflammatory and cancer-promoting effects [160] and can, thus, also have a negative influence on pre-existing clinical pictures.

In any case, the MIES potentially triggered by masks (Figures 3 and 4) contrasts with the WHO definition of health: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [178].

All the scientific facts found in our work expand the knowledge base for a differentiated view of the mask debate. This gain can be relevant for decision makers who have to deal with the issue of mandatory mask use during the pandemic under constant review of proportionality as well as for physicians who can advise their patients more appropriately on this basis. For certain diseases, taking into account the literature found in this study, it is also necessary for the attending physician to weigh up the benefits and risks with regard to a mask obligation. With an overall strictly scientific consideration, a recommendation for mask exemption can become justifiable within the framework of a medical appraisal (Figure 5).

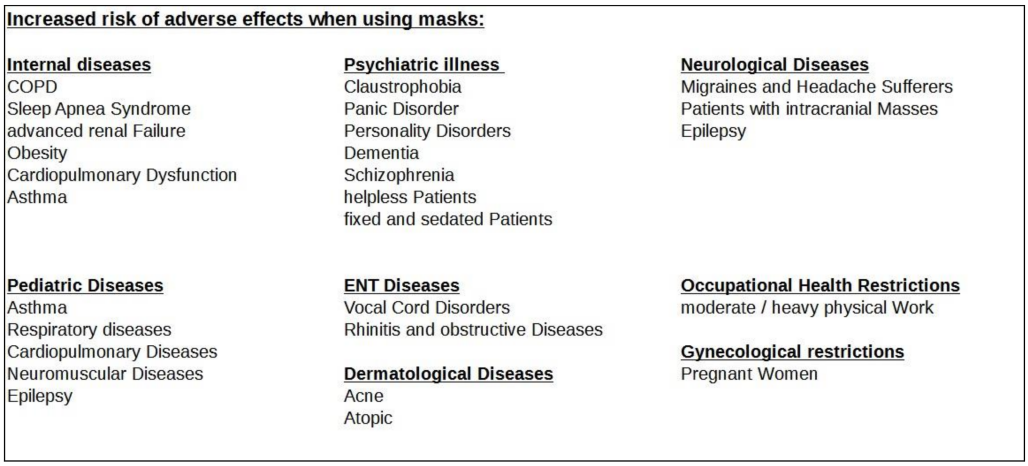


Figure 5. Diseases/predispositions with significant risks, according to the literature found, when using masks. Indications for weighing up medical mask exemption certificates.

In addition to protecting the health of their patients, doctors should also base their actions on the guiding principle of the 1948 Geneva Declaration, as revised in 2017. According to this, every doctor vows to put the health and dignity of his patient first and, even under threat, not to use his medical knowledge to violate human rights and civil liberties [9]. Within the framework of these findings, we, therefore, propagate an explicitly medically judicious, legally compliant action in consideration of scientific factual reality [2,4,5,16,130,132,143,175–177] against a predominantly assumption-led claim to a general effectiveness of masks, always taking into account possible unwanted individual ef-

fects for the patient and mask wearer concerned, entirely in accordance with the principles of evidence-based medicine and the ethical guidelines of a physician.

The results of the present literature review could help to include mask-wearing in the differential diagnostic pathophysiological cause consideration of every physician when corresponding symptoms are present (MIES, Figure 4). In this way, the physician can draw on an initial complaints catalogue that may be associated with mask-wearing (Figure 2) and also exclude certain diseases from the general mask requirement (Figure 5).

For scientists, the prospect of continued mask use in everyday life suggests areas for further research. In our view, further research is particularly desirable in the gynecological (fetal and embryonic) and pediatric fields, as children are a vulnerable group that would face the longest and, thus, most profound consequences of a potentially risky mask use. Basic research at the cellular level regarding mask-induced triggering of the transcription factor HIF with potential promotion of immunosuppression and carcinogenicity also appears to be useful under this circumstance. Our scoping review shows the need for a systematic review.

The described mask-related changes in respiratory physiology can have an adverse effect on the wearer's blood gases sub-clinically and in some cases also clinically manifest and, therefore, have a negative effect on the basis of all aerobic life, external and internal respiration, with an influence on a wide variety of organ systems and metabolic processes with physical, psychological and social consequences for the individual human being.

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Sun 3/3/2024 12:02 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

To whom it may concern,

I am writing requesting you change the wording in your regulation on masking school children. I would like to request the following:

“There will be no regulation requiring masking in schools for respiratory viral infections until evidence of their effectiveness has been demonstrated convincingly by multiple, rigorous randomized, controlled clinical trials.”

Trust the science! The Cochrane Review showed masking with simple cloth masks does not work! The results were either inconclusive or showed little to no difference with this type of masking. Our children, however, suffered irreparable harm from these masks, found to be true by Judge Lanphear. Mental health issues, dental conditions, skin infections, speech impediments, and language delays are among the many concerns and actual resulting impacts of masking children. Please do not let this happen again.

Respectfully,
Katrina Mooney
Glocester RI resident and parent

NO MORE MASK MANDATES EVER

Lori Wycall <lwycall@gmail.com>

Sun 3/3/2024 12:33 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good morning, Zachary.

I am one of the 34 plaintiffs from the Southwell vs. McKee lawsuit. We settled this suit in good faith that the RIDOH would agree to rigorous, randomized controlled trials (RTCs) prior to every imposing mask mandates again. Instead the RIDOH went back on their word and presented us with a bogus statement of imposing mask mandates regardless of scientific backing. This has caused tremendous lack of confidence and trust in public health. You should be ashamed.

I'm writing to express my opposition to the RIDOH stating it will impose mask mandates in the future as deemed necessary to slow any respiratory virus. After 4 years of this, the data and studies clearly show that masking in schools did nothing to slow or prevent the spread of respiratory virus COVID 19. It is also quite clear that health officials knew this and imposed the mask mandates anyway. The data and studies are also clear that the damage done to to students and society due to these unscientific mandates are far worse than any fabricated benefit. Irreparable harm was done to children during the COVID pandemic and we should not forget this. I have two school age children and the effects of masking during the pandemic were horrible. I also worked as a substitute teacher during the pandemic and all students were adversely affected by mask mandates. I witnessed it first hand.

I refuse to accept any rule for masking in school that does NOT state the following, "There will be no regulation requiring masking in schools for alleged prevention of respiratory viruses until evidence of their effectiveness has been demonstrated convincingly by multiple, rigorous, randomized controlled trials (RTCs) in school children."

That's how you follow the science. You're acting as a politician not a scientist unless you accept these standards.

See you on March 15th.

Lori Wycall
125 Winnapaug Road, Westerly, RI

Opposed to permanent mask mandate

REBECCA SHAFER <rshaferb@aol.com>

Mon 3/4/2024 9:29 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Stop 216-RICR-30-05-4 a permanent mask mandate regulation for all RI schools. Vote No.

This idea is incomprehensible, unnecessary and destructive to all children's development. It must be stopped. Grandparents are totally opposed to this.

Thank you for your consideration. Please vote NO.

Robert Elliott
Storrs, Connecticut

Re: 216-RICR-30-05-4

Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Mon 3/4/2024 2:00 PM
To:Danielle Cooper <scottdanijp@yahoo.com>

Good Afternoon,

Thank you for submitting your comments. They have been received and will be added to the rulemaking record.

Best,

Zachary J. Garceau (he/him/his)
Chief Program Development
Office: 401-222-7884
Cell: 401-408-2747
Zachary.Garceau@health.ri.gov

From: Danielle Cooper <scottdanijp@yahoo.com>
Sent: Monday, March 4, 2024 1:57 PM
To: Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Subject: 216-RICR-30-05-4

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Report Suspicious

Dear Department of Public Health Commissioner,

I do NOT support 216-RICR-30-05-4 a permanent mask mandate for Rhode Island schools. I will refuse to send my children to Rhode Island colleges if this bill passes. I strongly OPPOSE this legislation.

Danielle Cooper
Mystic, CT

No to 216-RICR-30-05-4

Danielle Cooper <danijp@rocketmail.com>

Mon 3/4/2024 2:04 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Dept. of Public Health Commissioner:

I am against 216-RICR-30-05-4 a permanent mask mandate for Rhode Island schools. I will refuse to send my children to Rhode Island colleges if this bill passes. I strongly oppose this legislation.

Scott Cooper
Mystic, CT

Mandate of masks in schools

Sheila Beliveau <sheila.beliveau@yahoo.com>

Mon 3/4/2024 7:25 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I am against mandate of RI Department of Health making children wear masks in schools.
Sent from my iPhone

Mask Mandate Regulation 216-RICR-30-05-4

Julie Sanfilippo <juliesanfilippo@me.com>

Tue 3/5/2024 8:34 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hi Zachary,

I am writing in response to the mask mandate regulation that is being proposed. This is regulation 216-RICR-30-05-4.

This regulation is detrimental to our state and must be denied. There are several reasons to support this:

1. Masking has never been proven effective in schools. Look at the numbers, areas that did not mask their children did not have higher rates of Covid-19.
2. Masking is detrimental learning. Children need to be able to see facial expressions to properly learn across all disciplines but especially for reading and speech. Many kids suffered delays in reading and speech due to masks.
3. Socialization was also affected by masking and for younger grades this is an integral part of their education.
4. Masks can be detrimental to health. While masks were not effective in maintaining the spread of Covid-19, they do restrict oxygen, which is the number 1 thing people need to survive. We are talking about a huge portion of a child's day.

If a parent chooses to mask their child or a teacher feels the need to wear a mask that's their choice, but it should not be mandated by the state.

Thank you for your time,
Julie Sanfilippo

Sent from my iPhone

Mask hearing

Kayla Amaral <keamaral1@gmail.com>
Wed 3/6/2024 11:56 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To whom it may concern,

I am writing today in opposition to the idea proposed and to be heard on March 15, 2024 giving the department the right to impose mask mandates for RI school children for any reason.

The science has been clearly demonstrated in a previous case that masking doesn't not stop or prevent pathogens from spreading but also causes more harm then good for school aged children.

The fact that this case is even moving forward is absolutely absurd especially after the findings presented in the Southwell vs. McKee case. I have copied the following text from the referenced court case:
"This Court heard credible testimony from multiple Plaintiffs that their children were suffering adverse effects from the requirement that they wear masks throughout the school day. These adverse effects include physical and emotional discomfort and interference with the children's ability to interact with teachers and peers. Plaintiffs themselves experienced the distress of witnessing their children's discomfort, and some Plaintiffs made the difficult decision to homeschool their children rather than send them to school with masks. While not disputing Plaintiffs' testimony on those facts, Defendants point to the lack of medical evidence on the health risks of wearing masks and state that Plaintiffs are attempting to shift their burden of proof on that issue.

Regardless of the uncertainty surrounding potential long-term medical problems resulting from mask wearing, this Court finds that Plaintiffs' testimony regarding the ongoing impact of the mask mandate on their children suffices to establish a finding of irreparable harm. *See, e.g.*, *Porretti v. Dzurenda*, 11 F.4th 1037, 1050 [casetext.com] (9th Cir. 2021) ("Emotional injuries, [or] psychological distress . . . may constitute irreparable harm."); *Harris v. Board of Supervisors, Los Angeles County*, 366 F.3d 754, 766 [casetext.com](9th Cir. 2004) (finding that patients' increased pain and suffering if hospital closed constituted irreparable harm); *Al-Joudi v. Bush*, 406 F.Supp.2d 13, 20 [casetext.com] (D.D.C. 2005) ("[W]here the health of a legally incompetent or vulnerable person is at stake, irreparable harm can be established."); *Texas Health & Human Services Commission v. Advocates for Patient Access, Inc.*, 399 S.W.3d 615, 630-31 [casetext.com] (Tex. Ct. App. 2013) (finding that "decline in [child's] condition and progress" due to interruption of speech-therapy services was irreparable harm)."

The fact of the matter is, in the state of RI, masking of school aged children has already been found in a court of law, to cause irreparable harm to children. That in itself should be enough evidence to object to the motion on 3/15/24 to allow the department to mask school children for any reason. This motion is a clear attempt to overturn a previous ruling. The parents in RI will not stand for it! In a February 4, 2024 news article from WJAR, 7000 RI school children have withdrawn or exited RI public schools since 2019:

https://turnto10.com/news/crisis-in-the-classroom/report-finds-7000-students-left-rhode-island-public-schools-since-2019-enrollment-absenteeism-homeschool-pandemic-private-feb-8-2024 [turnto10.com]

Make no mistake that the recent policies implemented by the state of RI and the RIDE are driving students and families out of the RI public school system and this is a prime example of why this is happening. The policies implemented by these departments cause irreparable and devastating harm to our children. This needs to be stopped immediately.

As a mother to school aged children, I can attest that masking has caused harm to my children and forced me to homeschool in the 2021-2022 school year. I will not allow my children to be masked again for any reason & my children will want to go back to homeschool over wearing masks as they now suffer post traumatic stress as it relates to masking and the claustrophobia they felt as they struggled to breath in the school buildings while wearing masks.

Thank you very much for reading an hearing my testimony. I hope that you have the morality to make the best decision for RI school children.

Sincerely,
Kayla Amaral
401-269-9294

* * *

After the district court determined that Porretti's case did not involve dueling experts disagreeing over medically acceptable treatments, the district court pointed out that Defendants stopped providing Wellbutrin and Seroquel because of an administrative policy, without the recommendation of any health-care provider, and without any evidence that Porretti abused Wellbutrin or Seroquel. The district court also pointed out that Defendants failed to provide Dr. Exum's recommended cognitive behavioral treatment, which suggests Porretti received *no* treatment at all for periods of time, despite his serious mental health condition. Considering these facts, among others, the district court did not clearly err in determining that Defendants likely acted with deliberate indifference to Porretti's serious medical need. *See Edmo* , 935 F.3d at 786–90 ; *Caro* , 280 F.3d at 1253. The district court therefore did not err in determining that Porretti's Eight Amendment claim will *1050 likely succeed on the merits. *See Edmo* , 935 F.3d at 786–90, 793–94 ; *Caro* , 280 F.3d at 1253.

B. Medicaid Claim

The district court also appropriately held that plaintiffs established a likelihood of success on their Medicaid discharge planning claim. Medicaid requires that participating hospitals plan for each patient's hospital discharge. Among other things, the regulations require hospitals to identify those patients who need a discharge plan and provide an evaluation to those patients and any others who request an evaluation. 42 C.F.R. § 482.43(a)-(b)(1). The evaluation must be timely so that arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge. 42 C.F.R. § 482.43(b)(5). The hospital must transfer or refer
766 patients to appropriate facilities, agencies, or outpatient services *766 for follow-up or ancillary care. 42 C.F.R. § 482.43(d).

Plaintiffs allege that the County will violate these provisions if Rancho closes and its patients are left without a transfer plan. Although the County introduced evidence that it was negotiating contracts with private providers to render care to the affected individuals, there was no evidence that any arrangements actually had been made.

Further, plaintiffs demonstrated that closing Rancho will impede the ability of other hospitals to meet their discharge planning obligations, since county hospitals rely heavily — and for some conditions, exclusively — on Rancho for rehabilitative care.

Again, in reviewing the district court's decision and the record, we find neither an erroneous factual finding nor reliance on an inappropriate legal standard. The district court's conclusion that plaintiffs are likely to succeed on their Medicaid claim is sound. There was no abuse of discretion.

The Government responds that "Guantanamo personnel have policies and practices in place for responding appropriately to hunger strikes such that no detainee's life or health will be endangered." Opp'n at 4. The Government
20 further claims that because *20 certain counsel have recently made trips to Guantanamo, or have trips planned in the near future, immediate access to their clients is unnecessary. However, as Petitioners' counsel argued at the hearing, "the access issue is not solved after one visit" since the detainees' conditions vary, and can deteriorate very rapidly. Tr. at 24.

Finally, the Government points out that, thus far, "no one has died." Id. at 43. It goes without saying that this Court need not wait to issue injunctive relief until a detainee has died. It can hardly serve either the national security interests of this country or enhance its image throughout the world to contribute in any way to the death of a detainee in its custody.

Facing requests for preliminary injunctive relief, courts often find a showing of irreparable harm where the movant's health is in imminent danger. See, e.g., Blackman v. District of Columbia, 185 F.R.D. 4, 6-7 (D.D.C. 1999) (referring to related case in which court found plaintiff had established irreparable harm where defendant was not administering necessary medication and catheterization to child); Wilson v. Group Hosp. Med. Servs., Inc., 791 F. Supp. 309, 314 (D.D.C. 1992) (granting preliminary injunction wher al ed] in serious doubt" and insu to ment that could save her life).

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1. *Probable, Imminent, Irreparable Injury:*

"Probable injury" includes the elements of imminent harm, irreparable injury, and no adequate remedy at law. *Univ. of Tex. Med. School v. Than*, 834 S.W.2d 425, 428 (Tex.App.-Houston [1st Dist.] 1992, no writ). For purposes of a temporary injunction, an injury is irreparable if the injured party cannot
630 be adequately compensated in damages or if the *630 damages cannot be measured by any certain pecuniary standard. *Butnaru*, 84 S.W.3d at 204;*see also Tex. Indus. Gas v. Phoenix Metallurgical Corp.*, 828 S.W.2d 529, 533 (Tex.App.-Houston [1st Dist.] 1992, no writ) (applicant for injunctive relief must establish that damages are incapable of calculation or party sought to be enjoined is incapable of responding in damages). "The general rule at equity is that before injunctive relief can be obtained, it must appear that there does not exist an adequate remedy at law." *Butnaru*, 84 S.W.3d at 210.

HHSC contends that there is no *direct* evidence that any child was actually deprived of EPSDT services due to the threat in the March 2012 letter that section 380.207(4) would be enforced or that a parent, guardian, or relative was required to be in attendance at the EPSDT services. While that may be true, there is sufficient evidence from which the trial court could have reasonably inferred that at least one of the plaintiff children was deprived of at least some EPSDT services as a result of the threatened enforcement of the MTP accompaniment rule, that the child regressed in his progress due to a lack of therapy, that he would not be able to regularly receive EPSDT services if the MTP accompaniment rule were enforced or section 32.024(s) were narrowly construed, and that the harm from delayed or denied EPSDT services would be irreparable. *See Lozano v. Lozano*, 52 S.W.3d 141, 149 (Tex.2001) (circumstantial evidence may be used to establish any material fact if inference is reasonable and more than mere suspicion).

At the evidentiary hearing, Mario Garza, an administrator for a pediatric rehabilitation company, testified that following the March 2012 letter, "as many as 90 percent of the children were not able to receive their therapeutic services." He also testified that, "[i]f the parents are not allowed to authorize the monitor to transport their kids back and forth and provide supervision of them at the clinic, then the vast majority of kids would not receive the therapeutic rehab services that they so desperately require." This, he said, would result in regression and deterioration in their medical condition. The regional manager of an MTP service provider similarly testified about the drastic impact of the March 2012 letter, stating that 7,742 trips had been authorized in February 2012 and 6,121 trips in March 2012, but only 2,515 trips were made in April 2012. Although there is no direct

testimony linking the dramatic reduction in children receiving transportation services to the dramatic reduction in the children receiving services at Garza's facility, the trial court could have reasonably inferred a connection between the two.

These circumstances were also elaborated on by Nayeli Garza with respect to one of the individual plaintiffs, her son, John Doe B. Garza testified that John Doe B regularly received speech-therapy services prior to March 2012 and was usually accompanied by a monitor employed by the speech-therapy provider and authorized by Garza to accompany him during transportation and while at therapy. However, sometime in March 2012, the transportation provider contacted her and informed her that they would not be able to pick her son up and take him to his therapy sessions. Although Garza did not provide a reason why transportation was denied, the trial court could reasonably have inferred from her testimony that it was because she was not available to accompany him. Indeed, she testified that because she was unable to accompany him herself or find relatives to assist her, there was a period of time during which her son was not able to receive speech therapy,
631 and during that time she noticed a decline in his condition *631 and progress. Although he later resumed speech-therapy services, all the evidence taken together is sufficient to support the trial court's finding that at least one plaintiff would probably suffer imminent, irreparable harm if the status quo were not maintained. [5]

[5] HHSC complains that the findings of fact in the August injunction order either exceed the scope of the evidence or are wholly unsupported by the evidence. While we share HHSC's concerns about the disparity between the evidentiary record and some of the trial court's fact findings, the unsupported findings are not essential for the injunctive relief granted and there is at least some evidence to support the relevant portions of the findings.

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Report: 7,000 students have left Rhode Island public schoo

by LIZ BATESON, NBC 10 NEWS
Thu, February 8th 2024 at 4:00 PM
Updated Thu, February 8th 2024 at 5:33 PM

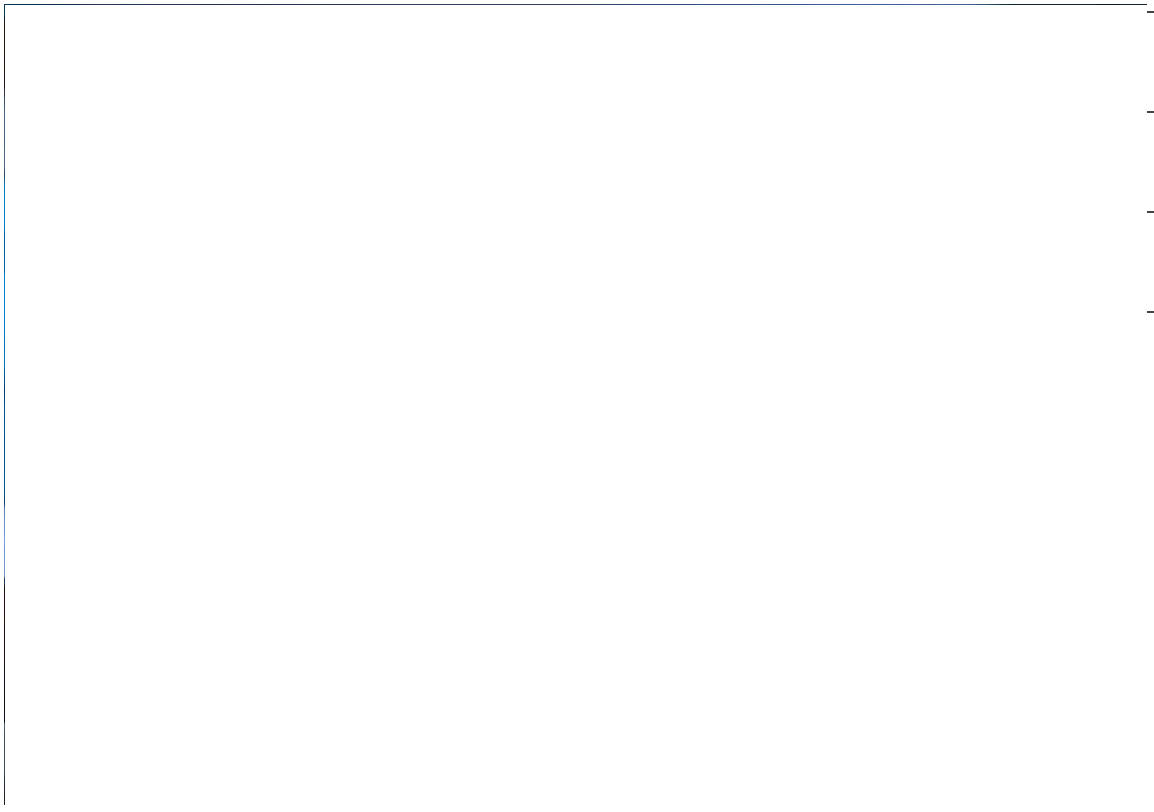


A report found that there are more empty seats in public school classrooms across the state, as enrollment numbers a absenteeism rises. (WJAR)

(WJAR) — A report by the Rhode Island Expenditure Council found that there seats in public school classrooms across the state, as enrollment numbers dr absenteeism rises.

The report found public school enrollment has dropped by more than 5.2%, c since 2019.

"Some of that decrease is explained by demographic change. By that, I mean school-aged kids in our schools," explained RIPEC Manager of Research Justir the students that left public school systems went to be homeschooled. While homeschooling population is small, it increased tremendously by over 63% o between 2019-2020."



A report found that there are more empty seats in public school classrooms across the state, as enrollment numbers a absenteeism rises. (WJAR)

seen significant drops.

"They've lost at least one in six kids in the last four years. A majority of those wealthier, coastal and often second-home communities, so for those districts decrease can be explained by demographic changes," said Oliva.

Oliva also believes more families are opting for private schools, although exa numbers aren't readily available, leaving hundreds of students unaccounted

"The way the state collects private school data, it does not compel private sch requests for enrollment data. Year over year enrollment data does not actual whether private school data has grown in the last few years," Oliva explained report] indicates for some families, that there's a sense that public education what they want for their children."



Providence Country Day, a private school, said it has seen an increase of enrollment since 2019. (WJAR)

NBC 10 stopped by Providence Country Day, a private school, to see if they're increase in students since the pandemic.

learning. I think there were significant concerns about what they saw. In publ
I continue to hear parents are worried about their kid being in a classroom w
other kids. Will their students get the attention that they need?"

- **CRISIS IN THE CLASSROOM:** **360 High School closing at end of school with Juanita Sanchez High**

The report also looks into the issue of chronic absenteeism, where students v
in public schools aren't showing up to class. Chronic absenteeism is defined b
missing at least 18 school days per year.

"During the pandemic, we saw chronic absenteeism rise from 19% to up to a
shrunk back down a little, but it's still over a quarter of students," Oliva said. "
students, close to 40% of economically disadvantaged students, missed 1 in 1
year."



Districts like Westerly, Narragansett, South Kingstown and Providence have seen significant drops in enrollment since t

Oliva said these issues could put districts at risk and lead to more school clos
make changes now.

on a frequent basis to achieve economic security, education, happiness," she

You can read the full report here.

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Conversation

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216-RICR-30-05-4

Lori Russo <lorirusso7@yahoo.com>

Wed 3/6/2024 9:59 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

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Report Suspicious

In regards to permanent regulation for future mask mandates, I strongly oppose as I'm enclosing strong evidence in the harm it creates.
Teachers & Parents report the difficulty of children wearing it properly to be protected. Young children & special needs children struggle the most.
Masks can interfere w/ brain development, bring on anxiety issues, brain development, & speech complications.
The WHO does not recommend masks for children under 5 yet the European (equivalent of CDC), recommends no masks under 12. Why is Rhode Island contemplating on doing this to children?
Diane Paul is with the American Speech, Language,& Hearing Association. She says: " Referral of children to speech therapy have increased since pandemic began".
CDC Director Rochelle Walensky quotes: "Constant use of masks impedes the learning process ".
Lastly, and might I say, most troubling revelations came from Dr. Margarite Griesg-Brisson MD PhD, leading Neurologist in Europe. She has stated on record: " The rebreathing of our exhaled air will without a doubt create oxygen deficiency and a flooding of carbon dioxide ".
Isn't the above enough to make a clear decision in this proposal?
I hope this contents is taken in consideration for a proper decision on our children.
They are our future……

Thank you,
Lori A. Russo

Sent from my iPhone

Mask Testimony

Sheryl Green <srgreen12@hotmail.com>

Thu 3/7/2024 5:58 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

1 attachments (50 KB)

mask testimony (1).pdf;

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Report Suspicious

Sheryl R. Green
80 Wills Swamp Rd, West Greenwich, RI

To Whom It May Concern;

I am writing to you to share my strong concerns as a teacher and parent regarding 216-RICR-30-05-4, which proposes a permanent regulation for future mask mandates. There is not enough evidence to support masking as a measure to prevent the spread of disease. However, I have months and months of first hand experience witnessing the physical and emotional damage all day masking has caused to children and teens that they continue to recover from to this day.

As a Middle School Health and Physical Education teacher of grades 5-8, I watched these mandates transform my chatty, energetic, social, rambunctious and full of life 10-14 year olds into silent, sullen and eerily quiet children with fear filled eyes. It is amazing how much covering a face can make a child unrecognizable. As soon as they entered the school building, fear filled teachers would instantly yell at them “Pull your masks UP” constantly and “Stay 6 feet apart”! I would watch them berate the children all the way down the hall and think “ My God we are literally abusing these children.” Trust me, I was not the only teacher who felt this way. They couldn't touch each other, hug each other, hold hands, talk at lunch time, sit close together, or just be kids!

Middle School teachers are a special breed. We are teachers, but on any given day we also act as psychologists, social workers, parents, mentors, referees and trusted adults. We are in charge of a group of students in the throes of puberty, and these small bodies are dealing with some monumental changes thanks to raging hormones that create mood swings, confusion, anxiousness, extreme sensitivity, etc. What the mask mandates did was add some additional emotions:
Fear.
Shame.
Guilt.
They were told that if they brought Covid home, they could kill their grandparents. Do you have any idea how many students in my district are being raised by their grandparents? The data showed clearly that the highest death rates were in the 80+ age range. Their grandparents are actually in their 40’s and 50’s! Masking children and putting this fear into them did nothing to prevent the spread of disease. Teaching them how to support a healthy body and immune system would be a lot more effective than fear, guilt and shame.

As a parent, both of my children had horrible experiences with masking. My oldest daughter was especially sensitive to covering her face all day long, and would call me often from the bathroom at school. “Mom, I feel lightheaded and dizzy.” One day, the Dean of Discipline called me at home, moments after my daughter came through the front door of our home sobbing because she thought she was getting detention (never had in her life and was a Junior in High School). Apparently, the phone call home was due to her putting her mask under her nose after yet

another light headed episode, AND she had forgotten to go step into the hallway at school when she took a sip of water. The teacher who reported her had been zooming into the class from home!!! In trouble for breathing and drinking water? How is this not absurd and abusive?

The most infuriating experience I witnessed by far was watching student athletes masked during full blown exercise, inside and OUTDOORS. There are so many examples: seeing cross country runners as I was driving home hundreds of feet apart from one another with masks on, having to watch my younger daughter play basketball sprinting up and down the court with a beet red face from my screen at home with a mask on hoping she wouldn't pass out, watching my students struggling to breathe and keep the masks on during P.E. class especially the children with issues such as autism, asthma, anxiety, obesity and more.

We **did** scare the children. We scared them, we arrested their natural adolescent development, we stunted their social growth as well as their academic growth. In my professional opinion, masking children contributed to the massive uptick in behaviors we are struggling with in the schools today, as well as addicted them to their screens. We are still struggling to make up for what they lost out on. The only thing that mandating masks for any "outbreak" will do is make the students in Rhode Island take more steps back. They cannot afford to take any more steps back. We need to move forward, let the children thrive, and make some common sense decisions that prepare them for life without undue psychological and physical harm.

Please strike down any regulation that allows authorities to force masking again!

Sincerely,
Sheryl Green

Unmask our children

Lori A. Reis-Brooks <LARBrooks@protonmail.com>

Thu 3/7/2024 1:56 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Good afternoon,

I am a two time angel mom and mom to a beautiful daughter and step son. I am writing to you to oppose the masking of our children, not only in RI but all over the world.

As I stated I have already lost two sons. This was due to the fact of being forced to do medical procedures against my own will. This led me to being an advocate in my local area here in RI.

I have and most definitely will take my daughter out of public school in RI if there is ever a time we are being forced to mask our kids again. I homeschooled my daughter for two school years when this fiasco began in 2020 and won't hesitate to do this again.

This time however, I will use my voice to bring other parents along with me through the networks I have created.

I ask you to stop any and all mask mandates today and in the future.

Sincerely,

Lori Reis-Brooks

Sent from Proton Mail [proton.me] for iOS

Testimony for mask mandate hearing, 3/15/24

Judith Walker Mullin <walker.judith@gmail.com>

Thu 3/7/2024 7:02 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

In response to your proposed regulation empowering the DOH to require RI schoolchildren to wear masks in order to preventing the spread of infectious diseases, I'd like to speak up against any such governmental powers.

-The efficacy of masking to prevent transmission is unclear at best, especially among children who often don't wear masks properly and whose masks are often not fitted well.
-The cost of masking must be seriously considered. Many studies show that masking has direct negative effects on children's learning and social development.
-Children are at extremely low risk of serious illness or death from COVID.
-Masking was not viewed as mandatory prior to COVID and should not be seen now as a normal part of disease prevention.
-Mandatory masking also infringes on the right of parents to make decisions concerning their children's health.

Please withdraw this regulation.

Sincerely,
Judith Walker
Westerly, RI

Opposition to 216-RICR-30-05-4

Sara V <saravieira803@hotmail.com>

Thu 3/7/2024 7:21 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To Whom It May Concern:

I am writing in opposition to a mask mandate regulation for RI children. As a professional working with children who have communication issues for the last 24 years, I have extensive experience on what the last mask mandate imposed on children (particularly those with communication impairments).

Most children come to see me because they do not produce sounds properly and cannot be understood by others. Usually, these speech errors impact their education in regard to reading and spelling as well. For instance, I provide specialized instruction for children who might make a speech sound error for /k/ and that child produces a /t/ sound instead. So, for the word 'cat' the child will say 'tat'. If the child says 'tat' , most likely the child will spell it that way as well. Not only did the child have to wear a mask- but myself. How am I supposed to correct a child when they cannot see me to model the production, or they cannot see themselves in a mirror to correct it? How am I supposed to help the child who cannot communicate when a mask is imposed on them? The mask also impacted speech volume which made their voices muffled and difficult to hear.

Because of the masks, I did not get referrals for children who had masks on until 2-3 years into their education experience. Imagine a child who was producing sounds incorrectly all that time and spelling words incorrectly all that time because the child had a mask on. What will be the long-term damage? What will be harm be? I can attest that harm was made- children did not get services in time that would have helped communication and spelling skills much earlier.

Regards,
Mrs. Sara Vieira

Mask mandate

Wendy Violette <wendy_violette@yahoo.com>

Thu 3/7/2024 7:57 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

For the record I oppose any type of mask mandates being imposed on children in R.I. schools. My son got horrible headaches from wearing masks and I had to homeschool him in 2021 because of this. They don't stop illness from spreading and they cause more harm than good. We as parents should be able to have the choice to have our children wear masks or not. Thank you. Wendy Violette

Yahoo Mail: Search, Organize, Conquer [mail.onelink.me]

stop masks

sid gonsalves <ntmd8rbud82@gmail.com>

Fri 3/8/2024 8:15 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To whom it may concern, I Sid Gonsalves oppose any type of mask mandates in our state of Rhode Island and nationwide for that matter! They are more of a hazard to our health mental and physically!

Sidonio Gonsalves, Tiverton RI resident

Unmask Our Children

jodi thompson <jodicat.thompson@gmail.com>

Fri 3/8/2024 10:44 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@homtail.com <consent4RI@homtail.com>

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Report Suspicious

Please mark your files that I am firmly opposed to *all* mask mandates for children in the State of Rhode Island.

Thank you,
Jodi C Thompson

opposition

Lauren Gilmore <lauren.gilmore24@gmail.com>

Fri 3/8/2024 11:09 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I oppose ANY regulation of mask mandates in RI.

Lauren Gilmore Lauren.gilmore24@gmail.com 401-524-1368 Sent from Gmail Mobile

Oppose the RIDOH power to mandate masking in schools

Donna Belden <dbelden6@gmail.com>

Fri 3/8/2024 5:10 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I oppose giving the Rhode Island Department of Health the power to impose masks on our children for ANY infectious disease (RSV, flu, chicken pox.). RIDOH should never have the ability to mandate this policy. We had RSV, flu and chicken pox before COVID and never mandated masks. Masks and the vaccines did not stop the spread. Young children did not wear them properly. Some older children became depressed.
Children had many issues with the masking from speech to understanding what is being said in the classroom.

Leave this decision to the **parents** and their doctors, not to an agency that has other stressing issues they need to address.

Donna Belden
2111 Frenchtown Rd
East Greenwich, RI

Opposition

Adriannah Perham <adriannahellen07@icloud.com>

Fri 3/8/2024 5:30 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I oppose ANY regulations mandating Facial Masks in RI
Sent from my iPhone

Masking

Madeline O'Dell <klondtrans@cox.net>

Sat 3/9/2024 11:49 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To Whom It May Concern:

It is a PROVEN FACT that masks DO NOT work!!! That is more apparent with CHILDREN. So, this mandatory MASK MANDATE IS GARBAGE!!!!!!!!!!!!

Madeline O'Dell
Grandmother of a school aged child in RI

Vote no to mandated masks

Kyra Little <kyralittle144@gmail.com>

Sat 3/9/2024 12:04 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello,

Regarding proposed rule 216-RICR-30-05-04-masking in schools we request that you side with masking being a personal choice.

Mandating masks is a violation of personal right to choose and advocate our own wishes in our health values. Mental health in children was at an all time low as a result of the masking and the emergency rooms flooded with children for psychological issues.

If a family wishes to mask, it should be a personal choice, not a mandate.

Thank u.

R 216-RICR-30-05-4

gcdesignbuildassociates <rdgaryc@gmail.com>

Sat 3/9/2024 4:31 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

RE: Masking

Hello,

Informing you we are in full support of mandatory masking in schools and other public spaces in the case of determined and/or declared public health crises or concerns.

Thank You.

Gary & Candace Charpentier
Barrington RI.

Sent from Mail [go.microsoft.com] for Windows

(No subject)

Anne Rich <richanne578@gmail.com>

Sat 3/9/2024 9:21 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

The children of Rhode Island should never be masked in school again .
Facts are the CDC has stated there is not even an isolation period for Covid at this point , it is being treated like any other respiratory illness .
Masks do nothing , children are not and never have been at risk , their mental health has suffered enough through all the nonsense these last 4 years , no one needs to bring this back into their lives!!!!
Anne Rich

Mask

Amanda Law <amandalynn11811@gmail.com>

Sun 3/10/2024 10:59 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I am 12 and I will never wear a mask again. It made me sick and dizzy and I couldn't breathe. I hated school when I had to wear it. I will not wear it again. No person can make me cover my face. My doctor said wearing the mask was very bad for my health and that is why I was getting headaches and a rash on my face. I couldn't hear the teacher talking or see her face. All of my friends that wore masks got covid anyways. It was stupid.

Sincerely,
Amanda

Opposition to regulation

Tammi Lawrence <tammi.lawrence1@gmail.com>

Sun 3/10/2024 11:38 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Dear Mr. Garceau,

The parents in RI have spoken loud and clear that we will not mask our children. EVEN Brown University found **no correlation** between mask mandates and Covid-19 rates among students! Masking is clearly unjustified.

Not only is it unjustified, it is unjust! The DPH has no jurisdiction over what my child puts on them or what medication goes into them. We have undeniable bodily autonomy rights.

What HAS been proven is a **decline** of mental health and academic achievement in students across the state. My daughter suffered both. She will never wear a mask again, you can count on that. While masked, my daughter did not engage with classmates and her teachers. A study regarding this phenomenon, showed that wearing masks frequently caused **anxiety** and **stress** reactions in children. They exhibited **depressive** experiences, social **withdrawal** and **reduced** participation (www.ncbi.nlm.nih.gov/pmc/articles/PMC7417296/ [ncbi.nlm.nih.gov].) Teachers also reported **negative impacts** on the learning environment. (Marchant,Supra, at 25.)

Masks caused **negative** physical changes, such as; i**ncreased** heart rate, **decreased** oxygen saturation, headaches, dizziness, listlessness, **impaired** thinking and concentration problems. It also impacts temperature regulation and **impairs** field of vision. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8072811/ [ncbi.nlm.nih.gov].)

Suffice to say, that the masking of children, or anyone for that matter, was an epic mistake in history that shall not be repeated.

Respectfully,
Tammi Lawrence

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PMCID: PMC7417296
PMID: 32917303

Masked education? The benefits and burdens of wearing face masks in schools during the current Corona pandemic

Manfred Spitzer[1]

Abstract

Face masks can prevent the spread of the virus SARS-CoV-2, in particular as this spread can occur from people with no symptoms. However, covering the lower half of the face reduces the ability to communicate, interpret, and mimic the expressions of those with whom we interact. Positive emotions become less recognizable, and negative emotions are amplified. Emotional mimicry, contagion, and emotionality in general are reduced and (thereby) bonding between teachers and learners, group cohesion, and learning – of which emotions are a major driver. The benefits and burdens of face masks in schools should be seriously considered and made obvious and clear to teachers and students. The school's specific situation must also inform any decision regarding face mask use.

Keywords: Masked education, Covid-19, Corona virus, Face masks, Emotions, School, Shutdown

1. Introduction

A new coronavirus, SARS-CoV-2, has caused a global pandemic of the disease Covid-19, with – as of July 31st – almost 300.000 new cases within a single day, more than 17 million confirmed infections, and more than 670.000 deaths [16]. Initially regarded as some form of flu with symptoms such as fever and cough, it has been found to be much more severe, affecting not only the l but also the liver, heart, kidneys, and brain, with symptoms such as anosmia [12] and cogni dysfunction due to defects of neuro-axonal integrity (even in mild to moderate cases; [1]). I

Feedback

verely ill patients, the virus causes a two-pronged attack by a dysfunctional immune system ("cytokine storm") and blood clotting system ("multi-organ thrombosis"; [33], [66]), causing strokes with chronic neurological deficits [60], [70].

Compared to adults, children are less likely to fall ill, and if so, their illness is usually mild [34]. However, in order to decrease the spread to the virus, along with other measures of physical distancing and economic lockdowns, school closures were implemented during March 2020 affecting more than 1.5 billion students (children and adolescents) around the globe [73]. These closures of schools lasted for a few weeks only (as in Denmark) up to several months (in Italy and many other countries; [15]) and led to marked decreases in educational gains [75], hunger (because school meals were no longer served), increases in child abuse (because children were no longer observed by school staff), and, in general, the risk of "scarring the life chances of a generation of young people"[2] (because of the long-term psychological, physiological, educational and even economic burden [3], that societies put on their most vulnerable members; [15]).

As long as there is no vaccine and no specific treatment, the first pandemic of the 21st century is fought with methods from the 14th to the 19th centuries: Distancing, hand washing, and covering mouth and nose with a piece of cloth. On a global scale, face masks have become an increasingly important part of national strategies to fight the current corona pandemic. Given that school closures already have come to an end, or will have to end eventually, the question of wearing face masks at schools during the next phase of the pandemic is heavily discussed, particularly, where new cases pop up in spots of waxing and waning infections, or in some states, in the form of additional waves of infection (as for example currently in Israel, Australia and Croatia).

Because the virus is still with us, this is all the more pressing for the following characteristics of the virus and its transmission [4], [8]:

- People without any symptoms may be infected and spread the SARS-CoV-2 virus.
- Upon speaking, the virus is released into the air, the louder the more.
- The virus can remain airborne for many hours in classrooms.
- Wearing masks is comparatively cheap and easy to implement and supervise.
- At the same time, wearing masks may have physical side effects.
- Face masks impair face recognition and face identification.
- Face masks impair verbal and non-verbal communication.
- Face masks block emotional signaling between teacher and learner.

Given these pros and cons, it is not clear whether face masks should play a major role in educational settings in times of the current viral pandemic. Moreover, given the diversity of educational settings in terms of country, culture and learners' as well as teachers' age, different considerations may weight in differently in any balanced decision as regards the use of face masks in classrooms. This matter should be discussed urgently, since it globally affects more than 1.5 billion students, teachers, and school staff directly, and, in addition, their families indirectly.

2. Face masks are effective against the spread of the new corona virus

This pandemic has been a moving target as regards our knowledge about it.[3] The issue of wearing face masks may serve as a prime example. During the time of school-closures (from about the middle of March into April and/or May 2020) it became clear that face masks covering mouth and nose in closed public spaces (public transportation, stores, restaurants etc.) are an effective means of preventing the spread of the virus and thus, the worsening of the pandemic. This had not been clear at the time when the pandemic started in most countries (February 2020), as institutions such as the World Health Organization (WHO), the US Centers of Disease Control and Prevention (CDC) and, for example, the German Robert-Koch-Institut (RKI), as well as many governments across the globe, did not recommend the use of face masks to fight Covid-19.[4]

Upon the reopening of schools in April and May, this situation had changed [2], [26], [45], and by June 2020 there was no longer any doubt (see Fig. 1) that wearing face masks is one of the most effective preventive measures people can take to protect themselves and others from becoming infected with the virus [65]. As mask wearing by infected individuals reduces transmission risk, and because of the high proportion of asymptomatic infected individuals [68] and transmissions, by now there is a strong case for the effectiveness of widespread use of face masks in reducing the spread of COVID-19. In short, since it is clear that people may be infected and infectious even though they do not yet show any symptoms of Covid-19 – which is a peculiar feature of the SARS-CoV-2 virus – face masks can definitely mitigate the effects of this especially dangerous virus.

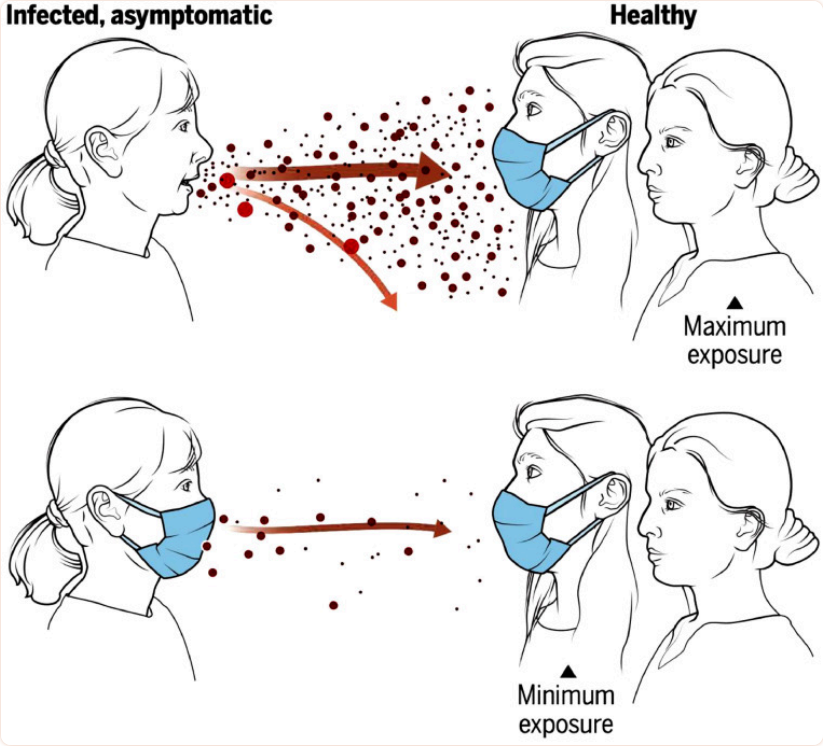


Fig. 1

Face masks reduce airborne transmission of the SARS-CoV-2 virus. The authors comment: "Infectious aerosol particles can be released during breathing and speaking by asymptomatic infected individuals. No masking maximizes exposure, whereas universal masking results in the least exposure" ([65], p. 1423, © Science Magazine, with permission).

In a Chinese study from Wuhan, for example, it has been estimated that up to 79% of viral infections were caused by undiagnosed, presumably asymptomatic people [47]. In two other studies, one from two surveys of 2812 and 2343 inhabitants of the small town of Vó near Padua in Italy, and another from 1032 healthcare workers (including frontline patient-facing staff such as doctors, nurses and physiotherapists) in the UK, similar findings have been reported [42]. In the Italian study, 42,5% of confirmed SARS-CoV-2 infections were asymptomatic, and in the British study, 60% had no or only very light symptoms. That is, you get sick from contact with people who are apparently healthy. This is why in the present Covid-19 pandemic, it is not possible to have only those people wear masks who are infectious. Everybody can be infectious while not knowing it [43]. The only way to stop infections from happening, therefore, is to have *everybody* wear face masks.

It is known for more than 70 years that the act of speaking generates oral fluid droplets that vary widely in size, from clearly visible to invisibly small aerosols [24], [55]. The louder someone speaks the more droplets and aerosols are produced. Regardless of their size, they all can harbor infectious virus particles and spread viral diseases [2], [5], [6]. In fact, the virus has been shown to remain airborne for many hours in a closed indoor space such as a classroom [49]. As Prather and coworkers note in their highly informative perspective, published in Science magazine online

on May 27th 2020: "[…] calculations predict that in still air, a 100-μm droplet will settle to the ground from 8 feet in 4.6 s, whereas a 1-μm aerosol particle will take 12.4 h [to settle down]. Measurements now show that intense coughs and sneezes that propel larger droplets more than 20 feet can also create thousands of aerosols that can travel even further. […] under many indoor conditions, where aerosols can remain airborne for hours, accumulate over time, and follow air-flows over distances further than 6 feet" ([65], p.6498). The authors summarize their perspective with a highly convincing drawing, which is reproduced in Fig. 1.

There is additional epidemiological evidence for the effectiveness of wearing face masks regarding the spread of the new coronavirus: In Hongkong, 96% of the populations used face mask, and the incidence of new cases in March was 129 per million inhabitants, whereas in Spain, Italy, and Germany, where at the time no face masks were used, the incidence was 2983 (Italy), 2251 (Spain), and 1242 (Germany) per million [31]. Shortly after the major of the German city of Jena (with about 110,000 inhabitants) implemented a face mask use order for the entire city on the 6th of April to fight the spread of the virus (three weeks before this was done for entire Germany), there were no new cases for 9 consecutive days. Compared with a "surrogate" Jena (a weighted mix of 4 German cities) as a control, this decline in new cases was 23% [56].

A natural experiment published on June 16th 2020 used the different timing (between April 8 and May 15) of state policies mandating public or community use of face masks or covers in 15 US states plus DC in mitigating covid-19 spread [52]. The study found that the changes in the daily county-level COVID-19 growth rates between March 31, 2020 and May 22, 2020, was associated with a decline in the daily COVID-19 growth rate by 2% by two to three weeks after the mandatory face mask use. At first blush, this may sound as a small effect, but three weeks of cumulated 2% decrease amounts to a decrease of over 40%. Accordingly, from their data, the authors estimated that as many as 230,000–450,000 Covid-19 cases had been averted by May 22, 2020.

Finally, a large comprehensive review and meta-analysis, published in the Lancet online on the 1st of June 2020, used data from 172 observational studies across 16 countries (among them 44 comparative studies in healthcare and non-healthcare settings [13]. Face masks (surgical type) reduced infection risk by 85%. Since face masks are comparatively cheap and easy to use, they are among the most simple and straight forward means to curb SARS-Cov-2 and Covid-19 transmission (see also [53]).

3. The side effects of face mask use

It is a medical truism that everything that has effects also has side effects. The physical side effects of face masks have been mostly reported by medical professionals working in surgery and related surgical environments, and science professionals working in labs. In a study of 158 health care workers during the Covid-19 pandemic, the most common side effect of prolonged face mask use was bilateral headache, reported by about 80% of the participants [58]. Headaches occurred one to four times during a 30-day period of mask use and was rated as mild by the majority (72%) of respondents. Within 30 min after removal of the face mask, the pain resolved spontaneously. Pain medication (such as non-steroid analgesics) was used in only a few cases.

Face masks may further cause perioral dermatitis with rashes and redness, i.e., an infection of the skin around the mouth because of saliva, sweat, and moist vapor between the mask and the skin. This may provide a breeding ground for bacteria. Itchy rashes may be caused by irritant dermatitis, caused by the mask and/or the attached rubber strings rubbing the skin of nose and ears [63].

An experimental study on the physical effects of wearing either a surgical or an N95/FFP-2 face mask was performed with 5 healthy male and 5 healthy female subjects, who performed intermittent exercise on a treadmill while wearing the protective facemasks in a climate chamber controlled at an air temperature of 25 °C and a relative humidity of 70%. Both types of face masks led to significant differences in temperature and humidity in the microclimates between face masks and skin. In particular, compared to the surgical mask, the N95 mask led to higher humidity and skin temperatures inside the facemask, higher heart rate, and increased negative „sensations, including feeling unfit, tight, itchy, [and] fatigued," as stated by the authors ([46], p. 501). A recent study on the cardiovascular effects of face masks (surgical or N95/FFP-2) in young healthy male subjects on a bike-ergometer showed a 2 percent decrease in maximum power (not significant) for the surgical mask and a 5 percent decrease of maximal power ($p < 0{,}01$) for the N95/FFP-2 mask [32]. Overall, in both studies subjects preferred the surgical face mask. This finding, among others, led to the fact that N95 masks were never recommend for wearing by the general public, as they not only are more expensive, but also – because of the discomfort they imply – much less likely to be worn by everybody for extended periods.

As regards the prevention of Covid-19, additional concerns of wearing face masks have been articulated, for example:

- Wearing a face mask may give a false sense of security and may make people less compliant with other infection control measures.
- Because of problems with understanding speech (see below), people may move closer together, without intention, and thereby increase infection risk.
- Wearing face masks may cause glasses to fog and thereby cause anything from discomfort to accidents.
- Wearing a face mask makes the exhaled air go into the eyes. "This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself" [44].
- "Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those phenomena increase breathing frequency and deepness, and they may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs," the authors add.
- When infected people re-breathe air in the mask, their virus load increases.

In other words: Whereas face masks are intended to ease the burden of the pandemic they may at the same time make it worse under certain conditions.

In addition to these problems of physical health, three more problems of using face masks have to be addressed: Impaired face recognition and identification, impaired communication, and blocked emotional signaling.

4. Face masks impair face recognition and face identification

In daily life, human observers are extremely proficient in recognizing faces, discriminating between them and using them to derive a vast range of information, be it about static features like age, gender or identity, or changeable features like gaze direction, lip movements or emotional states (see second next section).

Human beings are biologically programmed to recognize faces [68]. As soon as babies are born, they show a preference for looking at human faces above anything else, and they will even stare at a rudimentary drawing of a face if it is shown to them. But by the age of seven months babies able to recognize angry or fearful faces [62], [37]. The advantage of face-processing as compared to non-face stimuli declines during the second year of life [48].

On top of this innate preference, the role of social experience in face processing and recognition becomes ever more salient, as research with infants has shown using such different measures as behavioral data, eye-tracking data, and neuroscience data mainly from event related potentials (ERP), functional magnetic resonance imaging (fMRI), and near infrared spectroscopy (NIRS). By now, the role of experience in the process of perceptual narrowing in face processing has demonstrated enhanced behavioral and neural responsiveness to (1) mother over stranger, (2) female over male, (3) own-race over other-race, and (4) native over non-native faces. In addition, (5) infants' neural responses to faces in multimodal contexts, such as audiovisual speech, change during development, which finally leads to (6) the emergence of attentional biases that cause enhanced responsiveness and processing of faces commonly encountered in the native environment: We recognize and identify the faces of our peers faster than faces of strangers [67], just as we recognize the sounds (phonemes) of our mother tongue better than unfamiliar sounds (phonemes) from unfamiliar languages [61].

Hiding the lower part of the face with a face mask markedly impairs face recognition and face identification. In fact, this is why burglars and thieves wear them. As mask-wearing has become a normality in many societies, the magnitude with which covering our faces affects our social interactions and ability to recognize and identify other people becomes ever more clear. In school settings, the ability to know and recognize each other is normally taken for granted, and – like air for breathing – it does not come into focus unless it is lacking. But within seconds of absence, its importance is realized.

But there are also some quick fixes for this problem, such as clearly visible name tags, “personalized” masks, and our ability to recognize and identify each other from cues provided by our voice and body shape and posture.

5. Face masks impair verbal and non-verbal communication

One of the richest and most powerful tools in human communication is the face, from which observers can quickly and easily make a number of inferences — about identity, gender, sex, age, race, ethnicity, sexual orientation, physical health, attractiveness, emotional state, personality traits, pain or physical pleasure, deception, and even social status [38]. When strangers meet, who speak two different languages which they do not mutually understand, they can still interpret facial expressions such as smiles and frowns with ease and thereby communicate. In fact, the most basic form of communication between humans is by facial expressions. This is because facial expressions are a simple universal language that we instinctively understand [25]. It may be for this reason, that many people do not like the wearing masks at all in the first place.

Because we cannot see the lower half of the face when someone is wearing a mask, our ability to understand people is reduced considerably. We are forced to rely only on language and gesture, which limits the extent to which we can interpret nuance, with some input from interpreting eye movements, which are still visible above the mask. In fact, evidence from eye movement studies during gazing at a face suggests that the eye is the facial feature that is attended to first and longest during face processing, as they appear to be most informative in communication. Once we direct our gaze to something, this something thereby can become the focus of shared attention, which is a basic mechanism of doing things and solving problems *together*.

But second to the eyes are the regions of mouth and nose, when it comes to attending facial features. For effective verbal communication, covering the mouth with cloth has two detrimental consequences: First, the auditory signal is impaired, as faces masks may dampen sound amplitude, and especially may absorb frequency bands used in speech. Second, the visual signal from the lips is completely obstructed. While most people may never have realized, this signal is used by human beings to aid speech understanding. From birth to about 8 months, babies look at their mother's mouth in order to pars the stream of sound into meaningful units (phonemes) in order to learn their mother tongue. In fact, if they are reared bilingually, they have to learn a larger number of phonemes and therefore start to look at their mother's mouth earlier and for longer than monolinguals [64]. When grown up, we tend to look close at the mouth of somebody under circumstances of impaired sound comprehensibility, such as noisy environments, low quality sound in movies and video calls. Deaf people use lip-reading and thereby completely rely on visual cues for understanding speech (which is why there are special face masks with a transparent piece over the mouth to meet the demand for visual speech input).

Because speech transmission is impaired by mask-wearing, there is a risk of misunderstanding when face masks are used widely in schools. Speaking through a face mask may dampen higher frequencies and therefore may impair verbal communication. The size of the effect depends on the speaker, the type of mask, the listener's hearing, and background noise, and may therefore vary between negligible [54] and considerable [7]. In addition, it is well known that visual cues help in speech recognition, which may be an additional cause of face mask induced impairment of speech perception and communication.

6. Face masks block emotional signaling between teachers and students

Features of faces (such as the size and form of the nose, the color of the eyes etc.) and their configuration are not only used to identify faces but also to infer the emotion expressed by them [10]. Charles Darwin [18], [19], the founding father of evolutionary theory, was the first to study the evolutionary origins of facial expression of emotions. Even infants below one year of age are able to comprehend facial expressions as social cues representing the feelings of other people before they are one year old. They start to respond to fearful faces but also respond to happy faces soon thereafter.

Emotions play a large role in our social interactions, of which teaching and learning are among the culturally most relevant. Recently, anthropologists have proposed, that the most recent evolution of the human brain has been shaped by its increased capacity for the cultural transmission of knowledge, i.e., teaching and learning [36].

More than 50 years ago, building upon research by European ethologists from the school of Konrad Lorenz, the Californian psychologist Paul Ekman performed experiments to demonstrate the existence of basic emotions regardless of culture: surprise, fear, disgust, anger, happiness, and sadness [27], [28], [29].

It is long known, that negative affect implies more fine-grained perceptual and cognitive processing whereas positive affect leads to more holistic processing. Accordingly, it has been shown, that emotions which are perceived in faces have an effect on the style, faces are processed in the first place: A face that is perceived to have a negative emotion is processed in a less holistic manner than a face displaying a positive emotion [17]. Of course, this is the case for the processing of other (non-face) content: Smiling broadens cognition and thereby increases creative thinking [39], whereas criticism causes anxiety and a reduction in creativity. A student looking at the critical face of a teacher thereby becomes less creative, and thereby less able to solve math problems, which increases the likelihood of math anxiety to develop [51]. This decreases creativity further as well as increases anxiety of not being capable doing mathematics in a vicious circle – *independent of mathematical talent!*

As stated above, the face provides a universal language for communication, in particular, the communication of emotions. The mouth region on a face conveys information that is crucial for smiling, i.e., a positive emotion, which can work as social glue and facilitates positive social cognition and action [69]. Not seeing the bottom half of the face makes it particularly difficult to recognize a mask-wearer's positive emotions – pleasure, joy, happiness, amusement, sociability, and friendliness – as they are basically communicated by a smiling mouth. Therefore, face masks impair mainly our positive social interactions and our ability to understand, and empathize with, one another. Even though in some cultures, a smile may also be taken as a sign of stupidity, shallowness, and even dishonesty, as a large cross-cultural study on social perception of smiling individuals has shown [41]. The most prominent meaning of a smile, however, definitely is a positive emotion.

There are two types of smiles, true smiles and dishonest smiles. A true or genuine smile, also known as a *Duchenne* [5] *smile*, involves both the mouth (the zygomatic major muscle raises the corners of the mouth) and the eyes (the orbicularis oculi muscle raises the cheeks, forms crow's feet around the eyes, and causes the eyebrows to move closer as in frowning). In contrast, dishonest smiles, which are also called "fake smiles", "Botox smiles", "Pan Am smiles[6] " or "non-Duchhenne smiles", involve only the voluntary raising of the corners of the mouth in order to intentionally signal politeness. A recent meta-analysis of Duchenne versus Non-Duchenne smiles found that, overall, Duchenne smiles and people producing Duchenne smiles are rated more positively (i.e., authentic, genuine, real, attractive, trustworthy) than non-Duchenne smiles and people producing non-Duchenne smiles [35]. Moreover, the difference between Duchenne and non-Duchenne smiles was greater when the stimuli were videos rather than photographs (i.e., when smiles were more live-like) and when smiles were elicited naturally rather than through posing paradigms (i.e., when smiles were more authentic).

Given that the real smile involves the upper and the lower half of the face, with the upper half providing the distinctive "frowning" that renders a smile a true smile, there is a lot of room for misunderstanding: Face masks block the smile and allow only the frowning to be communicated – which may actually be *worse than no smile at all!* In general, as face masks cover the bottom half of the face, the ability to detect positive emotions and to discriminate between emotions is considerably impaired. Movements of the lips and the display of teeth are no longer perceptible by the observer, leaving only the top half of the face for detecting the mask-wearer's emotions.

I already mentioned the possibility of interpreting only partially-revealed facial expressions wrongly, i.e., misconstruing frowning and the squinting of the eyes without a visible mouth as skepticism rather than true smiling.[7] In addition, emotions such as surprise or disgust that utilize the mouth may be mistaken for strongly negative emotions such anger or sadness. In sum, masks may increase the perception of negative emotions and diminish the perception of positive emotions.

In 2017 researchers from the University of Bielefeld published results from an experimental study of emotion recognition, which clearly demonstrated the importance of the eyes and mouth in the perception of emotions from faces. The authors presented single faces of two different individuals expressing Ekman's six basic emotions (as well as a seventh neutral face expression) behind a 6 × 8 grid of 48 white tiles that were sequentially (in random order) uncovered to 94 student subjects, with subjects instructed to stop the uncovering as soon as they recognize the emotion of the face and name it correctly. For each subject, the experiment consisted of a total of 224 trials (2 face identities times 7 expressions times 16 repetitions per expression).

With this method, it was possible to discern which of the 48 parts of the face contributed to what extend to the observer's recognition of the facial expression being revealed. Results showed that observers relied mostly on tiles that covered and revealed the mouth and eyes when they correctly named the emotion being displayed. In particular, the subjects identified fear and sadness largely by focusing on the eyes whereas disgust and happiness were more successfully identified when subjects focused on the mouth region [74].

If applied to the use of face masks in school settings, these results suggest that happiness and disgust are less likely to be recognized, whereas fear and sadness may be recognized with a higher probability. Given that disgust is an emotion only rarely displayed in school settings, the net result of face masks may well be that the covering of the mouth, i.e., the "organ of smiling", leads to diminished perceived happiness.

In addition, the existence of a face mask may reduce the motivation of the wearer to produce facial expressions in the first place. Since such expressions serve the purpose of communication, the realization of wearing a communications-blocking device will reduce efforts to facially express emotions.

Moreover, according to the "embodied emotions hypothesis" first proposed by William James more than one hundred years ago, not physically displaying emotions reduces their experience. In their view, specific behaviors cause us to experience emotions (and not vice versa), as exemplified in the following statement: "You are not crying because you are sad, but you are sad because you are crying". Accordingly, once you no longer produce a smile, you are less happy. And since the perceiver of your face does not perceive the emotion because of the mask, both the sender and the receiver of the emotional communicative signal will be affected by the face mask.

At the same time, emotional mimicry and thereby emotional contagion [59] is interrupted by the mask as well, i.e., the social phenomenon that we are involuntarily copying the facial expression of other people with whom we communicate. As the emotions of the viewer also follow his expressions, his or her emotions will be blunted as a result. These reactions are typically outside of conscious awareness and occur within half a second [23].

In sum, recognition of, and response to, the outward emotional displays of one's peers' faces is a critical and necessary component of social interaction in schools. It helps pupils and teachers to modify their behavior in order to align with social communication and behavioral norms. When these emotional displays are inhibited by face masks, our ability to communicate effectively with one another is reduced and we are primarily left with mimicking negative (frown) emotions. All of this happens primarily outside of conscious awareness, and hence, is hard to be consciously controlled or even corrected. Since emotions are a major driver of group cohesion, the decreased emotionality, and decreased *positive* emotionality in particular, may interfere with smooth classroom action. Given the fact that the very process of learning is facilitated by emotions (this is their main raison d´être), face masks are likely to cause some interference with pedagogy.

7. Discussion: to mask or not to mask?

In their paper with the same Shakespearian title as this discussion, Eikenberry and coworkers close as follows: "Our findings suggest that face mask use should be as nearly universal (i.e., nation-wide) as possible and implemented without delay, even if most masks are homemade and of relatively low quality. This measure could contribute greatly to controlling the COVID-19 pandemic, with the benefit greatest in conjunction with other non-pharmaceutical interventions [such as physical distancing] that reduce community transmission" ([26], p. 305). German pediatricians

have voiced a similar opinion [76]. However, in the light of what has been discussed so far, this can hardly be the final verdict, when it comes to wearing face masks at school to prevent the spread of the present corona pandemic.

In a society within which the large majority of people wear masks, there is a lot of room for mutual emotional misinterpretation and therefore misunderstanding. People may feel that someone is being aggressive towards them, when there is no real intent of aggression (but in fact, a true smile), and may react accordingly – potentially leading to all sorts of difficult, and even dangerous, situations. This regards schools just as well.

Therefore, at the very least, all school professionals should be aware of the detrimental effects of face masks on face recognition and identification, communication, and social-emotional interaction. These should be weighed against the alternatives, i.e., school closures (with the enormous burden on the children and their parents) and school re-openings without masks (with their increased risk of new infections). In Germany, school authorities are rather reluctant to reopen schools after the summer break, but also face increasing criticism for not doing so. In addition, teachers' unions point to the increased risk of elderly teachers to contract a potentially lethal disease.

The ideas of what to do about schooling in times of a pandemic do not exist in a contextual vacuum. In fact, our dealings are far from balanced and contradiction-free: We have to make sure physical distancing in theatres but not in airplanes; we may shop with masks in supermarkets but eat without them in restaurants; we may have assemblies with friends and family but must not have seminars at the university, etc.

Of particular relevance for schools may be the experiences with face masks in hospitals, including psychiatric hospitals, such as the clinic which I am heading. I implemented the general use of face masks for all staff and patients on March 16th 2020, and it soon became clear that they interfere with practicing psychiatry: The decreased emotional observability made the job harder to do. A psychotherapist wrote me an email, noting that socially complicated and challenging inpatients in psychotherapy are very difficult to treat, "as dissociative states and tensions are much harder to detect early enough so that appropriate interventions can be performed. In addition, exposition training (such as in patients after trauma, patients with panic disorder, and patients with obsessive compulsive disorder, OCD) which implies the conscious provocation of anxiety, are hard to do with a face mask obstructing the perception of the patient's emotions. […] Even in diagnostic interviews, face masks interfere with decisions regarding diagnosis and therapy" (Bosch, personal communication [11]).

A hairdresser from another city sent me an email, once the lockdown was over such that he was able to restart his business: "Yesterday I had two new customers, and I must say that I just had to ask them to go outside so we could remove our masks briefly. It is so difficult to give advice as to what haircut should be done when you cannot fully see the face of the customer. I also talked to my team about how to communicate with masks, as smiles no longer work. We therefore attempt to verbally communicate in a more positive manner in order to counteract the lacking smiles" (taken from [71], p. 184; translation by the author)

I am in no position to rank the settings of psychotherapy, hairdressing or schools in terms of the importance of emotional connection, but these examples do make it clear that schools by no means are the only places where masks can cause difficulties. The general headmaster of the elementary and basic schools (up to grade 10) in Ulm told me that there was a lot of discussion as regards wearing face masks at schools, when the corona-pandemic was roaming through Germany by the middle of March 2020. But even in schools for the mentally retarded and behaviorally challenged students, face masks were implemented and worn by teachers and students. In some schools, physical distancing was implemented, with or without masks. Some teachers as well as other headmasters voiced concerns that they could not imagine teaching with face masks. The headmaster I talked to, in contrast, was quite positive about the possibility to do so in schools, even with young, and challenging, students.

As regards the problems of communication and emotional signaling, it should be noted that emotions can also be decoded from the body posture, a process quite similar to the decoding from faces [30], as well as from prosody (the "melody of speech") and gesture. So the decreases in facial emotion communication can be compensated to some degree. In addition, there is learning. We know from our experience with sensory handicapped people, that they learn to compensate by sharpening their remaining senses. Teachers willing to learn and engage, will find workarounds – even around the blocking by face masks. One of which is simply talking about emotions. Just as in psychotherapy, where learning to talk about emotions (and not just having them) is an important mechanism of coping with emotional distress, students and teachers can learn this – and the pandemic is a good reason to do so.

In addition to the considerations already discussed, the following general remark should be considered: Face masks serve the additional benefit of reminding everybody who is present at school – pupils, teachers, administrative and supporting staff – of the lingering presence of the pandemic and of the appropriate behaviors that are highly important for keeping everybody safe. A face masks protects the person wearing it and the person with whom he or she talks. So using a mask amounts to doing a favor to others and oneself. It may be considered as a prime example of a cultural norm that, if adhered by everybody, benefits the entire society considerably, with little cost to the individual. This idea, in general, is one of the most important pro-social ideas, which have traditionally been promoted by mandatory schooling systems and the states implementing them. So why not use wearing face masks as a simple tool for social behavior training? Other such "tools of the mind" have been widely proposed (music, sports, handcrafts martial arts) to increase attention, executive function, and cognitive control in 4–12 year olds [21],[22].

Finally, when it comes to weighing the pros and cons of face masks, general and specific medical and epidemiological considerations are an important part of the equation. During the height of the pandemic in Germany, little was known about such basics as "how infectious are children/adolescents?", "how effective are face masks really?", "how contagious is the virus" or "are things the same indoors and outdoors?" – This has changed.

We do know, for example, that viral particles in air will be more rapidly diluted outdoors, are sensitive to ambient temperature and relative humidity, and are inactivated by ultraviolet radiation in sunlight. This is why outdoor educational settings, wherever possible, should be highly

recommended.

In addition, the verdict on children as regarding their role in infecting other people is not yet in. Whereas some studies indicate that children are less likely to infect others [20], [50], some studies find children to be infectious [72]. Adolescents appear to be just as infectious as adults. Since they also have more daily contacts than older adults, they are the ones who definitely should wear masks in order to protect others, in particular, if they live with their parents and grandparents [9]. If small children in China, South Korea, Japan, and Vietnam can be taught basic rules of hygiene such as handwashing and careful hygiene behavior, children and adolescents in Western societies should be capable of doing it just as well, including wearing face masks.

Finally, the spread of the pandemic is modified by the number of currently infected cases. I write this paper on an island in the German state of Mecklenburg-Vorpommern, on which at the time of writing there were zero cases. So there is no question as to whether schools should open here this fall. In other places, things are less ideal. There is a remaining risk, and the many risks we face in life must always be balanced carefully. By now, schools plan for the fall on a global scale. They must do so responsibly. And face masks should be part of the decision-making process.

Ethical statement

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Footnotes

[2]This quote is taken from Couzin-Frankel et al. [15], p. 241], who cite an open letter published in June 2020, signed by more than 1500 members of the United Kingdom's Royal College of Paediatrics and Child Health (RCPCH).

[3]Historically, this was also the case one hundred years ago, after the French bacteriologist Charles Nicolle discovered that the agent that caused influenza was much smaller than any known bacterium in October 1918, i.e. at around the time of the cusp of the pandemic. This news led, even in small-town American newspapers, to statements such that using face masks against influenza is “like using barbed wire fences to shut out flies” [14]. This discouraged the wearing of masks and caused a lot of discussion and distrust in the general public.

[4]The reason for this misguiding advice became clear over time: There were too few masks. Responsible advisors wanted to make the most use what was available, and therefore gave masks and other protective equipment to hospitals, where there were in short supply and most dearly needed. They could have done better and tell people to make their own mask from cloth (and sell them, if they are good at sewing).

[5]While conducting research on the physiology of facial expressions in the mid-19th century, the French neurologist Guillaume Duchenne identified two distinct types of smiles, one of which later became named after him.

[6]It is named after Pan American World Airways (an airline that no longer exists), whose flight attendants were trained to always smile at their passengers.

[7]This is why plastic surgeons have proposed to use botox, which can be injected around the orbicularis occuli muscle to prevent wrinkles around the eyes (no “crow's feet” and no frowning), as a means to prevent mask-induced false social signaling [57]. In addition, oxytocin may be used to dampen down fearful signaling from the eyes and to amplify trust signals and thus work against the detrimental social effects of masks [40].

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Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?

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Paul B. Tchounwou, Academic Editor

Abstract

Many countries introduced the requirement to wear masks in public spaces for containing SARS-CoV-2 making it commonplace in 2020. Up until now, there has been no comprehensive investigation as to the adverse health effects masks can cause. The aim was to find, test, evaluate and compile scientifically proven related side effects of wearing masks. For a quantitative evaluation, 44 mostly experimental studies were referenced, and for a substantive evaluation, 65 publications were found. The literature revealed relevant adverse effects of masks in numerous disciplines. In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES). We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.

Keywords: personal protective equipment, masks, N95 face mask, surgical mask, risk, adverse effects, long-term adverse effects, contraindications, health risk assessment, hypercapnia, hypoxia, headache, dyspnea, physical exertion, MIES syndrome

Feedback

1. Introduction

At the beginning of the spread of the novel pathogen SARS-CoV-2, it was necessary to make far-reaching decisions even without available explicit scientific data. The initial assumption was that the pandemic emergency measures were set in place to reduce the acute threat of the public health system effectively and swiftly.

In April 2020, the World Health Organization (WHO) recommended the use of masks only for symptomatic, ill individuals and health care workers and did not recommend its widespread use.

In June 2020, they changed this recommendation to endorse the general use of masks in, e.g., crowded places [1,2]. In a meta-analysis study commissioned by the WHO (evidence level Ia), no clear, scientifically graspable benefit of moderate or strong evidence was derived from wearing masks [3].

While maintaining a distance of at least one meter showed moderate evidence with regard to the spreading of SARS-CoV-2, only weak evidence at best could be found for masks alone in everyday use (non-medical setting) [3]. Another meta-analysis conducted in the same year confirmed the weak scientific evidence for masks [4].

Accordingly, the WHO did not recommend general or uncritical use of masks for the general population and expanded its risk and hazard list within just two months. While the April 2020 guideline highlighted the dangers of self-contamination, possible breathing difficulties and false sense of security, the June 2020 guideline found additional potential adverse effects such as headache, development of facial skin lesions, irritant dermatitis, acne or increased risk of contamination in public spaces due to improper mask disposal [1,2].

However, under pressure from increasing absolute numbers of positive SARS-CoV-2 tests, many prescribers further extended mask-wearing according to certain times and situations, always justified by the desire to limit the spread of the virus [5]. The media, numerous institutions and most of the population supported this approach.

Among the medical profession and scientists, the users and observers of medical devices, there have been simultaneous calls for a more nuanced approach [6,7,8]. While there has been a controversial scientific discussion worldwide about the benefits and risks of masks in public spaces, they became the new social appearance in everyday life in many countries at the same time.

Although there seems to be a consensus among the decision makers who have introduced mandatory masks that medical exemptions are warranted, it is ultimately the responsibility of individual clinicians to weigh up when to recommend exemption from mandatory masks. Physicians are in a conflict of interest concerning this matter. On the one hand, doctors have a leading role in supporting the authorities in the fight against a pandemic. On the other hand, doctors must, in accordance with the medical ethos, protect the interests, welfare and rights of their patient's third parties with the necessary care and in accordance with the recognized state of medical knowledge [9,10,11].

A careful risk–benefit analysis is becoming increasingly relevant for patients and their practitioners regarding the potential long-term effects of masks. The lack of knowledge of legal legitimacy on the one hand and of the medical scientific facts on the other is a reason for uncertainty among clinically active colleagues.

The aim of this paper is to provide a first, rapid, scientific presentation of the risks of general mandatory mask use by focusing on the possible adverse medical effects of masks, especially in certain diagnostic, patient and user groups.

2. Materials and Methods

The objective was to search for documented adverse effects and risks of different types of mouth–nose-covering masks. Of interest here were, on the one hand, readymade and self-manufactured fabric masks, including so-called community masks and, on the other hand medical, surgical and N95 masks (FFP2 masks).

Our approach of limiting the focus to negative effects seems surprising at first glance. However, such an approach helps toprovide us with more information. This methodology is in line with the strategy of Villalonga-Olives and Kawachi, who also conducted a review exclusively on the negative effects [12].

For an analysis of the literature, we defined the risk of mouth–nose protection as the description of symptoms or the negative effects of masks. Reviews and expert presentations from which no measurable values could be extracted, but which clearly present the research situation and describe negative effects, also fulfill this criterion.

Additionally, we defined the quantifiable, negative effect of masks as the presentation of a measured, statistically significant change in a physiological parameter in a pathological direction ($p < 0.05$), a statistically significant detection of symptoms ($p < 0.05$) or the occurrence of symptoms in at least 50% of those examined in a sample ($n \geq 50\%$).

Up to and including 31 October 2020, we conducted a database search in PubMed/MEDLINE on scientific studies and publications on adverse effects and risks of different types of mouth–nose-covering masks according to the criteria mentioned above (see Figure 1: Review flowchart). Terms searched were “face masks”, “surgical mask” and “N95” in combination with the terms “risk” and “adverse effects” as well as “side effects”. The selection criteria of the papers were based on our above definition of risk and adverse effect of masks. Mainly English- and German-language publications of evidence levels I to III according to the recommendations of the Agency for Healthcare Research and Quality (AHQR) that were not older than 20 years at the time of the review were considered. The evaluation also excluded level IV evidence, such as case reports and irrelevant letters to the editor that exclusively reflect opinions without scientific evidence.

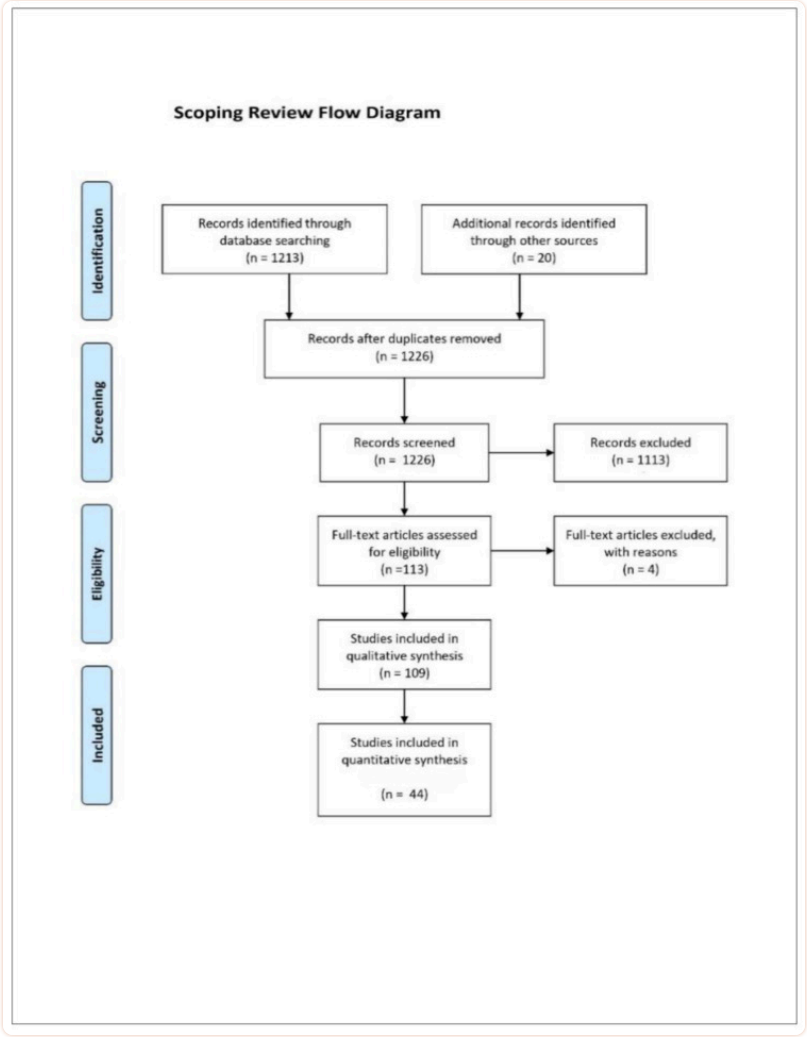


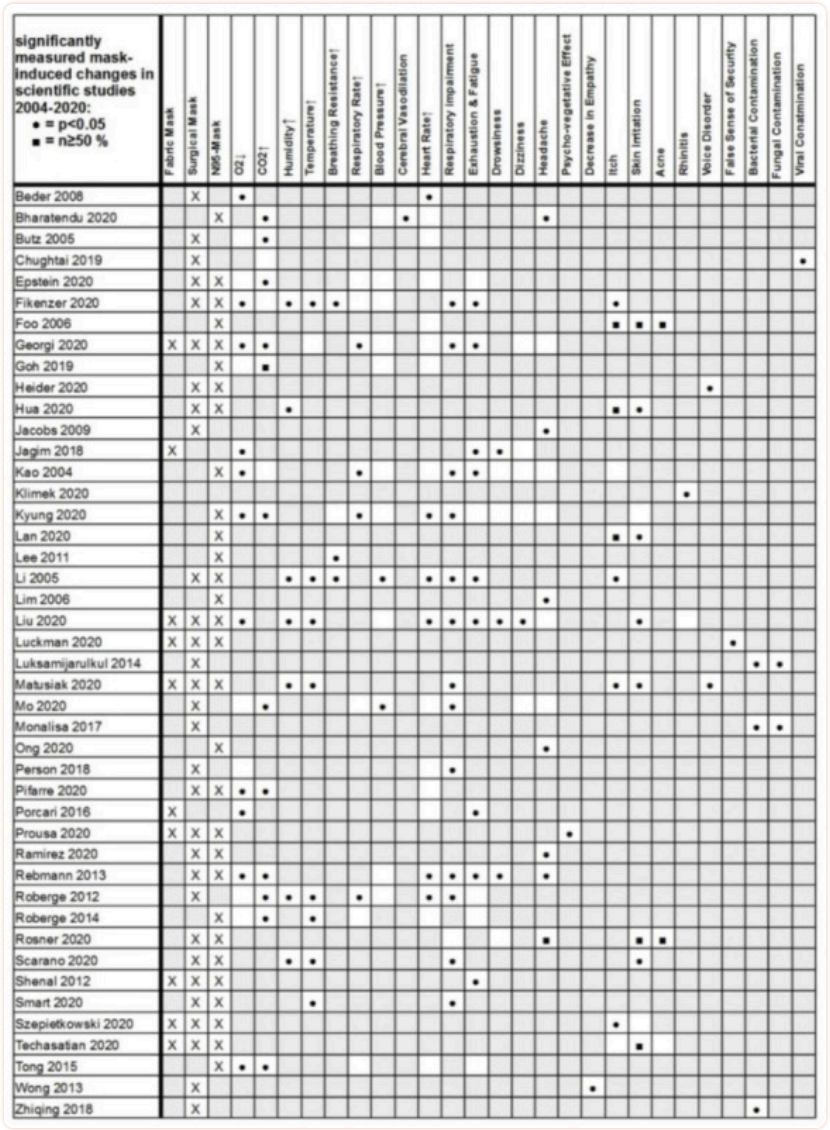
Figure 1

Scoping review flow diagram according to the PRISMA scheme.

After excluding 1113 papers that were irrelevant to the research question and did not meet the criteria mentioned (quantifiable, negative effects of masks, description of symptoms or the negative effects of masks), a total of 109 relevant publications were found for evaluation in the context of our scoping review (see Figure 1: Flow chart).

Sixty-five relevant publications concerning masks were considered being within the scope of the content-related evaluation. These included 14 reviews and 2 meta-analyses from the primary research. For the quantitative evaluation, 44 presentations of negative effects from the years 2004 to 2020 were eligible. Thirty-one of these studies were experimental (70%), and 13 studies were data collection studies in the sense of simple observational studies, especially in the dermatological field (30%). The observed study parameters and significant results from these 44 publications ($p < 0.05$ or $n \geq 50\%$) were compiled in an overall display (Figure 2). Based on this data, a correla-

tion analysis of the observed mask effects was performed. This included a correlation calculation of the recorded symptoms and physiological changes (for nominally scaled, dichotomous variables according to Fisher using R, R Foundation for Statistical Computing, Vienna, Austria, version 4.0.2).



significantly measured mask-induced changes in scientific studies 2004-2020: • = p<0.05 ▪ = n≥50 %	Fabric Mask	Surgical Mask	N95-Mask	O2↓	CO2↑	Humidity↑	Temperature↑	Breathing Resistance↑	Respiratory Rate↑	Blood Pressure↑	Cerebral Vasodilation	Heart Rate↑	Respiratory Impairment	Exhaustion & Fatigue	Drowsiness	Dizziness	Headache	Psycho-vegetative Effect	Decrease in Empathy	Itch	Skin Irritation	Acne	Rhinitis	Voice Disorder	False Sense of Security	Bacterial Contamination	Fungal Contamination	Viral Contamination
Beder 2008		X		•								•																
Bharatendu 2020			X		•						•						•											
Butz 2005		X			•																							
Chughtai 2019		X																										•
Epstein 2020		X	X		•																							
Fikenzer 2020		X	X	•		•	•	•					•	•						•								
Foo 2006			X																	▪	▪	▪						
Georgi 2020	X	X	X	•	•				•				•	•														
Goh 2019			X		▪																							
Heider 2020		X	X																					•				
Hua 2020		X	X			•														▪	•							
Jacobs 2009		X															•											
Jagim 2018	X			•										•	•													
Kao 2004			X	•					•				•	•														
Klimek 2020																							•					
Kyung 2020			X	•	•				•			•	•															
Lan 2020			X																	▪	•							
Lee 2011			X					•																				
Li 2005		X	X			•	•	•		•		•	•	•						•								
Lim 2006			X														•											
Liu 2020	X	X	X	•		•	•					•	•	•	•	•					•							
Luckman 2020	X	X	X																						•			
Luksamijarulkul 2014		X																								•	•	
Matusiak 2020	X	X	X			•	•						•							•	•			•				
Mo 2020		X			•					•			•															
Monalisa 2017		X																								•	•	
Ong 2020			X														•											
Person 2018		X											•															
Pifarre 2020		X	X	•	•																							
Porcari 2016	X			•										•														
Prousa 2020	X	X	X															•										
Ramirez 2020		X	X														•											
Rebmann 2013		X	X	•	•							•	•	•	•		•											
Roberge 2012		X			•	•	•		•			•	•															
Roberge 2014			X		•		•																					
Rosner 2020		X	X														▪				▪	▪						
Scarano 2020		X	X			•	•						•								•							
Shenal 2012	X	X	X											•														
Smart 2020		X	X				•						•															
Szepietkowski 2020	X	X	X																	•								
Techasatian 2020	X	X	X																		▪							
Tong 2015			X	•	•																							
Wong 2013		X																	•									
Zhiqing 2018		X																								•		

Figure 2

Overview including all 44 considered studies with quantified, significant adverse effects of masks (black dots and black rectangles). Not all studies examined each mentioned parameter, as focused or subject-related questions were often in the foreground. Gray fields correspond to a lack of coverage in the primary studies, white fields represent measured effects. We found an often combination of significant chemical, physical, physiological parameters and complaints. Drowsiness summarizes the symptom for any qualitative neurological deficits described in the scientific literature examined.

In addition, another 64 publications with a neighboring range of topics were consulted in connection with the mask effects we found. These included declarations, guidelines and legal principles. In order to expand the amount of data for the discussion, we proceeded according to the "snowball principle" by locating citations of selected papers in the bibliographies and including them where appropriate.

Since the findings from the topics presented for discussion were to an unexpected degree subject-related, we decided to divide the results according to the fields of medicine. Of course, there are overlaps between the respective fields, which we point out in detail.

3. Results

A total of 65 scientific papers on masks qualified for a purely content-based evaluation. These included 14 reviews and two meta-analyses.

Of the mathematically evaluable, groundbreaking 44 papers with significant negative mask effects ($p < 0.05$ or $n \geq 50\%$), 22 were published in 2020 (50%), and 22 were published before the COVID-19 pandemic. Of these 44 publications, 31 (70%) were of experimental nature, and the remainder were observational studies (30%). Most of the publications in question were English (98%). Thirty papers referred to surgical masks (68%), 30 publications related to N95 masks (68%), and only 10 studies pertained to fabric masks (23%).

Despite the differences between the primary studies, we were able to demonstrate a statistically significant correlation in the quantitative analysis between the negative side effects of blood-oxygen depletion and fatigue in mask wearers with $p = 0.0454$.

In addition, we found a mathematically grouped common appearance of statistically significant confirmed effects of masks in the primary studies ($p < 0.05$ and $n \geq 50\%$) as shown in Figure 2. In nine of the 11 scientific papers (82%), we found a combined onset of N95 respiratory protection and carbon dioxide rise when wearing a mask. We found a similar result for the decrease in oxygen saturation and respiratory impairment with synchronous evidence in six of the nine relevant studies (67%). N95 masks were associated with headaches in six of the 10 studies (60%). For oxygen deprivation under N95 respiratory protectors, we found a common occurrence in eight of 11 primary studies (72%). Skin temperature rise under masks was associated with fatigue in 50% (three out of six primary studies). The dual occurrence of the physical parameter temperature rise and respiratory impairment was found in seven of the eight studies (88%). A combined occurrence of the physical parameters temperature rise and humidity/moisture under the mask was found in 100% within six of six studies, with significant readings of these parameters (Figure 2).

The literature review confirms that relevant, undesired medical, organ and organ system-related phenomena accompanied by wearing masks occur in the fields of internal medicine (at least 11 publications, Section 3.2). The list covers neurology (seven publications, Section 3.3), psychology (more than 10 publications, Section 3.4), psychiatry (three publications, Section 3.5), gynecology (three publications, Section 3.6), dermatology (at least 10 publications, Section 3.7), ENT medicine (four publications, Section 3.8), dentistry (one publication, Section 3.8), sports medicine (four pub-

lications, Section 3.9), sociology (more than five publications, Section 3.10), occupational medicine (more than 14 publications, Section 3.11), microbiology (at least four publications, Section 3.12), epidemiology (more than 16 publications, Section 3.13), and pediatrics (four publications, Section 3.14) as well as environmental medicine (four publications, Section 3.15).

We will present the general physiological effects as a basis for all disciplines. This will be followed by a description of the results from the different medical fields of expertise and closing off with pediatrics the final paragraph.

3.1. General Physiological and Pathophysiological Effects for the Wearer

As early as 2005, an experimental dissertation (randomized crossover study) demonstrated that wearing surgical masks in healthy medical personnel (15 subjects, 18–40 years old) leads to measurable physical effects with elevated transcutaneous carbon dioxide values after 30 min [13]. The role of dead space volume and CO_2 retention as a cause of the significant change ($p < 0.05$) in blood gases on the way to hypercapnia, which was still within the limits, was discussed in this article. Masks expand the natural dead space (nose, throat, trachea, bronchi) outwards and beyond the mouth and nose.

An experimental increase in the dead space volume during breathing increases carbon dioxide (CO_2) retention at rest and under exertion and correspondingly the carbon dioxide partial pressure pCO_2 in the blood ($p < 0.05$) [14].

As well as addressing the increased rebreathing of carbon dioxide (CO_2) due to the dead space, scientists also debate the influence of the increased breathing resistance when using masks [15,16,17].

According to the scientific data, mask wearers as a whole show a striking frequency of typical, measurable, physiological changes associated with masks.

In a recent intervention study conducted on eight subjects, measurements of the gas content for oxygen (measured in O_2 Vol%) and carbon dioxide (measured in CO_2 ppm) in the air under a mask showed a lower oxygen availability even at rest than without a mask. A Multi-Rae gas analyzer was used for the measurements (RaeSystems®) (Sunnyvale, California CA, United States). At the time of the study, the device was the most advanced portable multivariant real-time gas analyzer. It is also used in rescue medicine and operational emergencies. The absolute concentration of oxygen (O_2 Vol%) in the air under the masks was significantly lower (minus 12.4 Vol% O_2 in absolute terms, statistically significant with $p < 0.001$) at 18.3% compared to 20.9% room air concentration. Simultaneously, a health-critical value of carbon dioxide concentration (CO_2 Vol%) increased by a factor of 30 compared to normal room air was measured (ppm with mask versus 464 ppm without mask, statistically significant with $p < 0.001$) [18].

These phenomena are responsible for a statistically significant increase in carbon dioxide (CO_2) blood content in mask wearers [19,20], on the one hand, measured transcutaneously via an increased $PtcCO_2$ value [15,17,19,21,22], on the other hand, via end-expiratory partial pressure of

carbon dioxide ($PETCO_2$) [23,24] or, respectively, the arterial partial pressure of carbon dioxide ($PaCO_2$) [25].

In addition to the increase in the wearer's blood carbon dioxide (CO_2) levels ($p < 0.05$) [13,15,17,19,21,22,23,24,25,26,27,28], another consequence of masks that has often been experimentally proven is a statistically significant drop in blood oxygen saturation (SpO_2) ($p < 0.05$) [18,19,21,23,29,30,31,32,33,34]. A drop in blood oxygen partial pressure (PaO_2) with the effect of an accompanying increase in heart rate ($p < 0.05$) [15,23,29,30,34] as well as an increase in respiratory rate ($p < 0.05$) [15,21,23,35,36] have been proven.

A statistically significant measurable increase in pulse rate ($p < 0.05$) and decrease in oxygen saturation SpO_2 after the first ($p < 0.01$) and second hour ($p < 0.0001$) under a disposable mask (surgical mask) were reported by researchers in a mask intervention study they conducted on 53 employed neurosurgeons [30].

In another experimental study (comparative study), surgical and N95 masks caused a significant increase in heart rate ($p < 0.01$) as well as a corresponding feeling of exhaustion ($p < 0.05$). These symptoms were accompanied by a sensation of heat ($p < 0.0001$) and itching ($p < 0.01$) due to moisture penetration of the masks ($p < 0.0001$) in 10 healthy volunteers of both sexes after only 90 min of physical activity [35]. Moisture penetration was determined via sensors by evaluating logs (SCXI-1461, National Instruments, Austin, TX, USA).

These phenomena were reproduced in another experiment on 20 healthy subjects wearing surgical masks. The masked subjects showed statistically significant increases in heart rate ($p < 0.001$) and respiratory rate ($p < 0.02$) accompanied by a significant measurable increase in transcutaneous carbon dioxide $PtcCO_2$ ($p < 0.0006$). They also complained of breathing difficulties during the exercise [15].

The increased rebreathing of carbon dioxide (CO_2) from the enlarged dead space volume in mask wearers can reflectively trigger increased respiratory activity with increased muscular work as well as the resulting additional oxygen demand and oxygen consumption [17]. This is a reaction to pathological changes in the sense of an adaptation effect. A mask-induced drop in blood oxygen saturation value (SpO_2) [30] or the blood oxygen partial pressure (PaO_2) [34] can in turn additionally intensify subjective chest complaints [25,34].

The documented mask-induced changes in blood gases towards hypercapnia (in-creased carbon dioxide/CO_2 blood levels) and hypoxia (decreased oxygen/O_2 blood levels) may result in additional nonphysical effects such as confusion, decreased thinking ability and disorientation [23,36,37,38,39], including overall impaired cognitive abilities and decrease in psychomotoric abilities [19,32,38,39,40,41]. This highlights the importance of changes in blood gas parameters (O_2 and CO_2) as a cause of clinically relevant psychological and neurological effects. The above parameters and effects (oxygen saturation, carbon dioxide content, cognitive abilities) were measured in a study on saturation sensors (Semi-Tec AG, Therwil, Switzerland), using a Borg Rating Scale, Frank Scale, Roberge Respirator Comfort Scale and Roberge Subjective Symptoms-during-Work Scale, as well as with a Likert scale [19]. In the other main study, conventional ECG, capnography

and symptom questionnaires were used in measuring carbon dioxide levels, pulse and cognitive abilities [23]. Other physiological data collection was done with pulse oximeters (Allegiance, MCGaw, USA), subjective complaints were assessed with a 5-point Likert scale and motoric speed was recorded with linear-position transducers (Tendo-Fitrodyne, Sport Machins, Trencin, Slovakia) [32]. Some researchers used standardized, anonymized questionnaires to collect data on subjective complaints associated with masks [37].

In an experimental setting with different mask types (community, surgical, N95) a significant increase in heart rate ($p < 0.04$), a decrease in oxygen saturation SpO_2 ($p < 0.05$) with an increase in skin temperature under the mask (face) and difficulty of breathing ($p < 0.002$) were recorded in 12 healthy young subjects (students). In addition, the investigators observed dizziness ($p < 0.03$), listlessness ($p < 0.05$), impaired thinking ($p < 0.03$) and concentration problems ($p < 0.02$), which were also statistically significant when wearing masks [29].

According to other researchers and their publications, masks also interfere with temperature regulation, impair the field of vision and of non-verbal and verbal communication [15,17,19,36,37,42,43,44,45].

The above-mentioned measurable and qualitative physiological effects of masks can have implications in various areas of expertise in medicine.

It is known from pathology that not only supra-threshold stimuli exceeding normal limits have disease-relevant consequences. Subthreshold stimuli are also capable of causing pathological changes if the exposure time is long enough. Examples occur from the slightest air pollution by hydrogen sulfide resulting in respiratory problems (throat irritation, coughing, reduced absorption of oxygen) and neurological diseases (headaches, dizziness) [46]. Furthermore, subthreshold but prolonged exposure to nitrogen oxides and particulate matter is associated with an increased risk of asthma, hospitalization and higher overall mortality [47,48]. Low concentrations of pesticides are also associated with disease-relevant consequences for humans such as mutations, development of cancer and neurological disorders [49]. Likewise, the chronic subthreshold intake of arsenic is associated with an increased risk of cancer [50], subthreshold intake of cadmium with the promotion of heart failure [51], subthreshold intake of lead is associated with hypertension, renal metabolic disorders and cognitive impairment [52] or subthreshold intake of mercury with immune deficiency and neurological disorders [53]. Subliminal UV radiation exposure over long periods is also known to cause mutation-promoting carcinogenic effects (especially white skin cancer) [54].

The mask-induced adverse changes are relatively minor at first glance, but repeated exposure over longer periods in accordance with the above-mentioned pathogenetic principle is relevant. Long-term disease-relevant consequences of masks are to be expected. Insofar, the statistically significant results found in the studies with mathematically tangible differences between mask wearers and people without masks are clinically relevant. They give an indication that with correspondingly repeated and prolonged exposure to physical, chemical, biological, physiological and psychological conditions, some of which are subliminal, but which are significantly shifted towards pathological areas, health-reducing changes and clinical pictures can develop such as high blood pres-

sure and arteriosclerosis, including coronary heart disease (metabolic syndrome) as well as neurological diseases. For small increases in carbon dioxide in the inhaled air, this disease-promoting effect has been proven with the creation of headaches, irritation of the respiratory tract up to asthma as well as an increase in blood pressure and heart rate with vascular damage and, finally, neuropathological and cardiovascular consequences [38]. Even slightly but persistently increased heart rates encourage oxidative stress with endothelial dysfunction, via increased inflammatory messengers, and finally, the stimulation of arteriosclerosis of the blood vessels has been proven [55]. A similar effect with the stimulation of high blood pressure, cardiac dysfunction and damage to blood vessels supplying the brain is suggested for slightly increased breathing rates over long periods [56,57]. Masks are responsible for the aforementioned physiological changes with rises in inhaled carbon dioxide [18,19,20,21,22,23,24,25,26,27,28], small sustained increases in heart rate [15,23,29,30,35] and mild but sustained increases in respiratory rates [15,21,23,34,36].

For a better understanding of the side effects and dangers of masks presented in this literature review, it is possible to refer to well-known principles of respiratory physiology (Figure 3).

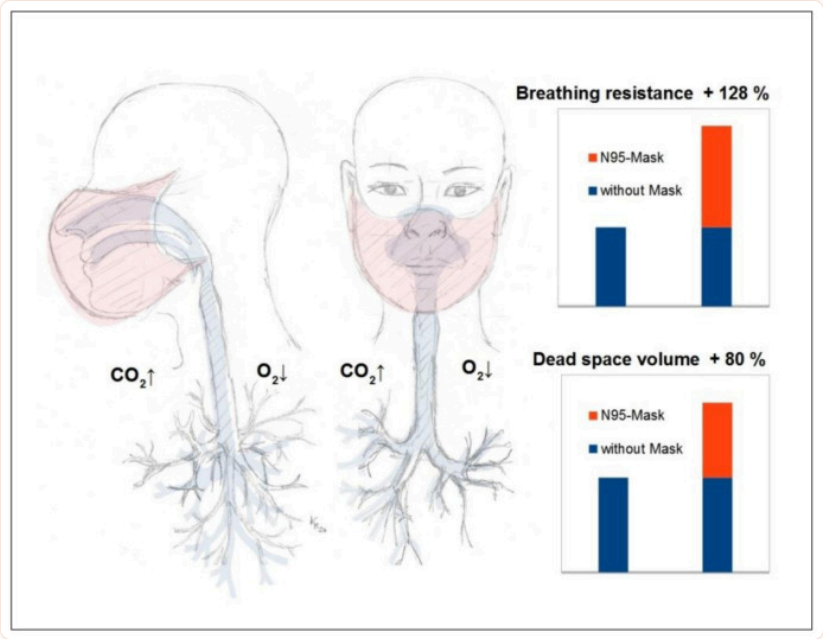


Figure 3

Pathophysiology of the mask (important physical and chemical effects): Illustration of the breathing resistance* and of the dead space volume of an N95 mask in an adult. When breathing, there is an overall significantly reduced possible gas exchange volume of the lungs of minus 37% caused by the mask (Lee 2011) [60] according to a decrease in breathing depth and volume due to the greater breathing resistance of plus128%* (exertion when inhaling greater than when exhaling) and due to the increased dead space volume of plus80%°, which does not participate directly in the gas exchange and is being only partially mixed with the environment. (* = averaged inspiration and expiration according to Lee 2011 [60] including moisture penetration according to Roberge 2010 [61], ** = averaged values according to Xu 2015 [59]).

The average dead space volume during breathing in adults is approximately 150–180 mL and is significantly increased when wearing a mask covering the mouth and nose [58]. With an N95 mask, for example, the dead space volume of approximately 98–168 mL was determined in an experimental study [59]. This corresponds to a mask-related dead space increase of approximately 65 to 112% for adults and, thus, almost a doubling. At a respiratory rate of 12 per minute, the pendulum volume respiration with such a mask would, thus, be at least 2.9–3.8 L per minute. Therefore, the dead space amassed by the mask causes a relative reduction in the gas exchange volume available to the lungs per breath by 37% [60]. This largely explains the impairment of respiratory physiology reported in our work and the resulting side effects of all types of masks in everyday use in healthy and sick people (increase in respiratory rate, increase in heart rate, decrease in oxygen saturation, increase in carbon dioxide partial pressure, fatigue, headaches, dizziness, impaired thinking, etc.) [36,58].

In addition to the effect of increased dead space volume breathing, however, mask-related breathing resistance is also of exceptional importance (Figure 3) [23,36].

Experiments show an increase in airway resistance by a remarkable 126% on inhalation and 122% on exhalation with an N95 mask [60]. Experimental studies have also shown that moisturization of the mask (N95) increases the breathing resistance by a further 3% [61] and can, thus, increase the airway resistance up to 2.3 times the normal value.

This clearly shows the importance of the airway resistance of a mask. Here, the mask acts as a disturbance factor in breathing and makes the observed compensatory reactions with an increase in breathing frequency and simultaneous feeling of breathlessness plausible (increased work of the respiratory muscles). This extra strain due to the amplified work of breathing against bigger resistance caused by the masks also leads to intensified exhaustion with a rise in heart rate and increased CO_2 production. Fittingly, in our review of the studies on side effects of masks (Figure 2), we also found a percentage clustering of significant respiratory impairment and a significant drop in oxygen saturation (in about 75% of all study results).

In the evaluation of the primary papers, we also determined a statically significant correlation of the drop in oxygen saturation (SpO_2) and fatigue with a common occurrence in 58% of the mask use studies with significant results (Figure 2, $p < 0.05$).

3.2. Internistic Side Effects and Dangers

As early as 2012, an experiment showed that walking in the 20 masked subjects compared to the identical activity without masks significantly increased heart rates (average +9.4 beats per minute, $p < 0.001$) and breathing rates ($p < 0.02$). These physiological changes were accompanied by transcutaneous significantly measurable increased transcutaneous carbon dioxide ($PtcCO_2$) levels ($p < 0.0006$) as well as respiratory difficulties in the mask wearers compared to the control group [15].

In a recent experimental comparative study from 2020, 12 healthy volunteers under surgical masks as well as under N95 masks experienced measurable impairments in the measured lung function parameters as well as cardiopulmonary capacity (lower maximum blood lactate re-

sponse) during moderate to heavy physical exertion compared to exertion without masks ($p < 0.001$) [31]. The mask-induced increased airway resistance led to increased respiratory work with increased oxygen consumption and demand, both of the respiratory muscles and the heart. Breathing was significantly impeded ($p < 0.001$) and participants reported mild pain. The scientists concluded from their results that the cardiac compensation of the pulmonary, mask-induced restrictions, which still functioned in healthy people, was probably no longer possible in patients with reduced cardiac output [31].

In another recent study, researchers tested fabric masks (community masks), surgical masks and FFP2/N95 masks in 26 healthy people during exercise on a cycle ergometer. All masks also showed a measurable carbon dioxide (CO_2) retention ($PtcCO_2$) (statistically significant with $p < 0.001$) and, for N95 masks, a decrease in the oxygen saturation value SpO_2 (statistically significant at 75 and 100 W with $p < 0.02$ and $p < 0.005$, respectively). The clinical relevance of these changes was shown in an increase in breathing frequency with fabric masks ($p < 0.04$) as well as in the occurrence of the previously described mask-specific complaints such as a feeling of heat, shortness of breath and headaches. The stress perception was recorded on a Borg scale from 1 to 20. During physical exertion under an N95 mask, the group with masks showed a significant increase in the feeling of exhaustion compared to the group without with 14.6 versus 11.9 on the scale of 20. During the exposure, 14 of the 24 subjects wearing masks complained of shortness of breath (58%), four of headaches and two of a feeling of heat. Most of the complaints concerned FFP2 masks (72%) [21].

The aforementioned physiological and subjective physical effects of masks on healthy people at rest and under exertion [21,31] give an indication of the effect of masks on sick and elderly people even without exertion.

In an observational study of ten 20 to 50 year-old nurses wearing N95 masks during their shift work, side effects such as breathing difficulties (“I can’t breathe”), feelings of exhaustion, headache ($p < 0.001$), drowsiness ($p < 0.001$) and a decrease in oxygen saturation SpO_2 ($p < 0.05$) as well as an increase in heart rate ($p < 0.001$) were statistically significant in association with an increase in obesity (BMI) [19]. The occurrence of symptoms under masks was also associated with older age (statistically significant correlation of fatigue and drowsiness with $p < 0.01$ each, nausea with $p < 0.05$, an increase in blood pressure with $p < 0.01$, headache with $p < 0.05$, breathing difficulties with $p < 0.001$) [19].

In an intervention study involving 97 patients with advanced chronic obstructive pulmonary disease (COPD) the respiratory rate, oxygen saturation and exhaled carbon dioxide equivalents (capnometry) changed unfavorably and significantly after the use of N95 masks (FFP2 equivalent) with an initial 10-minute rest and subsequent 6-minute walking. Seven patients discontinued the experiment due to serious complaints with a decrease in the oxygen saturation value SpO_2 and a pathological carbon dioxide (CO_2) retention as well as increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) [23]. In two patients, the $PETCO_2$ exceeded the normal limits and reached values of >50 mmHg. An FEV1 < 30% and a modified Medical Research Council (mMRC) Dyspnea Scale Score of ≥3, both indicators of advanced COPD, correlated with mask intolerance overall in this study. The most common symptom under mask was breathlessness at 86%. In the

dropouts of the study, dizziness (57%) and headaches were also often recorded. In the mask-tolerant COPD patients, significant increases in heart rate, respiratory rate and end-expiratory carbon dioxide partial pressure $PETCO_2$ could be objectified even at rest, after only 10 min of mask-wearing ($p < 0.001$), accompanied by a decrease in oxygen saturation SpO_2 ($p < 0.001$) [23]. The results of this study with an evidence level IIa are indicative for COPD mask wearers.

In another retrospective comparative study on COPD and surgical masks, examiners were able to demonstrate statistically an increase in arterial partial pressure of carbon dioxide ($PaCO_2$) of approximately +8 mmHg ($p < 0.005$) and a concomitant mask-related increase in systolic blood pressure of +11 mmHg ($p < 0.02$) [25]. This increase is relevant in hypertensive patients, but also in healthy people with borderline blood pressure values as pathological value range triggered by mask-wearing can be induced.

In 39 hemodialysis patients with end-stage renal disease, a type N95 mask (FFP2 equivalent) caused a significant drop in blood oxygen partial pressure (PaO_2) in 70% of patients at rest (on hemodialysis) within only 4 h ($p = 0.006$). Despite a compensatory increased respiratory rate ($p < 0.001$), malaise with chest pain occurred ($p < 0.001$) and even resulted in hypoxemia (drop in oxygen below the normal limit) in 19% of the subjects [34]. The researchers concluded from their findings that elderly or patients with reduced cardiopulmonary function have a higher risk of developing a severe respiratory failure while wearing a mask [34].

In a review paper on the risks and benefits of masks worn during the COVID-19 crisis, other authors provide an equally critical assessment of mandatory mask use for patients with pneumonia, both with and without COVID-19 pneumonia disease [16].

3.3. Neurological Side Effects and Dangers

In a scientific evaluation of syncope in the operating theatre, 36 of 77 affected persons (47%) were associated with wearing a mask [62]. However, other factors could not be ruled out as contributory causes.

In their level III evidence review, neurologists from Israel, the UK and the USA state that a mask is unsuitable for epileptics because it can trigger hyperventilation [63]. The use of a mask significantly increases the respiratory rate by about plus 15 to 20% [15,21,23,34,64]. However, an increase in breathing frequency leading to hyperventilation is known to be used for provocation in the diagnosis of epilepsy and causes seizure-equivalent EEG changes in 80% of patients with generalized epilepsy and in up to 28% of focal epileptics [65].

Physicians from New York studied the effects of wearing masks of the surgical-type mask and N95 among medical personnel in a sample of 343 participants (surveyed using standardized, anonymized questionnaires). Wearing the masks caused detectable physical adverse effects such as impaired cognition (24% of wearers) and headaches in 71.4% of the participants. Of these, 28% persisted and required medication. Headache occurred in 15.2% under 1 h of wear, in 30.6% after 1 h of wear and in 29.7% after 3 h of wear. Thus, the effect intensified with increasing wearing time [37].

Confusion, disorientation and even drowsiness (Likert scale questionnaire) and reduced motoric abilities (measured with a linear position transducer) with reduced reactivity and overall impaired performance (measured with the Roberge Subjective Symptoms-during-Work Scale) as a result of mask use have also been documented in other studies [19,23,29,32,36,37].

The scientists explain these neurological impairments with a mask-induced latent drop in blood gas oxygen levels O_2 (towards hypoxia) or a latent increase in blood gas carbon dioxide levels CO_2 (towards hypercapnia) [36]. In view of the scientific data, this connection also appears to be indisputable [38,39,40,41].

In a mask experiment from 2020, significant impaired thinking ($p < 0.03$) and impaired concentration ($p < 0.02$) were found for all mask types used (fabric, surgical and N95 masks) after only 100 min of wearing the mask [29]. The thought disorders correlated significantly with a drop in oxygen saturation ($p < 0.001$) during mask use.

Initial headaches ($p < 0.05$) were experienced by up to 82% of 158, 21–35 year-old mask wearers in another study of N95 respiratory protection with one third (34%) experiencing headaches up to four times daily. Participants wore the mask for 18.3 days over a 30-day period with a mean of 5.9 h per day [66].

Significantly increased headache ($p < 0.05$) could be observed not only for N95 but also for surgical masks in participants of another observational study of health care workers [67].

In another study, the researchers classified 306 users with an average age of 43 years and wearing different types of masks, of whom 51% had an initial headache as a specific symptom related exclusively to increased surgical and N95 mask use (1 to 4 h, $p = 0.008$) [68].

Researchers from Singapore were able to demonstrate in a trial involving 154 healthy N95 health service mask wearers that a significant increase in mask-induced blood carbon dioxide levels (measured by end-expiratory partial pressure of carbon dioxide $PETCO_2$) and a measurably greater vasodilatation with an increase in cerebral artery flow in the cerebri media resulted. This was associated with headaches in the trial group ($p < 0.001$) [27].

According to the researchers, the aforementioned changes also contribute to headaches during the prolonged use of masks with a shift towards hypoxia and hypercapnia. Furthermore, stress and mechanical factors such as the irritation of cervical nerves in the neck and head area caused by the tight mask straps pressuring the nerve strands also contribute to headaches [66].

In the analysis of the primary studies, we were able to detect an association between the N95 mask and headaches. In six out of 10 studies, the significant headache appeared in conjunction with the N95 mask (60% of all studies, Figure 2).

3.4. Psychological Side Effects and Dangers

According to an experimental study, wearing surgical masks and N95 masks can also lead to a reduced quality of life owing to reduced cardiopulmonary capacity [31]. Masks, along with causing physiological changes and discomfort with progressive length of use, can also lead to significant discomfort ($p < 0.03$ to $p < 0.0001$) and a feeling of exhaustion ($p < 0.05$ to 0.0001) [69].

Besides the shift in blood gases towards hypercapnia (increase in CO_2) and hypoxia (decrease in O_2), detailed under general physiological effects (Section 3.1), masks also restrict the cognitive abilities of the individual (measured using a Likert scale survey) accompanied by a decline in psycho-motoric abilities and consequently a reduced responsiveness (measured using a linear position transducer) as well as an overall reduced performance capability (measured with the Roberge Subjective Symptoms-during-Work Scale) [29,32,38,39,41].

The mask also causes an impaired field of vision (especially affecting the ground and obstacles on the ground) and also presents an inhibition to habitual actions such as eating, drinking, touching, scratching and cleaning the otherwise uncovered part of the face, which is consciously and subconsciously perceived as a permanent disturbance, obstruction and restriction [36]. Wearing masks, thus, entails a feeling of deprivation of freedom and loss of autonomy and self-determination, which can lead to suppressed anger and subconscious constant distraction, especially as the wearing of masks is mostly dictated and ordered by others [70,71]. These perceived interferences of integrity, self-determination and autonomy, coupled with discomfort, often contribute to substantial distraction and may ultimately be combined with the physiologically mask-related decline in psycho-motoric abilities, reduced responsiveness and an overall impaired cognitive performance. It leads to misjudging situations as well as delayed, incorrect and inappropriate behavior and a decline in the effectiveness of the mask wearer [36,37,39,40,41].

The use of masks for several hours often causes further detectable adverse effects such as headaches, local acne, mask-associated skin irritation, itching, sensations of heat and dampness, impairments and discomfort predominantly affecting the head and face [19,29,35,36,37,71,72,73]. However, the head and face are significant for well-being due to their large representation in the sensitive cerebral cortex (homunculus) [36].

According to a questionnaire survey, masks also frequently cause anxiety and psycho-vegetative stress reactions in children—as well as in adults—with an increase in psychosomatic and stress-related illnesses and depressive self-experience, reduced participation, social withdrawal and lowered health-related self-care [74]. Over 50% of the mask wearers studied had at least mild depressive feelings [74]. Additional fear-inducing and often exaggerated media coverage can further intensify this. A recent retrospective analysis of the general media in the context of the 2014 Ebola epidemic showed a scientific truth content of only 38% of all publicly published information [75]. Researchers classified a total of 28% of the information as provocative and polarizing and 42% as exaggerating risks. In addition, 72% of the media content aimed to stir up health-related negative feelings. The feeling of fear, combined with insecurity and the primal human need to belong [76], causes a social dynamic that seems partly unfounded from a medical and scientific point of view.

The mask, which originally served purely hygienic purpose, has been transformed into a symbol of conformity and pseudo-solidarity. The WHO, for example, lists the advantages of the use of masks by healthy people in public to include a potentially reduced stigmatization of mask wearers, a sense of contribution to preventing the spread of the virus and a reminder to comply with other measures [2].

3.5. Psychiatric Side Effects and Dangers

As explained earlier, masks can cause increased rebreathing with an accumulation of carbon dioxide in the wearer due to increased dead space volume [16,17,18,20] (Figure 3), with often statistically significant measurable elevated blood carbon dioxide (CO2) levels in sufferers [13,15,17,19,20,21,22,23,24,25,26,27,28] (Figure 2). However, changes that lead to hypercapnia are known to trigger panic attacks [77,78]. This makes the significantly measurable increase in CO_2 caused by wearing a mask clinically relevant.

Interestingly, breath provocation tests by inhaling CO_2 are used to differentiate anxiety states in panic disorders and premenstrual dysphoria from other psychiatric clinical pictures. Here, absolute concentrations of 5% CO_2 already suffice to trigger panic reactions within 15–16 min [77]. The normal exhaled air content of CO_2 is about 4%.

It is obvious from experimental studies on masked subjects that concentration changes in the respiratory gases in the above-mentioned range with values above 4% could occur during rebreathing with prolonged mask use [18,23].

The activation of the locus coeruleus by CO_2 is used to generate panic reactions via respiratory gases [78,79]. This is because the locus coeruleus is an important part of the system of vegetative noradrenergic neurons, a control center in the brainstem, which reacts to an appropriate stimulus and changes in the gas concentrations in the blood by releasing the stress hormone noradrenaline [78].

From the physiological, neurological and psychological side effects and dangers described above (Section 3.1, Section 3.3 and Section 3.4), additional problems can be derived for the use of masks in psychiatric cases. People undergoing treatment for dementia, paranoid schizophrenia, personality disorders with anxiety and panic attacks, but also panic disorders with claustrophobic components, are difficult to reconcile with a mask requirement, because even small increases in CO_2 can cause and intensify panic attacks [44,77,78,79].

According to a psychiatric study, patients with moderate to severe dementia have no understanding of COVID-19 protection measures and have to be persuaded to wear masks constantly [80].

According to a comparative study, patients with schizophrenia have a lower acceptance of mask-wearing (54.9% agreement) than ordinary practice patients (61.6%) [81]. The extent to which mask-wearing can lead to an exacerbation of schizophrenia symptoms has not yet been researched in detail.

When wearing masks, confusion, impaired thinking, disorientation (standardized recording via special rating and Likert scales, $p < 0.05$) and in some cases a decrease in maximum speed and reaction time (measured with the linear-position transducer, $p < 0.05$) were observed [19,32,36,38,39,40,41]. Psychotropic drugs reduce psycho-motoric functions in psychiatric patients. This can become clinically relevant especially with regard to the further reduced ability to react and the additional increased susceptibility to accidents of such patients when wearing masks.

In order to avoid an unintentional CO_2-triggered anesthesia [39], fixed and medically sedated patients, without the possibility of continuous monitoring, should not be masked according to the criteria of the Centers for Disease Control and Prevention, USA (CDC). This is because of the possible CO_2 retention described above, as there is a risk of unconsciousness, aspiration and asphyxia [16,17,20,38,82,83].

3.6. Gynaecological Side Effects and Dangers

As a critical variable, a low blood carbon dioxide level in pregnant women is maintained via an increased respiratory minute volume, stimulated by progesterone [22]. For a pregnant woman and her unborn child, there is a metabolic need for a fetal–maternal carbon dioxide (CO_2) gradient. The mother's blood carbon dioxide level should always be lower than that of the unborn child in order to ensure the diffusion of CO_2 from the fetal blood into the maternal circulation via the placenta.

Therefore, mask-related phenomena described above (Section 3.1 and Section 3.2), such as the measurable changes in respiratory physiology with increased breathing resistance, increased dead space volume (Figure 3) and the retention of exhaled carbon dioxide (CO_2) are of importance. If CO_2 is increasingly rebreathed under masks, this manifestation could, even with subliminal carbon dioxide increases, act as a disturbing variable of the fetal–maternal CO_2 gradient increasing over time of exposure and, thus, develop clinical relevance, also with regard to a reduced compensation reserve of the expectant mothers [20,22,28].

In a comparative study, 22 pregnant women wearing N95 masks during 20 min of exercise showed significantly higher percutaneous CO_2 values, with average $PtcCO_2$ values of 33.3 mmHg compared to 31.3 mmHg than in 22 pregnant women without masks ($p = 0.04$) [22]. The heat sensation of the expectant mothers was also significantly increased with masks, with $p < 0.001$ [22].

Accordingly, in another intervention study, researchers demonstrated that breathing through an N95 mask (FFP2 equivalent) impeded gas exchange in 20 pregnant women at rest and during exercise, causing additional stress on their metabolic system [28]. Thus, under an N95 mask, 20 pregnant women showed a decrease in oxygen uptake capacity VO_2 of about 14% (statistically significant, $p = 0.013$) and a decrease in carbon dioxide output capacity VCO_2 of about 18% (statistically significant, $p = 0.001$). Corresponding significant changes in exhaled oxygen and carbon dioxide equivalents were also documented with increases in exhaled carbon dioxide ($FeCO_2$) ($p < 0.001$) and decreases in exhaled oxygen (FeO_2) ($p < 0.001$), which were explained by an altered metabolism due to respiratory mask obstruction [28].

In experiments with predominantly short mask application times, neither the mothers nor the fetuses showed statistically significant increases in heart rates or changes in respiratory rates and oxygen saturation values. However, the exact effects of prolonged mask use in pregnant women remain unclear overall. Therefore, in pregnant women, extended use of surgical and N95 masks is viewed critically [20].

In addition, it is unclear whether the substances contained in industrially manufactured masks that can be inhaled over longer periods of time (e.g., formaldehyde as an ingredient of the textile and thiram as an ingredient of the ear bands) are teratogenic [20,84].

3.7. Dermatological Side Effects and Dangers

Unlike garments worn over closed skin, masks cover body areas close to the mouth and nose, i.e., body parts that are involved with respiration.

Inevitably, this leads not only to a measurable temperature rise [15,44,85], but also to a severe increase in humidity due to condensation of the exhaled air, which in turn changes the natural skin milieu considerably of perioral and perinasal areas [36,61,82]. It also increases the redness, pH-value, fluid loss through the skin epithelium, increased hydration and sebum production measurably [73]. Preexisting skin diseases are not only perpetuated by these changes, but also exacerbated. In general, the skin becomes more susceptible to infections and acne.

The authors of an experimental study were able to prove a disturbed barrier function of the skin after only 4 h of wearing a mask in 20 healthy volunteers, both for surgical masks and for N95 masks [73]. In addition, germs (bacteria, fungi and viruses) accumulate on the outside and inside of the masks due to the warm and moist environment [86,87,88,89]. They can cause clinically relevant fungal, bacterial or viral infections. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German Robert Koch Institute (RKI) from 2020 [90] could be another indication of this phenomenon.

In addition, a region of the skin that is not evolutionarily adapted to such stimuli is subjected to increased mechanical stress. All in all, the above-mentioned facts cause the unfavorable dermatological effects with mask related adverse skin reactions like acne, rashes on the face and itch symptoms [91].

A Chinese research group reported skin irritation and itching when using N95 masks among 542 test participants and also a correlation between the skin damage that occurred and the time of exposure (68.9% at ≤6 h/day and 81.7% at >6 h/day) [92].

A New York study evaluated in a random sample of 343 participants the effects of frequent wearing of surgical mask type and N95 masks among healthcare workers during the COVID-19 pandemic. Wearing the masks caused headache in 71.4% of participants, in addition to drowsiness in 23.6%, detectable skin damage in 51% and acne in 53% of mask users [37].

On the one hand, direct mechanical skin lesions occur on the nose and cheekbones due to shear force, especially when masks are frequently put on and taken off [37,92].

On the other hand, masks create an unnaturally moist and warm local skin environment [29,36,82]. In fact, scientists were able to demonstrate a significant increase in humidity and temperature in the covered facial area in another study in which the test individuals wore masks for one hour [85]. The relative humidity under the masks was measured with a sensor (Atmo-Tube, San Francisco, CA, USA). The sensation of humidity and temperature in the facial area is more crucial for well-being than other body regions [36,44]. This can increase discomfort under the masks. In addition, the increase in temperature favors bacterial optimization.

The pressure of the masks also causes an obstruction of the flow physiology of lymph and blood vessels in the face, with the consequence of increased disturbance of skin function [73] and ultimately also contributing to acne in up to 53% of all wearers and other skin irritations in up to 51% of all wearers [36,37,82].

Other researchers examined 322 participants with N95 masks in an observational study and detected acne in up to 59.6% of them, itching in 51.4% and redness in 35.8% as side effects [72].

In up to 19.6% (273) of the 1393 wearers of different masks (community masks, surgical, N95 masks), itching could be objectified in one study, in 9% even severely. An atopic predisposition (allergy tendency) correlated with the risk of itching. The length of use was significantly related to the risk of itching ($p < 0.0001$) [93].

In another dermatological study from 2020, 96.9% of 876 users of all mask types (community masks, surgical masks, N95 masks) confirmed adverse problems with a significant increase in itching (7.7%), accompanied by fogging-up of glasses (21.3%), flushing (21.3%), slurred speech (12.3%) and difficulty breathing (35.9%) ($p < 0.01$) [71].

Apart from an increased incidence of acne [37,72,91] under masks, contact eczema and urticaria [94] are generally described in connection with hypersensitivities to ingredients of the industrially manufactured masks (surgical mask and N95) such as formaldehyde (ingredient of the textile) and thiram (ingredient of the ear bands) [73,84]. The hazardous substance thiram, originally a pesticide and corrosive, is used in the rubber industry as a optimization accelerator. Formaldehyde is a biocide and carcinogen and is used as a disinfectant in the industry.

Even isolated permanent hyperpigmentation as a result of post-inflammatory or pigmented contact dermatitis has been described by dermatologists after prolonged mask use [72,91].

3.8. ENT and Dental Side Effects and Dangers

There are reports from dental communities about negative effects of masks and are accordingly titled “mask mouth” [95]. Provocation of gingivitis (inflammation of the gums), halitosis (bad breath), candidiasis (fungal infestation of the mucous membranes with Candida albicans) and cheilitis (inflammation of the lips), especially of the corners of the mouth, and even plaque and

caries are attributed to the excessive and improper use of masks. The main trigger of the oral diseases mentioned is an increased dry mouth due to a reduced saliva flow and increased breathing through the open mouth under the mask. Mouth breathing causes surface dehydration and reduced salivary flow rate (SFR) [95]. Dry mouth is scientifically proven due to mask wear [29]. The bad habit of breathing through the open mouth while wearing a mask seems plausible because such breathing pattern compensates for the increased breathing resistance, especially when inhaling through the masks [60,61]. In turn, the outer skin moisture [71,73,85] with altered skin flora, which has already been described under dermatological side effects (Section 3.7), is held responsible as an explanation for the inflammation of the lips and corners of the mouth (cheilitis) [95]. This clearly shows the disease-promoting reversal of the natural conditions caused by masks. The physiological internal moisture with external dryness in the oral cavity converts into internal dryness with external moisture.

ENT physicians recently discovered a new form of irritant rhinitis due to N95 mask use in 46 patients. They performed endoscopies and nasal irrigations on mask wearers, which were subsequently assessed pathologically. Clinical problems were recorded with standardized questionnaires. They found statistically significant evidence of mask-induced rhinitis and itching and swelling of the mucous membranes as well as increased sneezing ($p < 0.01$). Endoscopically, it showed an increased secretion and evidence of inhaled mask polypropylene fibers as the trigger of mucosal irritation [96].

In a study of 221 health care workers, ENT physicians objectified a voice disorder in 33% of mask users. The VHI-10 score of 1 to 10, which measures voice disorders, was on average 5.72 higher in these mask users (statistically significant with $p < 0.001$). The mask not only acted as an acoustic filter, provoking excessively loud speech, it also seems to trigger impaired vocal cord coordination because the mask compromises the pressure gradients required for undisturbed speech [43]. The researchers concluded from their findings that masks could pose a potential risk of triggering new voice disorders as well as exacerbating existing ones.

3.9. Sports Medicine Side Effects and Dangers

According to the literature, performance-enhancing effects of masks regarding cardiovascular optimization and improvement of oxygen uptake capacity cannot be proven.

For example, in an experimental reference study (12 subjects per group), the training mask that supposedly mimics altitude training (ETM: elevation training mask) only had training effects on the respiratory muscles. However, mask wearers showed significantly lower oxygen saturation values (SpO_2%) during exercise (SpO_2 of 94% for mask wearers versus 96% for mask-less, $p < 0.05$) [33], which can be explained by an increased dead space volume and increased resistance during breathing. The measured oxygen saturation values were significantly lower than the normal values in the group of mask wearers, which indicates a clinical relevance.

The proven adaptation effect of the respiratory muscles in healthy athletes [33] clearly suggests that masks have a disruptive effect on respiratory physiology.

In another intervention study on mask use in weightlifters, researchers documented statistically significant effects of reduced attention (questionnaire recording, Likert scale) and a slowed maximum speed of movement detectable by means of sensors (both significant at $p < 0.001$), leading the researchers to conclude that mask use in sport is not without risks. As a secondary finding, they also detected a significant decrease in oxygen saturation SpO_2 when performing special weight-lifting exercises ("back squats") in the mask group after only 1 min of exercise compared to the mask-free group ($p < 0.001$) [32]. The proven tendency of the masks to shift the chemical parameter oxygen saturation SpO_2 in a pathological direction (lower limit value 95%) may well have clinical relevance in untrained or sick individuals.

Sports medicine confirmed an increase in carbon dioxide (CO_2) retention, with an elevation in CO_2 partial pressure in the blood with larger respiratory dead space volumes [14].

In fact, dead space-induced CO_2 retention while wearing a mask during exercise was also experimentally proven. The effects of a short aerobic exercise under N95 masks were tested on 16 healthy volunteers. A significantly increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) with plus 8 mmHg ($p < 0.001$) was found [24]. The increase in blood carbon dioxide (CO_2) in the mask wearers under maximum load was plus 14% CO_2 for surgical masks and plus 23% CO_2 for N95 masks, an effect that may well have clinical relevance in the pre-diseased, elderly and children, as these values strongly approached the pathological range [24].

In an interesting endurance study with eight middle-aged subjects (19–66), the gas content for O_2 and CO_2 under the masks was determined before and after exercise. Even at rest, the oxygen availability under the masks was 13% lower than without the masks and the carbon dioxide (CO_2) concentration was 30 times higher. Under stress (Ruffier test), the oxygen concentration (% O_2) below the mask dropped significantly by a further 3.7%, while the carbon dioxide concentration (% CO_2) increased significantly by a further 20% (statistically significant with $p < 0.001$). Correspondingly, the oxygen saturation of the blood (SpO_2) of the test persons also decreased significantly from 97.6 to 92.1% ($p < 0.02$) [18]. The drop in the oxygen saturation value (SpO_2) to 92%, clearly below the normal limit of 95%, is to be classified as clinically relevant and detrimental to health.

These facts are an indication that the use of masks also triggers the effects described above leading to hypoxia and hypercapnia in sports. Accordingly, the WHO and Centers for Disease Control and Prevention, GA, USA (CDC) advise against wearing masks during physical exercise [82,97].

3.10. Social and Sociological Side Effects and Dangers

The results of a Chilean study with health care workers show that masks act like an acoustic filter and provoke excessively loud speech. This causes a voice disorder [43]. The increased volume of speech also contributes to increased aerosol production by the mask wearer [98]. These experimental data measured with the Aerodynamic Particle Sizer (APS, TSI, model 332, TSI Incorporated, Minnesota, MI, USA) are highly relevant.

Moreover, mask wearers are prevented from interacting normally in everyday life due to impaired clarity of speech [45], which tempts them to get closer to each other.

This results in a distorted prioritization in the general public, which counteracts the recommended measures associated with the COVID-19 pandemic. The WHO prioritizes social distancing and hand hygiene with moderate evidence and recommends wearing a mask with weak evidence, especially in situations where individuals are unable to maintain a physical distance of at least 1 m [3].

The disruption of non-verbal communication due to the loss of facial expression recognition under the mask can increase feelings of insecurity, discouragement and numbness as well as isolation, which can be extremely stressful for the mentally and hearing-impaired [16].

Experts point out that masks disrupt the basics of human communication (verbal and nonverbal). The limited facial recognition caused by masks leads to a suppression of emotional signals. Masks, therefore, disrupt social interaction, erasing the positive effect of smiles and laughter but at the same time greatly increasing the likelihood of misunderstandings because negative emotions are also less evident under masks [42].

A decrease in empathy perception through mask use with disruption of the doctor–patient relationship has already been scientifically proven on the basis of a randomized study (statistically significant, with $p = 0.04$) [99]. In this study, the Consultation Empathy Care Measury, the Patient Enablement Instrument (PEI) Score and a Satisfaction Rating Scale were assessed in 1030 patients. The 516 doctors, who wore masks throughout, conveyed reduced empathy towards the patients and, thus, nullified the positive health-promoting effects of a dynamic relationship. These results demonstrate a disruption of interpersonal interaction and relationship dynamics caused by masks.

The WHO guidance on the use of masks in children in the community, published in August 2020, points out that the benefits of mask use in children must be weighed up against the potential harms, including social and communicational concerns [100].

Fears that widespread pandemic measures will lead to dysfunctional social life with degraded social, cultural and psychological interactions have also been expressed by other experts [6,7,8,42].

3.11. Social and Occupational Medicine Side Effects and Hazards

In addition to mask-specific complaints such as a feeling of heat, dampness, shortness of breath and headache, various physiological phenomena were documented, such as the significant increase in heart and respiratory rate, the impairment of lung function parameters, the decrease in cardiopulmonary capacity (e.g., lower maximum blood lactate response) [15,19,21,23,29,30,31], as well as the changes in oxygen and carbon dioxide both in the end-expiratory and the air under the mask that was measured in the blood of the individuals [13,15,18,19,21,22,23,24,25,27,28,29,30,31,32,33,34]. The significant changes were measurable after only a few minutes of wearing a mask and in some cases reached magnitudes of minus 13% reduced O_2 concentration and 30-fold increased CO_2 concentration of the inhaled air under masks ($p < 0.001$) [18]. The changes observed were not only statistically significant, but also clinically relevant; the subjects also showed pathological oxygen saturation after exposure to masks ($p < 0.02$) [18].

Shortness of breath during light exertion (6 min walking) under surgical masks has been recorded with statistical significance in 44 healthy subjects in a prospective experimental intervention study ($p < 0.001$) [101]. Here, the complaints were assessed using a subjective, visual analogue scale.

In another study from 2011, all tested masks caused a significantly measurable increase in discomfort and a feeling of exhaustion in the 27 subjects during prolonged usage ($p < 0.0001$) [69].

These symptoms lead to additional stress for the occupational mask wearer and, thus, in relation to the feeling of exhaustion, contribute to the self-perpetuating vicious circle caused by the vegetative sympathetic activation, which further increases the respiratory and heart rate, blood pressure and increased sense of exhaustion [16,20,35,83].

Other studies showed that the psychological and physical effects of the masks can lead to an additional reduction in work performance (measured with the Roberge Subjective Symptoms-during-Work Scale, a Likert scale of 1–5) via increased feelings of fatigue, dissatisfaction and anxiety [58,102,103].

Wearing masks over a longer period of time also led to physiological and psychological impairments in other studies and, thus, reduced work performance [19,36,58,69]. In experiments on respiratory-protective equipment, an increase in the dead space volume by 350 mL leads to a reduction in the possible performance time by approx. −19%, furthermore to a decrease in breathing comfort by −18% (measured via a subjective rating scale) [58]. In addition, the time spent working and the flow of work is interrupted and reduced by putting on and taking off the masks and changing them. The reduced work performance has been recorded in the literature found as described above (especially in Section 3.1 and Section 3.2) but has not been quantified further in detail [36,58].

Surgical mask type and N95 protective equipment frequently caused adverse effects in medical personnel such as headaches, breathing difficulties, acne, skin irritation, itching, decreased alertness, decreased mental performance and feelings of dampness and heat [19,29,37,71,85]. Subjective, work performance-reducing, mask-related impairments in users, measured with special survey scores and Likert scales, have also been described in other studies [15,21,27,32,35,43,66,67,68,72,96,99].

In Section 3.7 on dermatology, we already mentioned a paper that demonstrated a significant temperature increase of 1.9 °C on average (to over 34.5 °C) in the mask-covered facial area ($p < 0.05$) [85]. Due to the relatively larger representation in the sensitive cerebral cortex (homunculus), the temperature sensation in the face is more decisive for the feeling of well-being than other body regions [36,44]. The perception of discomfort when wearing a mask can, thus, be intensified. Interestingly, in our analysis, we found a combined occurrence of the physical variable temperature rise under the mask and the symptom respiratory impairment in seven of eight studies concerned, with a mutual significantly measured occurrence in 88%. We also detected a combined occurrence of significantly measured temperature rise under the mask and significantly measured fatigue in 50% of the relevant primary studies (three of six papers, Figure 2). These clustered associations of temperature rise with symptoms of respiratory impairment and fatigue suggest a

clinical relevance of the detected temperature rise under masks. In the worst case scenario, the effects mentioned can reinforce each other and lead to decompensation, especially in the presence of COPD, heart failure and respiratory insufficiency.

The sum of the disturbances and discomforts that can be caused by a mask also contributes to distraction (see also psychological impairment). These, in conjunction with a decrease in psycho-motoric skills, reduced responsiveness and overall impaired cognitive performance (all of which are pathophysiological effects of wearing a mask) [19,29,32,39,40,41] can lead to a failure to recognize hazards and, thus, to accidents or avoidable errors at work [19,36,37]. Of particular note here are mask-induced listlessness ($p < 0.05$), impaired thinking ($p < 0.05$) and concentration problems ($p < 0.02$) as measured by a Likert scale (1–5) [29]. Accordingly, occupational health regulations take action against such scenarios. The German Industrial Accident Insurance (DGUV) has precise and extensive regulations for respiratory protective equipment where they document the limitation of wearing time, levels of work intensity and defined instruction obligation [104].

The standards and norms prescribed in many countries regarding different types of masks to protect their workers are also significant from an occupational health point of view [105]. In Germany, for example, there are very strict safety specifications for masks from other international countries. These specify the requirements for the protection of the wearer [106]. All these standards and the accompanying certification procedures were increasingly relaxed with the introduction of mandatory masks for the general public. This meant that non-certified masks such as community masks were also used on a large scale in the work and school sectors for longer periods during the pandemic measures [107]. Most recently, in October 2020, the German Social Accident Insurance (DGUV) recommended the same usage time limits for community masks as for filtering half masks, namely, a maximum of three shifts of 120 min per day with recovery breaks of 30 min in between. In Germany, FFP2 (N95) masks must be worn for 75 min, followed by a 30-minute break. An additional suitability examination by specialized physicians is also obligatory and stipulated for occupationally used respirators [104].

3.12. Microbiological Consequences for Wearer and Environment: Foreign/Self-Contamination

Masks cause retention of moisture [61]. Poor filtration performance and incorrect use of surgical masks and community masks, as well as their frequent reuse, imply an increased risk of infection [108,109,110]. The warm and humid environment created by and in masks without the presence of protective mechanisms such as antibodies, the complement system, defense cells and pathogen-inhibiting and on a mucous membrane paves the way for unimpeded growth and, thus, an ideal growth and breeding ground for various pathogens such as bacteria and fungi [88] and also allows viruses to accumulate [87]. The warm and humid mask microclimate favors the accumulation of various germs on and underneath the masks [86], and the germ density is measurably proportional to the length of time the mask is worn. After only 2 h of wearing the mask, the pathogen density increases almost tenfold in experimental observation studies [87,89].

From a microbiological and epidemiological point of view, masks in everyday use pose a risk of contamination. This can occur as foreign contamination but also as self-contamination. On the one hand, germs are sucked in or attach themselves to the masks through convection currents. On the

other hand, potential infectious agents from the nasopharynx accumulate excessively on both the outside and inside of the mask during breathing [5,88]. This is compounded by contact with contaminated hands. Since masks are constantly penetrated by germ-containing breath and the pathogen reproduction rate is higher outside mucous membranes, potential infectious pathogens accumulate excessively on the outside and inside of masks. On and in the masks, there are quite serious, potentially disease-causing bacteria and fungi such as *E. coli* (54% of all germs detected), Staphylococcus aureus (25% of all germs detected), Candida (6%), Klebsiella (5%), Enterococci (4%), Pseudomonads (3%), Enterobacter (2%) and Micrococcus (1%) even detectable in large quantities [88].

In another microbiological study, the bacterium Staphylococcus aureus (57% of all bacteria detected) and the fungus Aspergillus (31% of all fungi detected) were found to be the dominant germs on 230 surgical masks examined [86].

After more than six hours of use, the following viruses were found in descending order on 148 masks worn by medical personnel: adenovirus, bocavirus, respiratory syncytial virus and influenza viruses [87].

From this aspect, it is also problematic that moisture distributes these potential pathogens in the form of tiny droplets via capillary action on and in the mask, whereby further proliferation in the sense of self- and foreign contamination by the aerosols can then occur internally and externally with every breath [35]. In this regard, it is also known from the literature that masks are responsible for a proportionally disproportionate production of fine particles in the environment and, surprisingly, much more so than in people without masks [98].

It was shown that all mask-wearing subjects released significantly more smaller particles of size 0.3–0.5 µm into the air than mask-less people, both when breathing, speaking and coughing (fabric, surgical, N95 masks, measured with the Aerodynamic Particle Sizer, APS, TS, model 3329) [98]. The increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be a further indication of this phenomenon, as masks were consistently used by the general population in public spaces in that year.

3.13. Epidemiological Consequences

The possible side effects and dangers of masks described in this paper are based on studies of different types of masks. These include the professional masks of the surgical mask type and N95/KN95 (FFP2 equivalent) that are commonly used in everyday life, but also the community fabric masks that were initially used. In the case of N95, the N stands for National Institute for Occupational Safety and Health of the United States (NIOSH), and 95 indicates the 95 per cent filtering capacity for fine particles up to at least 0.3 µm [82].

A major risk of mask use in the general public is the creation of a false sense of security with regard to protection against viral infections, especially in the sense of a falsely assumed strong self-protection. Disregarding infection risks may not only neglect aspects of source control, but also result in other disadvantages. Although there are quite a few professional positive accounts of the

widespread use of masks in the general populace [111], most of the serious and evident scientific reports conclude that the general obligation to wear masks conveys a false sense of security [4,5]. However, this leads to a neglect of those measures that, according to the WHO, have a higher level of effectiveness than mask-wearing: social distancing and hand hygiene [2,112]. Researchers were able to provide statistically significant evidence of a false sense of security and more risky behavior when wearing masks in an experimental setting [112].

Decision makers in many countries informed their citizens early on in the pandemic in March 2020 that people without symptoms should not use a medical mask, as this created a false sense of security [113]. The recommendation was ultimately changed in many countries. At least Germany pointed out that wearers of certain types of masks such as the common fabric masks (community masks) cannot rely on them to protect them or others from transmission of SARS-CoV-2 [114].

However, scientists not only complain about the lack of evidence for fabric masks in the scope of a pandemic [16,110], but also about the high permeability of fabric masks with particles and the potential risk of infection they pose [108,109]. Ordinary fabric masks with a 97% penetration for particle dimensions of ≥0.3 µm are in stark contrast to medical-type surgical masks with a 44% penetration. In contrast, the N95 mask has a penetration rate of less than 0.01% for particles ≥ 0.3 µm in the laboratory experiment [108,115].

For the clinical setting in hospitals and outpatient clinics, the WHO guidelines recommend only surgical masks for influenza viruses for the entire patient treatment except for the strongly aerosol-generating measures, for which finer filtering masks of the type N95 are suggested. However, the WHO's endorsement of specific mask types is not entirely evidence-based due to the lack of high-quality studies in the health sector [108,109,116,117].

In a laboratory experiment (evidence level IIa study), it was demonstrated that both surgical masks and N95 masks have deficits in protection against SARS-CoV-2 and influenza viruses using virus-free aerosols [118]. In this study, the FFP2-equivalent N95 mask performed significantly better in protection (8–12 times more effective) than the surgical mask, but neither mask type established reliable, hypothesis-generated protection against corona and influenza viruses. Both mask types could be penetrated unhindered by aerosol particles with a diameter of 0.08 to 0.2 µm. Both the SARS-CoV-2 pathogens with a size of 0.06 to 0.14 µm [119] and the influenza viruses with 0.08 to 0.12 µm are unfortunately well below the mask pore sizes [118].

The filtering capacity of the N95 mask up to 0.3 µm [82] is usually not achieved by surgical masks and community masks. However, aerosol droplets, which have a diameter of 0.09 to 3 µm in size, are supposed to serve as a transport medium for viruses. These also penetrate the medical masks by 40%. Often, there is also a poor fit between the face and the mask, which further impairs their function and safety [120]. The accumulation of aerosol droplets on the mask is problematic. Not only do they absorb nanoparticles such as viruses [6], but they also follow the airflow when inhaling and exhaling, causing them to be carried further. In addition, a physical decay process has been described for aerosol droplets at increasing temperatures, as also occurs under a mask [15,44,85]. This process can lead to a decrease in size of the fine water droplets up to the diame-

ter of a virus [121,122]. The masks filter larger aerosol droplets but cannot retain viruses themselves and such smaller, potentially virus-containing aerosol droplets of less than 0.2 µm and hence cannot stop the spread of virus [123].

Similarly, in an in vivo comparative studies of N95 and surgical masks, there were no significant differences in influenza virus infection rates [124,125]. Although this contrasts with encouraging in vitro laboratory results with virus-free aerosols under non-natural conditions, even with fabric masks [126], it should be noted that under natural in-vivo conditions, the promising filtration functions of fabric masks based on electrostatic effects also rapidly diminish under increasing humidity [127]. A Swiss textile lab test of various masks available on the market to the general public recently confirmed that most mask types filter aerosols insufficiently. For all but one of the eight reusable fabric mask types tested, the filtration efficacy according to EN149 was always less than 70% for particles of 1 µm in size. For disposable masks, only half of all eight mask types tested were efficient enough at filtering to retain 70% of particles 1 µm in size [128].

A recent experimental study even demonstrated that all mask-wearing people (surgical, N95, fabric masks) release significantly and proportionately smaller particles of size 0.3 to 0.5 µm into the air than mask-less people, both when breathing, speaking and coughing [98]. According to this, the masks act like nebulizers and contribute to the production of very fine aerosols. Smaller particles, however, spread faster and further than large ones for physical reasons. Of particular interest in this experimental reference study was the finding that a test subject wearing a single-layer fabric mask was also able to release a total of 384% more particles (of various sizes) when breathing than a person without [98].

It is not only the aforementioned functional weaknesses of the masks themselves that lead to problems, but also their use. This increases the risk of a false sense of security. According to the literature, mistakes are made by both healthcare workers and lay people when using masks as hygienically correct mask use is by no means intuitive. Overall, 65% of healthcare professionals and as many as 78% of the general population, use masks incorrectly [116]. With both surgical masks and N95 masks, adherence to the rules of use is impaired and not adequately followed due to reduced wearability with heat discomfort and skin irritation [29,35,116,129]. This is exacerbated by the accumulation of carbon dioxide due to the dead space (especially under the N95 masks) with the resulting headaches described [19,27,37,66,67,68,83]. Increased heart rate, itching and feelings of dampness [15,29,30,35,71] also lead to reduced safety and quality during use (see also social and occupational health side effects and hazards). For this reason, (everyday) masks are even considered a general risk for infection in the general population, which does not come close to imitating the strict hygiene rules of hospitals and doctors' offices: the supposed safety, thus, becomes a safety risk itself [5].

In a meta-analysis of evidence level Ia commissioned by the WHO, no effect of masks in the context of influenza virus pandemic prevention could be demonstrated [130]. In 14 randomized controlled trials, no reduction in the transmission of laboratory-confirmed influenza infections was shown. Due to the similar size and distribution pathways of the virus species (influenza and Corona, see above), the data can also be transferred to SARS-CoV-2 [118]. Nevertheless, a combination of occasional mask-wearing with adequate hand-washing caused a slight reduction in infec-

tions for influenza in one study [131]. However, since no separation of hand hygiene and masks was achieved in this study, the protective effect can rather be attributed to hand hygiene in view of the aforementioned data [131].

A recently published large prospective Danish comparative study comparing mask wearers and non-mask wearers in terms of their infection rates with SARS-CoV2 could not demonstrate any statistically significant differences between the groups [132].

3.14. Paediatric Side Effects and Hazards

Children are particularly vulnerable and may be more likely to receive inappropriate treatment or additional harm. It can be assumed that the potential adverse mask effects described for adults are all the more valid for children (see Section 3.1 to Section 3.13: physiological internal, neurological, psychological, psychiatric, dermatological, ENT, dental, sociological, occupational and social medical, microbiological and epidemiological impairments and also Figure 2 and Figure 3).

Special attention must be paid to the respiration of children, which represents a critical and vulnerable physiological variable due to higher oxygen demand, increased hypoxia susceptibility of the CNS, lower respiratory reserve, smaller airways with a stronger increase in resistance when the lumen is narrowed. The diving reflex caused by stimulating the nose and upper lip can cause respiratory arrest to bradycardia in the event of oxygen deficiency.

The masks currently used for children are exclusively adult masks manufactured in smaller geometric dimensions and had neither been specially tested nor approved for this purpose [133].

In an experimental British research study, the masks frequently led to feelings of heat ($p < 0.0001$) and breathing problems ($p < 0.03$) in 100 school children between 8 and 11 years of age especially during physical exertion, which is why the protective equipment was taken off by 24% of the children during physical activity [133]. The exclusion criteria for this mask experiment were lung disease, cardiovascular impairment and claustrophobia [133].

Scientists from Singapore were able to demonstrate in their level Ib study published in the renowned journal “nature” that 106 children aged between 7 and 14 years who wore FFP2 masks for only 5 min showed an increase in the inspiratory and expiratory CO_2 levels, indicating disturbed respiratory physiology [26].

However, a disturbed respiratory physiology in children can have long-term disease-relevant consequences. Slightly elevated CO_2 levels are known to increase heart rate, blood pressure, headache, fatigue and concentration disorders [38].

Accordingly, the following conditions were listed as exclusion criteria for mask use [26]: any cardiopulmonary disease including but not limited to: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema; any condition that may be aggravated by physical exertion, including but not limited to: exercise-induced asthma; lower respiratory tract infections (pneumonia, bronchitis within the last 2 weeks), anxiety disorders, diabetes, hypertension or epilepsy/attack disor-

der; any physical disability due to medical, orthopedic or neuromuscular disease; any acute upper respiratory illness or symptomatic rhinitis (nasal obstruction, runny nose or sneezing); any condition with deformity that affects the fit of the mask (e.g., increased facial hair, craniofacial deformities, etc.).

It is also important to emphasize the possible effects of masks in neurological diseases, as described earlier (Section 3.3).

Both masks and face shields caused fear in 46% of children (37 out of 80) in a scientific study. If children are given the choice of whether the doctor examining them should wear a mask they reject this in 49% of the cases. Along with their parents, the children prefer the practitioner to wear a face visor (statistically significant with $p < 0.0001$) [134].

A recent observational study of tens of thousands of mask-wearing children in Germany helped the investigators objectify complaints of headaches (53%), difficulty concentrating (50%), joylessness (49%), learning difficulties (38%) and fatigue in 37% of the 25,930 children evaluated. Of the children observed, 25% had new onset anxiety and even nightmares [135]. In children, the threat scenarios generated by the environment are further maintained via masks, in some cases, even further intensified, and in this way, existing stress is intensified (presence of subconscious fears) [16,35,136,137].

This can in turn lead to an increase in psychosomatic and stress-related illnesses [74,75]. For example, according to an evaluation, 60% of mask wearers showed stress levels of the highest grade 10 on a scale of 1 to a maximum of 10. Less than 10% of the mask wearers surveyed had a stress level lower than 8 out of a possible 10 [74].

As children are considered a special group, the WHO also issued a separate guideline on the use of masks in children in the community in August 2020, explicitly advising policy makers and national authorities, given the limited evidence, that the benefits of mask use in children must be weighed up against the potential harms associated with mask use. This includes feasibility and discomfort, as well as social and communication concerns [100].

According to experts, masks block the foundation of human communication and the exchange of emotions and not only hinder learning but deprive children of the positive effects of smiling, laughing and emotional mimicry [42]. The effectiveness of masks in children as a viral protection is controversial, and there is a lack of evidence for their widespread use in children; this is also addressed in more detail by the scientists of the German University of Bremen in their thesis paper 2.0 and 3.0 [138].

3.15. Effects on the Environment

According to WHO estimates of a demand of 89 million masks per month, their global production will continue to increase under the Corona pandemic [139]. Due to the composition of, e.g., disposable surgical masks with polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester [140], an increasing global challenge, also

from an environmental point of view, can be expected, especially outside Europe, in the absence of recycling and disposal strategies [139]. The aforementioned single use polymers have been identified as a significant source of plastic and plastic particles for the pollution of all water cycles up to the marine environment [141].

A significant health hazard factor is contributed by mask waste in the form of microplastics after decomposition into the food chain. Likewise, contaminated macroscopic disposable mask waste—especially before microscopic decay—represents a widespread medium for microbes (protozoa, bacteria, viruses, fungi) in terms of invasive pathogens [86,87,88,89,142]. Proper disposal of bio-contaminated everyday mask material is insufficiently regulated even in western countries.

4. Discussion

The potential drastic and undesirable effects found in multidisciplinary areas illustrate the general scope of global decisions on masks in general public in the light of combating the pandemic. According to the literature found, there are clear, scientifically recorded adverse effects for the mask wearer, both on a psychological and on a social and physical level.

Neither higher level institutions such as the WHO or the European Centre for Disease Prevention and Control (ECDC) nor national ones, such as the Centers for Disease Control and Prevention, GA, USA (CDC) or the German RKI, substantiate with sound scientific data a positive effect of masks in the public (in terms of a reduced rate of spread of COVID-19 in the population) [2,4,5].

Contrary to the scientifically established standard of evidence-based medicine, national and international health authorities have issued their theoretical assessments on the masks in public places, even though the compulsory wearing of masks gives a deceptive feeling of safety [5,112,143].

From an infection epidemiological point of view, masks in everyday use offer the risk of self-contamination by the wearer from both inside and outside, including via contaminated hands [5,16,88]. In addition, masks are soaked by exhaled air, which potentially accumulates infectious agents from the nasopharynx and also from the ambient air on the outside and inside of the mask. In particular, serious infection-causing bacteria and fungi should be mentioned here [86,88,89], but also viruses [87]. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be an indication of this phenomenon. Clarification through further investigations would therefore be desirable.

Masks, when used by the general public, are considered by scientists to pose a risk of infection because the standardized hygiene rules of hospitals cannot be followed by the general public [5]. On top of that, mask wearers (surgical, N95, fabric masks) exhale relatively smaller particles (size 0.3 to 0.5 µm) than mask-less people and the louder speech under masks further amplifies this increased fine aerosol production by the mask wearer (nebulizer effect) [98].

The history of modern times shows that already in the influenza pandemics of 1918–1919, 1957–58, 1968, 2002, in SARS 2004–2005 as well as with the influenza in 2009, masks in everyday use could not achieve the hoped-for success in the fight against viral infection scenarios [67,144]. The experiences led to scientific studies describing as early as 2009 that masks do not show any significant effect with regard to viruses in an everyday scenario [129,145]. Even later, scientists and institutions rated the masks as unsuitable to protect the user safely from viral respiratory infections [137,146,147]. Even in hospital use, surgical masks lack strong evidence of protection against viruses [67].

Originally born out of the useful knowledge of protecting wounds from surgeons' breath and predominantly bacterial droplet contamination [144,148,149], the mask has been visibly misused with largely incorrect popular everyday use, particularly in Asia in recent years [150]. Significantly, the sociologist Beck described the mask as a cosmetic of risk as early as 1992 [151]. Unfortunately, the mask is inherent in a vicious circle: strictly speaking, it only protects symbolically and at the same time represents the fear of infection. This phenomenon is reinforced by the collective fear mongering, which is constantly nurtured by main stream media [137].

Nowadays, the mask represents a kind of psychological support for the general population during the virus pandemic, promising them additional anxiety-reduced freedom of movement. The recommendation to use masks in the sense of "source control" not out of self-protection but out of "altruism" [152] is also very popular with the regulators as well as the population of many countries. The WHO's recommendation of the mask in the current pandemic is not only a purely infectiological approach, but is also clear on the possible advantages for healthy people in the general public. In particular, a reduced potential stigmatization of mask wearers, the feeling of a contribution made to preventing the spread of the virus, as well as the reminder to adhere to other measures are mentioned [2].

It should not go unmentioned that very recent data suggest that the detection of SARS-CoV-2 infection does not seem to be directly related to popular mask use. The groups examined in a retrospective comparative study (infected with SARS-CoV-2 and not infected) did not differ in their habit of using masks: approximately 70% of the subjects in both groups always wore masks and another 14.4% of them frequently [143].

In a Danish prospective study on mask-wearing carried out on about 6000 participants and published in 2020, scientists found no statistically significant difference in the rates of SARS-CoV-2 infection when comparing the group of 3030 mask wearers with the 2994 mask-less participants in the study ($p = 0.38$) [132].

Indeed, in the case of viral infections, masks appear to be not only less effective than expected, but also not free of undesirable biological, chemical, physical and psychological side effects [67]. Accordingly, some experts claim that well-intentioned unprofessionalism can be quite dangerous [6].

The dermatological colleagues were the first to describe common adverse effects of mask-wearing in larger collectives. Simple, direct physical, chemical and biological effects of the masks with increases in temperature, humidity and mechanical irritation caused acne in up to 60% of wearers [37,71,72,73,85]. Other significantly documented consequences were eczema, skin damage and overall impaired skin barrier function [37,72,73].

These direct effects of mask use are an important pointer to further detrimental effects affecting other organ systems.

In our work, we have identified scientifically validated and numerous statistically significant adverse effects of masks in various fields of medicine, especially with regard to a disruptive influence on the highly complex process of breathing and negative effects on the respiratory physiology and gas metabolism of the body (see Figure 2 and Figure 3). The respiratory physiology and gas exchange play a key role in maintaining a health-sustaining balance in the human body [136,153]. According to the studies we found, a dead space volume that is almost doubled by wearing a mask and a more than doubled breathing resistance (Figure 3) [59,60,61] lead to a rebreathing of carbon dioxide with every breathing cycle [16,17,18,39,83] with—in healthy people mostly—a subthreshold but, in sick people, a partly pathological increase in the carbon dioxide partial pressure ($PaCO_2$) in the blood [25,34,58]. According to the primary studies found, these changes contribute reflexively to an increase in respiratory frequency and depth [21,23,34,36] with a corresponding increase in the work of the respiratory muscles via physiological feedback mechanisms [31,36]. Thus, it is not, as initially assumed, purely positive training through mask use. This often increases the subliminal drop in oxygen saturation SpO_2 in the blood [23,28,29,30,32], which is already reduced by increased dead space volume and increased breathing resistance [18,31].

The overall possible resulting measurable drop in oxygen saturation O_2 of the blood on the one hand [18,23,28,29,30,32] and the increase in carbon dioxide (CO_2) on the other [13,15,19,21,22,23,24,25,26,27,28] contribute to an increased noradrenergic stress response, with heart rate increase [29,30,35] and respiratory rate increase [15,21,23,34], in some cases also to a significant blood pressure increase [25,35].

In panic-prone individuals, stress-inducing noradrenergic sympathetic activation can be partly directly mediated via the carbon dioxide (CO_2) mechanism at the locus coeruleus in the brainstem [39,78,79,153], but also in the usual way via chemo-sensitive neurons of the nucleus solitarius in the medulla [136,154]. The nucleus solitarius [136] is located in the deepest part of the brainstem, a gateway to neuronal respiratory and circulatory control [154]. A decreased oxygen (O_2) blood level there causes the activation of the sympathetic axis via chemoreceptors in the carotids [155,156].

Even subthreshold changes in blood gases such as those provoked when wearing a mask cause reactions in these control centers in the central nervous system. Masks, therefore, trigger direct reactions in important control centers of the affected brain via the slightest changes in oxygen and carbon dioxide in the blood of the wearer [136,154,155].

A link between disturbed breathing and cardiorespiratory diseases such as hypertension, sleep apnea and metabolic syndrome has been scientifically proven [56,57]. Interestingly, decreased oxygen/O_2 blood levels and also increased carbon dioxide/CO_2 blood levels are considered the main triggers for the sympathetic stress response [38,136]. The aforementioned chemo-sensitive neurons of the nucleus solitarius in the medulla are considered to be the main responsible control centers [136,154,155]. Clinical effects of prolonged mask-wearing would, thus, be a conceivable intensification of chronic stress reactions and negative influences on the metabolism leading towards a metabolic syndrome. The mask studies we found show that such disease-relevant respiratory gas changes (O_2 and CO_2) [38,136] are already achieved by wearing a mask [13,15,18,19,21,22,23,24,25,26,27,28,29,30,31,32,33,34].

A connection between hypoxia, sympathetic reactions and leptin release is scientifically known [136].

Additionally important is the connection of breathing with the influence on other bodily functions [56,57], including the psyche with the generation of positive emotions and drive [153]. The latest findings from neuro-psychobiological research indicate that respiration is not only a function regulated by physical variables to control them (feedback mechanism), but rather independently influences higher-level brain centers and, thus, also helps to shape psychological and other bodily functions and reactions [153,157,158]. Since masks impede the wearer's breathing and accelerate it, they work completely against the principles of health-promoting breathing [56,57] used in holistic medicine and yoga. According to recent research, undisturbed breathing is essential for happiness and healthy drive [157,159], but masks work against this.

The result of significant changes in blood gases in the direction of hypoxia (drop in oxygen saturation) and hypercapnia (increase in carbon dioxide concentration) through masks, thus, has the potential to have a clinically relevant influence on the human organism even without exceeding normal limits.

According to the latest scientific findings, blood-gas shifts towards hypoxia and hypercapnia not only have an influence on the described immediate, psychological and physiological reactions on a macroscopic and microscopic level, but additionally on gene expression and metabolism on a molecular cellular level in many different body cells. Through this, the drastic disruptive intervention of masks in the physiology of the body also becomes clear down to the cellular level, e.g., in the activation of hypoxia-induced factor (HIF) through both hypercapnia and hypoxia-like effects [160]. HIF is a transcription factor that regulates cellular oxygen supply and activates signaling pathways relevant to adaptive responses. e.g., HIF inhibits stem cells, promotes tumor cell growth and inflammatory processes [160]. Based on the hypoxia- and hypercapnia-promoting effects of masks, which have been comprehensively described for the first time in our study, potential disruptive influences down to the intracellular level (HIF-a) can be assumed, especially through the prolonged and excessive use of masks. Thus, in addition to the vegetative chronic stress reaction in mask wearers, which is channeled via brain centers, there is also likely to be an adverse influence on metabolism at the cellular level. With the prospect of continued mask use in everyday life, this also opens up an interesting field of research for the future.

The fact that prolonged exposure to latently elevated CO_2 levels and unfavorable breathing air compositions has disease-promoting effects was recognized early on. As early as 1983, the WHO described "Sick Building Syndrome" (SBS) as a condition in which people living indoors experienced acute disease-relevant effects that increased with time of their stay, without specific causes or diseases [161,162]. The syndrome affects people who spend most of their time indoors, often with subliminally elevated CO_2 levels, and are prone to symptoms such as increased heart rate, rise in blood pressure, headaches, fatigue and difficulty concentrating [38,162]. Some of the complaints described in the mask studies we found (Figure 2) are surprisingly similar to those of Sick Building Syndrome [161]. Temperature, carbon dioxide content of the air, headaches, dizziness, drowsiness and itching also play a role in Sick Building Syndrome. On the one hand, masks could themselves be responsible for effects such as those described for Sick Building Syndrome when used for a longer period of time. On the other hand, they could additionally intensify these effects when worn in air-conditioned buildings, especially when masks are mandatory indoors. Nevertheless, there was a tendency towards higher systolic blood pressure values in mask wearers in some studies [21,31,34], but statistical significance was only found in two studies [25,35]. However, we found more relevant and significant evidence of heart rate increase, headache, fatigue and concentration problems associated with mask wearers (Figure 2) indicating the clinical relevance of wearing masks.

According to the scientific results and findings, masks have measurably harmful effects not only on healthy people, but also on sick people and their relevance is likely to increase with the duration of use [69]. Further research is needed here to shed light on the long-term consequences of widespread mask use with subthreshold hypoxia and hypercapnia in the general population, also regarding possible exacerbating effects on cardiorespiratory lifestyle diseases such as hypertension, sleep apnea and metabolic syndrome. The already often elevated blood carbon dioxide (CO_2) levels in overweight people, sleep apnea patients and patients with overlap-COPD could possibly increase even further with everyday masks. Not only a high body mass index (BMI) but also sleep apnea are associated with hypercapnia during the day in these patients (even without masks) [19,163]. For such patients, hypercapnia means an increase in the risk of serious diseases with increased morbidity, which could then be further increased by excessive mask use [18,38].

The hypercapnia-induced effects of sympathetic stress activation are even cycle phase-dependent in women. Controlled by a progesterone mechanism, the sympathetic reaction, measured by increased blood pressure in the luteal phase, is considerably stronger [164]. This may also result in different sensitivities for healthy and sick women to undesirable effects masks have, which are related to an increase in carbon dioxide (CO_2).

In our review, negative physical and psychological changes caused by masks could be objectified even in younger and healthy individuals.

The physical and chemical parameters did not exceed the normal values in most cases but were statistically significantly measurable ($p < 0.05$) tending towards pathological ranges. They were accompanied by physical impairments (see Figure 2). It is well known that subthreshold stimuli are capable of causing pathological changes when exposed to them for a long time: not only a single high dose of a disturbance, but also a chronically persistent, subthreshold exposure to it often

leads to illness [38,46,47,48,50,51,52,53,54]. The scientifically repeatedly measurable physical and chemical mask effects were often accompanied by typical subjective complaints and pathophysiological phenomena. The fact that these frequently occur simultaneously and together indicates a syndrome under masks.

Figure 2 sums up the significant mask-dependent physiological, psychological, somatic and general pathological changes and their frequent occurrence together is striking. Within the framework of the quantitative evaluation of the experimental studies, we were actually able to prove a statistically significant correlation of the observed side effects of fatigue and oxygen depletion under mask use with $p < 0.05$. In addition, we found a frequent, simultaneous and joint occurrence of further undesirable effects in the scientific studies (Figure 2). Statistically significant associations of such co-occurring, adverse effects have already been described in primary studies [21,29]. We detected a combined occurrence of the physical parameter temperature rise under the mask with the symptom respiratory impairment in seven of the nine studies concerned (88%). We found a similar result for the decrease in oxygen saturation under mask and the symptom respiratory impairment with a simultaneous detection in six of the eight studies concerned (67%). We detected a combined occurrence of carbon dioxide rise under N95 mask use in nine of the 11 scientific papers (82%). We found a similar result for oxygen drop under N95 mask use with simultaneous co-occurrence in eight of 11 primary papers (72%). The use of N95 masks was also associated with headache in six of the 10 primary studies concerned (60%). A combined occurrence of the physical parameters temperature rise and humidity under masks was even found 100% within six of the six studies with significant measurements of these parameters (Figure 2).

Since the symptoms were described in combination in mask wearers and were not observed in isolation in the majority of cases, we refer to them as general Mask-Induced Exhaustion Syndrome (MIES) because of the consistent presentation in numerous papers from different disciplines. These include the following, predominantly statistically significantly ($p < 0.05$) proven pathophysiological changes and subjective complaints, which often occur in combination as described above (see also Section 3.1 to Section 3.11, Figure 2, Figure 3 and Figure 4):

- Increase in dead space volume [22,24,58,59] (Figure 3, Section 3.1 and Section 3.2).
- Increase in breathing resistance [31,35,61,118] (Figure 3, Figure 2: Column 8).
- Increase in blood carbon dioxide [13,15,19,21,22,23,24,25,26,27,28] (Figure 2: Column 5).
- Decrease in blood oxygen saturation [18,19,21,23,28,29,30,31,32,33,34] (Figure 2: Column 4).
- Increase in heart rate [15,19,23,29,30,35] (Figure 2: Column 12).
- Decrease in cardiopulmonary capacity [31] (Section 3.2).
- Feeling of exhaustion [15,19,21,29,31,32,33,34,35,69] (Figure 2: Column 14).
- Increase in respiratory rate [15,21,23,34] (Figure 2: Column 9).
- Difficulty breathing and shortness of breath [15,19,21,23,25,29,31,34,35,71,85,101,133] (Figure 2: Column 13).
- Headache [19,27,37,66,67,68,83] (Figure 2: Column 17).
- Dizziness [23,29] (Figure 2: Column 16).
- Feeling of dampness and heat [15,16,22,29,31,35,85,133] (Figure 2: Column 7).
- Drowsiness (qualitative neurological deficits) [19,29,32,36,37] (Figure 2: Column 15).

- Decrease in empathy perception [99] (Figure 2: Column 19).
- Impaired skin barrier function with acne, itching and skin lesions [37,72,73] (Figure 2: Column 20–22).

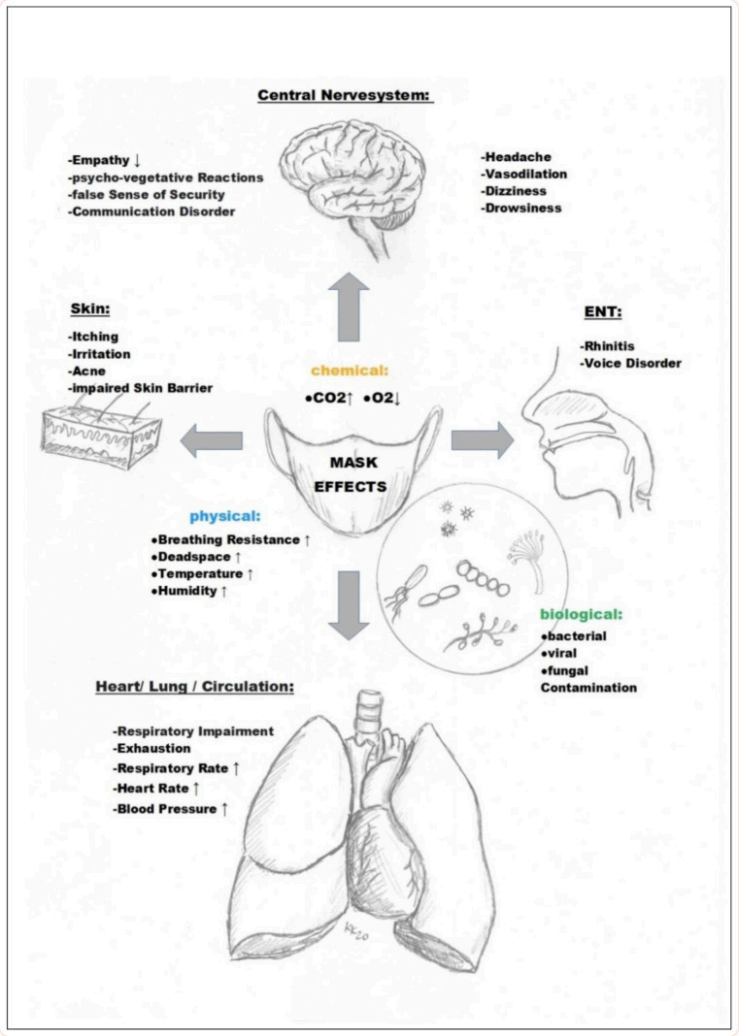


Figure 4

Unfavorable mask effects as components of Mask-Induced Exhaustion Syndrome (MIES). The chemical, physical and biological effects, as well as the organ system consequences mentioned, are all documented with statistically significant results in the scientific literature found (Figure 2). The term drowsiness is used here to summarize any qualitative neurological deficits described in the examined scientific literature.

It can be deduced from the results that the effects described in healthy people are all more pronounced in sick people, since their compensatory mechanisms, depending on the severity of the illness, are reduced or even exhausted. Some existing studies on and with patients with measurable pathological effects of the masks support this assumption [19,23,25,34]. In most scientific studies, the exposure time to masks in the context of the measurements/investigations was significantly less (in relation to the total wearing and duration of use) than is expected of the general public under the current pandemic regulations and ordinances.

The exposure time limits are little observed or knowingly disregarded in many areas today as already mentioned in Section 3.11 on occupational medicine. The above facts allow the conclusion that the described negative effects of masks, especially in some of our patients and the very elderly, may well be more severe and adverse with prolonged use than presented in some mask studies.

From a doctor's viewpoint, it may also be difficult to advise children and adults who, due to social pressure (to wear a mask) and the desire to feel they belong, suppress their own needs and concerns until the effects of masks have a noticeable negative impact on their health [76]. Nevertheless, the use of masks should be stopped immediately at the latest when shortness of breath, dizziness or vertigo occur [23,25]. From this aspect, it seems sensible for decision makers and authorities to provide information, to define instruction obligations and offer appropriate training for employers, teachers and other persons who have a supervisory or caregiving duty. Knowledge about first aid measures could also be refreshed and expanded accordingly in this regard.

Elderly, high-risk patients with lung disease, cardiac patients, pregnant women or stroke patients are advised to consult a physician to discuss the safety of an N95 mask as their lung volume or cardiopulmonary performance may be reduced [23]. A correlation between age and the occurrence of the aforementioned symptoms while wearing a mask has been statistically proven [19]. Patients with reduced cardiopulmonary function are at increased risk of developing serious respiratory failure with mask use according to the referenced literature [34]. Without the possibility of continuous medical monitoring, it can be concluded that they should not wear masks without close monitoring. The American Asthma and Allergy Society has already advised caution in the use of masks with regard to the COVID-19 pandemic for people with moderate and severe lung disease [165]. Since the severely overweight, sleep apnea patients and overlap-COPD sufferers are known to be prone to hypercapnia, they also represent a risk group for serious adverse health effects under extensive mask use [163]. This is because the potential of masks to produce additional CO_2 retention may not only have a disruptive effect on the blood gases and respiratory physiology of sufferers, but may also lead to further serious adverse health effects in the long term. Interestingly, in an animal experiment an increase in CO_2 with hypercapnia leads to contraction of smooth airway muscles with constriction of bronchi [166]. This effect could explain the observed pulmonary decompensations of patients with lung disease under masks (Section 3.2) [23,34].

Patients with renal insufficiency requiring dialysis are, according to the literature available, further candidates for a possible exemption from the mask requirement [34]. According to the criteria of the Centers for Disease Control and Prevention, GA, USA (CDC), sick and helpless people who cannot remove a mask on their own should be exempted from the mask requirement [82].

Since it can be assumed that children react even more sensitively to masks, the literature suggests that masks are a contraindication for children with epilepsies (hyperventilation as a trigger for seizures) [63]. In the field of pediatrics, special attention should also be paid to the mask symptoms described under psychological, psychiatric and sociological effects with possible triggering of panic attacks by CO_2 rebreathing in the case of predisposition and also reinforcement of claustrophobic fears [77,78,79,167]. The mask-related disturbance of verbal [43,45,71] and non-verbal

communication and, thus, of social interaction is particularly serious for children. Masks restrict social interaction and block positive perceptions (smiling and laughing) and emotional mimicry [42]. The proven mask-induced mild to moderate cognitive impairment with impaired thinking, decreased attention and dizziness [19,23,29,32,36,37,39,40,41,69], as well as the psychological and neurological effects [135], should be additionally taken into account when masks are compulsory at school and in the vicinity of both public and non-public transport, also regarding the possibility of an increased risk of accidents (see also occupational health side effects and hazards) [19,29,32,36,37]. The exclusion criteria mentioned in pediatric studies on masks (see pediatric impairments, Section 3.14) [26,133] should also apply to an exclusion of these children from the general mask obligation in accordance with the scientific findings for the protection of the sick children concerned. The long-term sociological, psychological and educational consequences of a comprehensive masking requirement extended to schools are also unpredictable with regard to the psychological and physical development of healthy children [42,135]. Interestingly, according to the Corona Thesis Paper of the University of Bremen children "are infected less often, they become ill less often, the lethality is close to zero, and they also pass on the infection less often", according to the Thesis Paper 2.0 of the German University of Bremen on page 6 [138]. Studies conducted under real-life conditions with outcome endpoints showing hardly any infections, hardly any morbidity, hardly any mortality and only low contagiousness in children are clearly in the majority, according to Thesis Paper 3.0 of the German University of Bremen [138]. A recent German observational study (5600 reporting pediatricians) also showed a surprisingly low incidence of COVID-19 disease in children [168]. The infection of adults with SARS-CoV-2 by children has been considered in only one suspected case, but could not be proven with certainty, since the parents also had numerous contacts and exposure factors for viral infections due to their occupation. In this case, the circulating headlines in the public media that children contribute more to the incidence of infection are to be regarded as anecdotal.

In pregnant women, the use of masks during exertion or at rest over long periods of time is to be regarded as critical as little research has been done on this [20]. If there is clear scientific evidence of increased dead space ventilation with possible accumulation of CO_2 in the mother's blood, the use of masks by pregnant women for more than 1 h, as well as under physical stress, should be avoided in order to protect the unborn child [20,22]. The hypercapnia-promoting masks could act as a confounder of the fetal/maternal CO_2 gradient in this case (Section 3.6) [20,22,28].

According to the literature cited in the Section 3.5 on psychiatric side effects (personality disorders with anxiety and panic attacks, claustrophobia, dementia and schizophrenia), masking should only be done, if at all, with careful consideration of the advantages and disadvantages. Attention should be paid to possible provocation of the number and severity of panic attacks [77,78,79].

In patients with headaches, a worsening of symptoms can be expected with prolonged mask use (see also Section 3.3., neurological side effects) [27,66,67,68]. As a result of the increase in blood carbon dioxide (CO_2) when the mask is used, vasodilatation occurs in the central nervous system and the pulsation of the blood vessels decreases [27]. In this connection, it is also interesting to note radiological experiments that demonstrate an increase in brain volume under subthreshold, but still within normal limits of CO_2 increase in the blood by means of structural MRI. The blood

carbon dioxide increase was produced in seven subjects via rebreathing with resulting median carbon dioxide concentration of 42 mmHg and an interquartile range of 39.44 mmHg, corresponding to only a subthreshold increase given the normal values of 32–45 mmHg. In the experiment, there was a significant increase in brain parenchymal volume measurable under increased arterial CO_2 levels ($p < 0.02$), with a concomitant decrease in CSF spaces ($p < 0.04$), entirely in accordance with the Monroe–Kelly doctrine, according to which the total volume within the skull always remains the same. The authors interpreted the increase in brain volume as an expression of an increase in blood volume due to a CO_2 increase-induced dilation of the cerebral vessels [169]. The consequences of such equally subthreshold carbon dioxide (CO_2) increases even under masks [13,15,18,19,22,23,25] are unclear for people with pathological changes inside the skull (aneurysms, tumors, etc.) with associated vascular changes [27] and brain volume shifts [169] especially due to longer exposure while wearing a mask, but could be of great relevance due to the blood gas-related volume shifts that take place.

In view of the increased dead space volume, the long-term and increased accumulation and rebreathing of other respiratory air components apart from CO_2 is also unexplained, both in children and in old and sick people. Exhaled air contains over 250 substances, including irritant or toxic gases such as nitrogen oxides (NO), hydrogen sulfide (H2S), isoprene and acetone [170]. For nitrogen oxides [47] and hydrogen sulfide [46], pathological effects relevant to disease have been described in environmental medicine even at a low but chronic exposure [46,47,48]. Among the volatile organic compounds in exhaled air, acetone and isoprene dominate in terms of quantity, but allyl methyl sulfide, propionic acid and ethanol (some of bacterial origin) should also be mentioned [171]. Whether such substances also react chemically with each other underneath masks and in the dead space volume created by masks (Figure 3), and with the mask tissue itself, and in what quantities these and possible reaction products are rebreathed, has not yet been clarified. In addition to the blood gas changes described above (O_2 drop and CO_2 rise), these effects could also play a role with regard to undesirable mask effects. Further research is needed here and is of particular interest in the case of prolonged and ubiquitous use of masks.

The WHO sees the integration of individual companies and communities that produce their own fabric masks as a potential social and economic benefit. Due to the global shortage of surgical masks and personal protective equipment, it sees this as a source of income and points out that the reuse of fabric masks can reduce costs and waste and contribute to sustainability [2]. In addition to the question of certification procedures for such fabric masks, it should also be mentioned that due to the extensive mask obligation, textile (artificial) substances in the form of micro- and nanoparticles, some of which cannot be degraded in the body, are chronically absorbed into the body through inhalation to an unusual extent. In the case of medical masks, disposable polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester should be mentioned [140]. ENT physicians have already been able to detect such particles in the nasal mucosa of mask wearers with mucosal reactions in the sense of a foreign body reaction with rhinitis [96]. In the case of community masks, other substances from the textile industry are likely to be added to those mentioned above. The body will try to absorb these substances through macrophages and scavenger cells in the respiratory tract and alveoli as part of a foreign body reaction, whereby toxin release and corresponding local and generalized reactions may occur in an unsuccessful attempt to break them down [172]. Extensive respiratory protection

in permanent long-term use (24/7), at least from a theoretical point of view, also potentially carries the risk of leading to a mask-related pulmonary [47] or even generalized disorder, as is already known from textile workers chronically exposed to organic dusts in the Third World (byssinosis) [172].

For the general public, from a scientific angle, it is necessary to draw on the long-standing knowledge of respiratory protection in occupational medicine in order to protect children in particular from harm caused by uncertified masks and improper use.

The universal undefined and extended mask requirement—without taking into account multiple predispositions and susceptibilities—contradicts the claim of an increasingly important individualized medicine with a focus on the unique characteristics of each individual [173].

A systematic review on the topic of masks is necessary according to the results of our scoping review. The primary studies often showed weaknesses in operationalization, especially in the evaluation of cognitive and neuropsychological parameters. Computerized test procedures will be useful here in the future. Mask research should also set itself the future goal of investigating and defining subgroups for whom respiratory protection use is particularly risky.

5. Limitations

Our approach with a focus on negative effects is in line with Villalonga-Olives and Kawachi [12]. With the help of such selective questioning in the sense of dialectics, new insights can be gained that might otherwise have remained hidden. Our literature search focused on adverse negative effects of masks, in particular to point out risks especially for certain patient groups. Therefore, publications presenting only positive effects of masks were not considered in this review.

For a compilation of studies with harmless results when using masks, reference must, therefore, be made to reviews with a different research objective, whereby attention must be paid to possible conflicts of interest there. Some of the studies excluded by us lacking negative effects have shown methodological weaknesses (small, non-uniform experimental groups, missing control group even without masks due to corona constraints, etc.) [174]. In other words, if no negative concomitant effects were described in publications, it does not necessarily mean that masks have exclusively positive effects. It is quite possible that negative effects were simply not mentioned in the literature and the number of negative effects may well be higher than our review suggests.

We only searched one database, so the number of papers on negative mask effects may be higher than we reported.

In order to be able to describe characteristic effects for each mask type even more extensively, we did not have enough scientific data on the respective special designs of the masks. There is still a great need for research in this area due to the current pandemic situation with extensive mandatory masking.

In addition, the experiments evaluated in this paper do not always have uniform measurement parameters and study variables and, depending on the study, take into account the effect of masks at rest or under stress with subjects having different health conditions. Figure 2, therefore, represents a compromise. The results of the primary studies on mask use partially showed no natural variation in parameters, but often showed such clear correlations between symptoms and physiological changes, so that a statistical correlation analysis was not always necessary. We found a statistically significant correlation of oxygen deprivation and fatigue in 58% of the studies ($p < 0.05$). A statistically significant correlation evidence for other parameters has been previously demonstrated in primary studies [21,29].

The most commonly used personal particulate matter protective equipment in the COVID-19 pandemic is the N95 mask [23]. Due to its characteristics (better filtering function, but greater airway resistance and more dead space volume than other masks), the N95 mask is able to highlight negative effects of such protective equipment more clearly than others (Figure 3). Therefore, a relatively frequent consideration and evaluation of N95 masks within the studies found (30 of the 44 quantitatively evaluated studies, 68%) is even advantageous within the framework of our research question. Nevertheless, it remains to be noted that the community masks sold on the market are increasingly similar to the protective equipment that has been better investigated in scientific studies, such as surgical masks and N95 masks, since numerous manufacturers and users of community masks are striving to approximate the professional standard (surgical mask, N95/FFP2). Recent study results on community masks indicate similar effects for respiratory physiology as described for medical masks: in a recent publication, fabric masks (community masks) also provoked a measurable increase in carbon dioxide $PtcCO_2$ in wearers during exertion and came very close to surgical masks in this effect [21].

Most of the studies cited in our paper included only short observation and application periods (mask-wearing durations investigated ranged from 5 min [26] to 12 h [19]. In only one study, a maximum observation period of an estimated 2-month period was chosen [37]. Therefore, the actual negative effects of masks over a longer application period might be more pronounced than presented in our work.

6. Conclusions

On the one hand, the advocacy of an extended mask requirement remains predominantly theoretical and can only be sustained with individual case reports, plausibility arguments based on model calculations and promising in vitro laboratory tests. Moreover, recent studies on SARS-CoV-2 show both a significantly lower infectivity [175] and a significantly lower case mortality than previously assumed, as it could be calculated that the median corrected infection fatality rate (IFR) was 0.10% in locations with a lower than average global COVID-19 population mortality rate [176]. In early October 2020, the WHO also publicly announced that projections show COVID-19 to be fatal for approximately 0.14% of those who become ill—compared to 0.10% for endemic influenza—again a figure far lower than expected [177].

On the other hand, the side effects of masks are clinically relevant.

In our work, we focused exclusively on the undesirable and negative side effects that can be produced by masks. Valid significant evidence of combined mask-related changes were objectified ($p < 0.05$, $n \geq 50\%$), and we found a clustered and common occurrence of the different adverse effects within the respective studies with significantly measured effects (Figure 2). We were able to demonstrate a statistically significant correlation of the observed adverse effect of hypoxia and the symptom of fatigue with $p < 0.05$ in the quantitative evaluation of the primary studies. Our review of the literature shows that both healthy and sick people can experience Mask-Induced Exhaustion Syndrome (MIES), with typical changes and symptoms that are often observed in combination, such as an increase in breathing dead space volume [22,24,58,59], increase in breathing resistance [31,35,60,61], increase in blood carbon dioxide [13,15,17,19,21,22,23,24,25,26,27,28,29,30,35], decrease in blood oxygen saturation [18,19,21,23,28,29,30,31,32,33,34], increase in heart rate [23,29,30,35], increase in blood pressure [25,35], decrease in cardiopulmonary capacity [31], increase in respiratory rate [15,21,23,34,36], shortness of breath and difficulty breathing [15,17,19,21,23,25,29,31,34,35,60,71,85,101,133], headache [19,27,29,37,66,67,68,71,83], dizziness [23,29], feeling hot and clammy [17,22,29,31,35,44,71,85,133], decreased ability to concentrate [29], decreased ability to think [36,37], drowsiness [19,29,32,36,37], decrease in empathy perception [99], impaired skin barrier function [37,72,73] with itching [31,35,67,71,72,73,91,92,93], acne, skin lesions and irritation [37,72,73], overall perceived fatigue and exhaustion [15,19,21,29,31,32,34,35,69] (Figure 2, Figure 3 and Figure 4).

Wearing masks does not consistently cause clinical deviations from the norm of physiological parameters, but according to the scientific literature, a long-term pathological consequence with clinical relevance is to be expected owing to a longer-lasting effect with a subliminal impact and significant shift in the pathological direction. For changes that do not exceed normal values, but are persistently recurring, such as an increase in blood carbon dioxide [38,160], an increase in heart rate [55] or an increase in respiratory rate [56,57], which have been documented while wearing a mask [13,15,17,19,21,22,23,24,25,26,27,28,29,30,34,35] (Figure 2), a long-term generation of high blood pressure [25,35], arteriosclerosis and coronary heart disease and of neurological diseases is scientifically obvious [38,55,56,57,160]. This pathogenetic damage principle with a chronic low-dose exposure with long-term effect, which leads to disease or disease-relevant conditions, has already been extensively studied and described in many areas of environmental medicine [38,46,47,48,49,50,51,52,53,54]. Extended mask-wearing would have the potential, according to the facts and correlations we have found, to cause a chronic sympathetic stress response induced by blood gas modifications and controlled by brain centers. This in turn induces and triggers immune suppression and metabolic syndrome with cardiovascular and neurological diseases.

We not only found evidence in the reviewed mask literature of potential long-term effects, but also evidence of an increase in direct short-term effects with increased mask-wearing time in terms of cumulative effects for: carbon dioxide retention, drowsiness, headache, feeling of exhaustion, skin irritation (redness, itching) and microbiological contamination (germ colonization) [19,22,37,66,68,69,89,91,92].

Overall, the exact frequency of the described symptom constellation MIES in the mask-using populace remains unclear and cannot be estimated due to insufficient data.

Theoretically, the mask-induced effects of the drop in blood gas oxygen and increase in carbon dioxide extend to the cellular level with induction of the transcription factor HIF (hypoxia-induced factor) and increased inflammatory and cancer-promoting effects [160] and can, thus, also have a negative influence on pre-existing clinical pictures.

In any case, the MIES potentially triggered by masks (Figure 3 and Figure 4) contrasts with the WHO definition of health: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [178].

All the scientific facts found in our work expand the knowledge base for a differentiated view of the mask debate. This gain can be relevant for decision makers who have to deal with the issue of mandatory mask use during the pandemic under constant review of proportionality as well as for physicians who can advise their patients more appropriately on this basis. For certain diseases, taking into account the literature found in this study, it is also necessary for the attending physician to weigh up the benefits and risks with regard to a mask obligation. With an overall strictly scientific consideration, a recommendation for mask exemption can become justifiable within the framework of a medical appraisal (Figure 5).

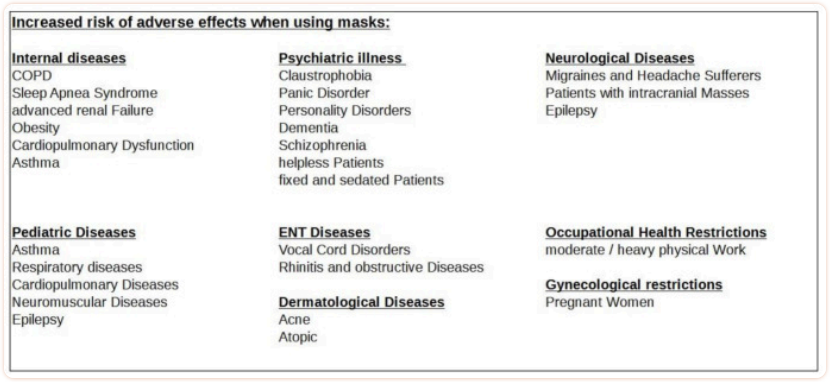


Figure 5

Diseases/predispositions with significant risks, according to the literature found, when using masks. Indications for weighing up medical mask exemption certificates.

In addition to protecting the health of their patients, doctors should also base their actions on the guiding principle of the 1948 Geneva Declaration, as revised in 2017. According to this, every doctor vows to put the health and dignity of his patient first and, even under threat, not to use his medical knowledge to violate human rights and civil liberties [9]. Within the framework of these findings, we, therefore, propagate an explicitly medically judicious, legally compliant action in consideration of scientific factual reality [2,4,5,16,130,132,143,175,176,177] against a predominantly assumption-led claim to a general effectiveness of masks, always taking into account possible unwanted individual effects for the patient and mask wearer concerned, entirely in accordance with the principles of evidence-based medicine and the ethical guidelines of a physician.

The results of the present literature review could help to include mask-wearing in the differential diagnostic pathophysiological cause consideration of every physician when corresponding symptoms are present (MIES, Figure 4). In this way, the physician can draw on an initial complaints catalogue that may be associated with mask-wearing (Figure 2) and also exclude certain diseases from the general mask requirement (Figure 5).

For scientists, the prospect of continued mask use in everyday life suggests areas for further research. In our view, further research is particularly desirable in the gynecological (fetal and embryonic) and pediatric fields, as children are a vulnerable group that would face the longest and, thus, most profound consequences of a potentially risky mask use. Basic research at the cellular level regarding mask-induced triggering of the transcription factor HIF with potential promotion of immunosuppression and carcinogenicity also appears to be useful under this circumstance. Our scoping review shows the need for a systematic review.

The described mask-related changes in respiratory physiology can have an adverse effect on the wearer's blood gases sub-clinically and in some cases also clinically manifest and, therefore, have a negative effect on the basis of all aerobic life, external and internal respiration, with an influence on a wide variety of organ systems and metabolic processes with physical, psychological and social consequences for the individual human being.

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against masks

Brenna Lawrence <brennalaw16@gmail.com>

Sun 3/10/2024 12:07 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I am a student in High School. I hated wearing a mask. I was short of breath and never felt good while wearing it. I would lose my appetite and wouldn't eat during lunch periods. It gave me acne, which I never had before, and it was pretty bad and needed to get a prescription for it. A couple of me my friends left school to be homeschooled because they hated wearing the mask. I don't think it helped anyone. I think it hurt everyone. If you are in the health field you should pay attention to that and be against masking children.

Thank you,
Brenna

Oppose Proposed Masking Regulation 216-RICR-30-30-4

Ana Roque <anaroque980406@yahoo.com>

Sun 3/10/2024 7:58 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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My name is Ana Roque and I reside on 91 Japonica Street Pawtucket.

I am a parent on the lawsuit and I am opposing this regulation due to the frustration of having to speak on this again.

On the regulation section 4.3 part B, it states the following…..
“An absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the Department from considering a face mask requirement.”

1. If not science, what are they following?
2. What is the basis for a regulation if they don’t have to use scientific evidence that something works for a specific pathogen, to be able to consider a face mask requirement?
3. Are there other things that the department of health offers up in terms of solutions or public health advice that don’t have scientific backing?
4. If the departments can have a regulation like this, and specifically say it’s not based on evidence, what else can they make you do? What other type of regulation can they impose on people?

Let me remind you that masks came off our kids in February 2022 due to over 400 people testifying opposing the mask mandate.

Let me also remind you that parents are not going to ignore this any longer.

Our children have a God-given right to breathe freely without restrictions!!!!!

WE THE PARENTS do not Co-Parent with the Government!!!

Be prepared for hours of testimony!!!!!!

Sent from my iPhone

Masking proposed policy

peter lawrence <peterlaw76@hotmail.com>

Sun 3/10/2024 8:47 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;Leclair, Cheryl (RIDOH) <Cheryl.Leclair@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Good Evening,

MY POLICY for my children:

My child will not wear a face mask. I will have the final say on what goes on my child. If there was an infectious disease that would cause severe harm to my children, they would not participate in school with or without a mask.

The actions taken for Covid response at the state and municipal level was an overreach of power and exaggeration of the threat. The social-emotional and academic damage that occurred as a result, has still yet to fully manifest itself.

Please add your medical/health degrees, training, and on the job experience that qualify you to mandate a decree to all children for any reason.

Respectfully,

Peter Lawrence

Unmask our children

Victoria Gaspar <vgaspar@qmail.qcc.edu>

Mon 3/11/2024 7:24 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:concent4RI@hotmail.com <concent4RI@hotmail.com>

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I oppose any further mask mandates in RI. I oppose any further mask mandates on any children.

~Victoria Gaspar

Re: Unmask our children

Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Tue 3/12/2024 8:45 AM
To:Mom Of Many Meals <momofmany87@gmail.com>

Good Morning,

Thank you for submitting your comments. They have been received and will be added to the rulemaking record.

Best,

Zachary J. Garceau (he/him/his)
Chief Program Development
Office: 401-222-7884
Cell: 401-408-2747
Zachary.Garceau@health.ri.gov

From: Mom Of Many Meals <momofmany87@gmail.com>
Sent: Monday, March 11, 2024 7:45 AM
To: Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Subject: Unmask our children

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Report Suspicious

I oppose any further mask mandate for children

No Mask Mandates

Stephanie McGehearty <stephurban42@gmail.com>

Mon 3/11/2024 8:24 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Good morning,

I'm writing to record my written testimony that I am 100% against any mask mandate for our children in Rhode Island. There was plenty of research when these mask mandates were forced upon us that masks were NOT a successful way to stop the transmission of viruses.

Here are 170 other studies that show the same. Please take note of the longitudinal mask study for the flu virus.

https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/ [brownstone.org]

My daughters shut down during mask wearing feeling uncomfortable to speak and unable to fully understand the lessons being taught to them from teachers that they could not hear correctly, see facial expressions or engage with. My daughters will NEVER wear a mask again.

Stephanie McGehearty
2 Carol Ann Ave
Smithfield, Ri

More than 170 Comparative Studies and Articles on Mask Ineffectiveness and Harms

BY  PAUL ELIAS ALEXANDER DECEMBER 20, 2021 MASKS, POLICY, PSYCHOLOGY 72 MINUTE READ

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It is not unreasonable to conclude that surgical and cloth masks, used as they currently are being used (without other forms of PPE protection), have no impact on controlling the transmission of Covid-19 virus. Current evidence implies that face masks can be actually harmful. The body of evidence indicates that face masks are largely ineffective.

My focus is on COVID face masks and the prevailing science that we have had for nearly 20 months. Yet I wish to address this mask topic at a 50,000-foot level on the lockdown restrictive policies in general. I build on the backs of the fine work done by Gupta, Kulldorff, and Bhattacharya on the Great Barrington Declaration (GBD) and similar impetus by Dr. Scott Atlas (advisor to POTUS Trump) who, like myself, was a strong proponent for a focused type of protection that was based on an age-risk stratified approach.

Because we saw very early on that the lockdowns were the single greatest mistake in public health history. We knew the history and knew they would not work. We also knew very early of COVID's risk stratification. Sadly, our children will bear the catastrophic consequences and not just educationally, of the deeply flawed school closure policy for decades to come (particularly our minority children who were least able to afford this). Many are still pressured to wear masks and punished for not doing so.

I present the masking 'body of evidence' below (n=167 studies and pieces of evidence), comprised of comparative effectiveness research as well as related evidence and high-level

reporting. To date, the evidence has been stable and clear that masks do not work to control the virus and they can be harmful and especially to children.

Table 1: The evidence on COVID-19 face masks and mask mandates and harms

MASK-INEFFECTIVENESS	
1) Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers, Bundgaard, 2021	"Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point (95% CI, −1.2 to 0.4 percentage point; P = 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P = 0.33). Multiple imputation accounting for loss to follow-up yielded similar results…the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use."
2) SARS-CoV-2 Transmission among Marine Recruits during Quarantine, Letizia, 2020	"Our study showed that in a group of predominantly young male military recruits, approximately 2% became positive for SARS-CoV-2, as determined by qPCR assay, during a 2-week, strictly enforced quarantine. Multiple, independent virus strain transmission clusters were identified…all recruits wore double-layered cloth masks at all times indoors and outdoors."
3) Physical interventions to interrupt or reduce the spread of respiratory viruses, Jefferson, 2020	"There is low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18. There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants)…the pooled results of randomised trials did not show a clear reduction

	in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."
4) The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh, Abaluck, 2021 Heneghan et al.	A cluster-randomized trial of community-level mask promotion in rural Bangladesh from November 2020 to April 2021 (N=600 villages, N=342,126 adults. Heneghan writes: "In a Bangladesh study, surgical masks reduced symptomatic COVID infections by between 0 and 22 percent, while the efficacy of cloth masks led to somewhere between an 11 percent increase to a 21 percent decrease. Hence, based on these randomized studies, adult masks appear to have either no or limited efficacy."
5) Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review, Liu/CATO, 2021	"The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle."
6) Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures, CDC/Xiao, 2020	"Evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza…none of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group…the overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies."
7) CIDRAP: Masks-for-all for COVID-19 not based on sound data, Brosseau, 2020	"We agree that the data supporting the effectiveness of a cloth mask or face covering are very limited. We do, however, have data from laboratory studies that indicate cloth masks or face coverings offer very low filter collection efficiency for the smaller inhalable particles we believe are largely responsible for

	transmission, particularly from pre- or asymptomatic individuals who are not coughing or sneezing…though we support mask wearing by the general public, we continue to conclude that cloth masks and face coverings are likely to have limited impact on lowering COVID-19 transmission, because they have minimal ability to prevent the emission of small particles, offer limited personal protection with respect to small particle inhalation, and should not be recommended as a replacement for physical distancing or reducing time in enclosed spaces with many potentially infectious people."
8) Universal Masking in Hospitals in the Covid-19 Era, Klompas/NEJM, 2020	"We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic…The calculus may be different, however, in health care settings. First and foremost, a mask is a core component of the personal protective equipment (PPE) clinicians need when caring for symptomatic patients with respiratory viral infections, in conjunction with gown, gloves, and eye protection…universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."

9) Masks for prevention of viral respiratory infections among health care workers and the public: PEER umbrella systematic review, Dugré, 2020	"This systematic review found limited evidence that the use of masks might reduce the risk of viral respiratory infections. In the community setting, a possible reduced risk of influenza-like illness was found among mask users. In health care workers, the results show no difference between N95 masks and surgical masks on the risk of confirmed influenza or other confirmed viral respiratory infections, although possible benefits from N95 masks were found for preventing influenza-like illness or other clinical respiratory infections. Surgical masks might be superior to cloth masks but data are limited to 1 trial."
10) Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis, Saunders-Hastings, 2017	"Facemask use provided a non-significant protective effect (OR = 0.53; 95% CI 0.16–1.71; I^2 = 48%) against 2009 pandemic influenza infection."
11) Experimental investigation of indoor aerosol dispersion and accumulation in the context of COVID-19: Effects of masks and ventilation, Shah, 2021	"Nevertheless, high-efficiency masks, such as the KN95, still offer substantially higher apparent filtration efficiencies (60% and 46% for R95 and KN95 masks, respectively) than the more commonly used cloth (10%) and surgical masks (12%), and therefore are still the recommended choice in mitigating airborne disease transmission indoors."
12) Exercise with facemask; Are we handling a devil's sword?- A physiological hypothesis, Chandrasekaran, 2020	"Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus."
13) Surgical face masks in modern operating rooms–a costly and unnecessary ritual?,	"Following the commissioning of a new suite of operating rooms air movement studies showed a flow of air away from the

Mitchell, 1991	operating table towards the periphery of the room. Oral microbial flora dispersed by unmasked male and female volunteers standing one metre from the table failed to contaminate exposed settle plates placed on the table. The wearing of face masks by non-scrubbed staff working in an operating room with forced ventilation seems to be unnecessary."
14) Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial, Alfelali, 2020	"By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections (odds ratio [OR], 1.4; 95% confidence interval [CI], 0.9 to 2.1, p = 0.18) nor against clinical respiratory infection (OR, 1.1; 95% CI, 0.9 to 1.4, p = 0.40)."
15) Simple respiratory protection–evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles, Rengasamy, 2010	"Results obtained in the study show that common fabric materials may provide marginal protection against nanoparticles including those in the size ranges of virus-containing particles in exhaled breath."
16) Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range, Lee, 2008	"The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses. An exhalation valve on the N95 respirator does not affect the respiratory protection; it appears to be an appropriate alternative to reduce the breathing resistance."
17) Aerosol penetration and leakage characteristics of masks used in the health care industry, Weber, 1993	"We conclude that the protection provided by surgical masks may be insufficient in environments containing potentially hazardous sub-micrometer-sized aerosols."
18) Disposable surgical face masks for preventing surgical wound infection in clean surgery, Vincent, 2016	"We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials… from the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery."

19) Disposable surgical face masks: a systematic review, Lipp, 2005	“From the limited results it is unclear whether wearing surgical face masks results in any harm or benefit to the patient undergoing clean surgery.”
20) Comparison of the Filter Efficiency of Medical Nonwoven Fabrics against Three Different Microbe Aerosols, Shimasaki , 2018	“We conclude that the filter efficiency test using the phi-X174 phage aerosol may overestimate the protective performance of nonwoven fabrics with filter structure compared to that against real pathogens such as the influenza virus.”
21) The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence21) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2012	The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence“None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.”
22) Facial protection for healthcare workers during pandemics: a scoping review, Godoy, 2020	“Compared with surgical masks, N95 respirators perform better in laboratory testing, may provide superior protection in inpatient settings and perform equivalently in outpatient settings. Surgical mask and N95 respirator conservation strategies include extended use, reuse or decontamination, but these strategies may result in inferior protection. Limited evidence suggests that reused and improvised masks should be used when medical-grade protection is unavailable.”
23) Assessment of Proficiency of N95 Mask Donning Among the General Public in Singapore, Yeung, 2020	“These findings support ongoing recommendations against the use of N95 masks by the general public during the COVID-19 pandemic.[5] N95 mask use by the general public may not translate into effective protection but instead provide false reassurance. Beyond N95 masks, proficiency among the general public in donning surgical masks needs to be assessed.”

24) Evaluating the efficacy of cloth facemasks in reducing particulate matter exposure, Shakya, 2017	“Standard N95 mask performance was used as a control to compare the results with cloth masks, and our results suggest that cloth masks are only marginally beneficial in protecting individuals from particles<2.5 µm.”
25) Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial, Jacobs, 2009	“Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds.”
26) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	“Among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza.”
27) Does Universal Mask Wearing Decrease or Increase the Spread of COVID-19?, Watts up with that? 2020	“A survey of peer-reviewed studies shows that universal mask wearing (as opposed to wearing masks in specific settings) does not decrease the transmission of respiratory viruses from people wearing masks to people who are not wearing masks.”
28) Masking: A Careful Review of the Evidence, Alexander, 2021	“In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, have absolutely no impact on controlling the transmission of Covid-19 virus, and current evidence implies that face masks can be actually harmful.”
29) Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020, Fisher, 2020	Reported characteristics of symptomatic adults ≥18 years who were outpatients in 11 US academic health care facilities and who received positive and negative SARS-CoV-2 test results (N = 314)* — United States, July 1–29, 2020, revealed that 80% of infected persons wore face masks almost all or most of the time.
30) Impact of non-pharmaceutical interventions against COVID-19 in Europe: a quasi-experimental study, Hunter, 2020	Face masks in public was not associated with reduced incidence.

31) Masking lack of evidence with politics, CEBM, Heneghan, 2020	"It would appear that despite two decades of pandemic preparedness, there is considerable uncertainty as to the value of wearing masks. For instance, high rates of infection with cloth masks could be due to harms caused by cloth masks, or benefits of medical masks. The numerous systematic reviews that have been recently published all include the same evidence base so unsurprisingly broadly reach the same conclusions."
32) Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study, Marks, 2021	"We observed no association of risk of transmission with reported mask usage by contacts, with the age or sex of the index case, or with the presence of respiratory symptoms in the index case at the initial study visit."
33) Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza, WHO, 2020	"Ten RCTs were included in the meta-analysis, and there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza."
34) The Strangely Unscientific Masking of America, Younes, 2020	"One report reached its conclusion based on observations of a "dummy head attached to a breathing simulator." Another analyzed use of surgical masks on people experiencing at least two symptoms of acute respiratory illness. Incidentally, not one of these studies involved cloth masks or accounted for real-world mask usage (or misusage) among lay people, and none established efficacy of widespread mask-wearing by people not exhibiting symptoms. There was simply no evidence whatsoever that healthy people ought to wear masks when going about their lives, especially outdoors."
35) Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review, Brainard, 2020	"31 eligible studies (including 12 RCTs). Narrative synthesis and random-effects meta-analysis of attack rates for primary and secondary prevention in 28 studies were performed. Based on the RCTs we would conclude that wearing facemasks can be very slightly protective against primary infection from casual community contact, and modestly protective against household

	infections when both infected and uninfected members wear facemasks. However, the RCTs often suffered from poor compliance and controls using facemasks."
36) The Year of Disguises, Koops, 2020	"The healthy people in our society should not be punished for being healthy, which is exactly what lockdowns, distancing, mask mandates, etc. do…Children should not be wearing face coverings. We all need constant interaction with our environments and that is especially true for children. This is how their immune system develops. They are the lowest of the low-risk groups. Let them be kids and let them develop their immune systems… The "Mask Mandate" idea is a truly ridiculous, knee-jerk reaction and needs to be withdrawn and thrown in the waste bin of disastrous policy, along with lockdowns and school closures. You can vote for a person without blindly supporting all of their proposals!"
37) Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden, Ludvigsson, 2020	"1,951,905 children in Sweden (as of December 31, 2019) who were 1 to 16 years of age, were examined…social distancing was encouraged in Sweden, but wearing face masks was not…No child with Covid-19 died."
38) Double-Masking Benefits Are Limited, Japan Supercomputer Finds, Reidy, 2021	"Wearing two masks offers limited benefits in preventing the spread of droplets that could carry the coronavirus compared to one well-fitted disposable mask, according to a Japanese study that modeled the dispersal of droplets on a supercomputer."
39) Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 – Face masks, eye protection and person distancing: systematic review and meta-analysis, Jefferson, 2020	"There was insufficient evidence to provide a recommendation on the use of facial barriers without other measures. We found insufficient evidence for a difference between surgical masks and N95 respirators and limited evidence to support effectiveness of quarantine."
40) Should individuals in the community without respiratory symptoms wear facemasks to reduce the spread of COVID-19?, NIPH, 2020	"Non-medical facemasks include a variety of products. There is no reliable evidence of the effectiveness of non-medical facemasks in community settings. There is likely to be substantial variation in effectiveness between products. However, there is only limited

	evidence from laboratory studies of potential differences in effectiveness when different products are used in the community."
41) Is a mask necessary in the operating theatre?, Orr, 1981	"It would appear that minimum contamination can best be achieved by not wearing a mask at all but operating in silence. Whatever its relation to contamination, bacterial counts, or the dissemination of squames, there is no direct evidence that the wearing of masks reduces wound infection."
42) The surgical mask is a bad fit for risk reduction, Neilson, 2016	"As recently as 2010, the US National Academy of Sciences declared that, in the community setting, "face masks are not designed or certified to protect the wearer from exposure to respiratory hazards." A number of studies have shown the inefficacy of the surgical mask in household settings to prevent transmission of the influenza virus."
43) Facemask versus No Facemask in Preventing Viral Respiratory Infections During Hajj: A Cluster Randomised Open Label Trial, Alfelali, 2019	"Facemask use does not prevent clinical or laboratory-confirmed viral respiratory infections among Hajj pilgrims."
44) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	"The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression."

45) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2011	"None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene."
46) Are Face Masks Effective? The Evidence., Swiss Policy Research, 2021	"Most studies found little to no evidence for the effectiveness of face masks in the general population, neither as personal protective equipment nor as a source control."
47) Postoperative wound infections and surgical face masks: A controlled study, Tunevall, 1991	"These results indicate that the use of face masks might be reconsidered. Masks may be used to protect the operating team from drops of infected blood and from airborne infections, but have not been proven to protect the patient operated by a healthy operating team."
48) Mask mandate and use efficacy in state-level COVID-19 containment, Guerra, 2021	"Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID-19 growth surges."
49) Twenty Reasons Mandatory Face Masks are Unsafe, Ineffective and Immoral, Manley, 2021	"A CDC-funded review on masking in May 2020 came to the conclusion: "Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza… None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group." If masks can't stop the regular flu, how can they stop SAR-CoV-2?"
50) A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, MacIntyre, 2015	"First RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection…the rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to

	100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%."
51) Horowitz: Data from India continues to blow up the 'Delta' fear narrative, Blazemedia, 2021	"Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the "Delta" variant — continues to refute every current premise of COVID fascism…Masks failed to stop the spread there."
52) An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021, Hetemäki, 2021	Reporting on a nosocomial hospital outbreak in Finland, Hetemäli et al. observed that "both symptomatic and asymptomatic infections were found among vaccinated health care workers, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment."
53) Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021, Shitrit, 2021	In a hospital outbreak investigation in Israel, Shitrit et al. observed "high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals." They added that "this suggests some waning of immunity, albeit still providing protection for individuals without comorbidities." Again, despite use of personal protective equipment.
54) 47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects, Lifesite news staff, 2021	"No studies were needed to justify this practice since most understood viruses were far too small to be stopped by the wearing of most masks, other than sophisticated ones designed for that task and which were too costly and complicated for the general public to properly wear and keep changing or cleaning. It was also understood that long mask wearing was unhealthy for wearers for common sense and basic science reasons."
55) Are EUA Face Masks Effective in Slowing the Spread of a Viral Infection?, Dopp, 2021	The vast evidence shows that masks are ineffective.

56) CDC Study finds overwhelming majority of people getting coronavirus wore masks, Boyd/Federalist, 2021	"A Centers for Disease Control report released in September shows that masks and face coverings are not effective in preventing the spread of COVID-19, even for those people who consistently wear them."
57) Most Mask Studies Are Garbage, Eugyppius, 2021	"The other kind of study, the proper kind, would be a randomised controlled trial. You compare the rates of infection in a masked cohort against rates of infection in an unmasked cohort. Here things have gone much, much worse for mask brigade. They spent months trying to prevent the publication of the Danish randomised controlled trial, which found that masks do zero. When that paper finally squeaked into print, they spent more months trying desperately to poke holes in it. You could feel their boundless relief when the Bangladesh study finally appeared to save them in early September. Every last Twitter blue-check could now proclaim that Science Shows Masks Work. Such was their hunger for any scrap of evidence to prop up their prior convictions, that none of them noticed the sad nature of the Science in question. The study found a mere 10% reduction in seroprevalence among the masked cohort, an effect so small that it fell within the confidence interval. Even the study authors couldn't exclude the possibility that masks in fact do zero."
58) Using face masks in the community: first update, ECDC, 2021	"No high-quality evidence in favor of face masks and recommended their use only based on the 'precautionary principle."
59) Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?, Cochrane, 2020	"Seven studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask, wearing a mask may make little to no difference in how many people caught a flu-like illness (9 studies; 3507 people); and probably makes no difference in how many people have flu confirmed by a laboratory test (6 studies; 3005 people). Unwanted effects were rarely reported, but included discomfort."

60) Mouth-nose protection in public: No evidence of effectiveness, Thieme/ Kappstein, 2020	“The use of masks in public spaces is questionable simply because of the lack of scientific data. If one also considers the necessary precautions, masks must even be considered a risk of infection in public spaces according to the rules known from hospitals… If masks are worn by the population, the risk of infection is potentially increased, regardless of whether they are medical masks or whether they are so-called community masks designed in any way. If one considers the precautionary measures that the RKI as well as the international health authorities have pronounced, all authorities would even have to inform the population that masks should not be worn in public spaces at all. Because no matter whether it is a duty for all citizens or voluntarily borne by the citizens who want it for whatever reason, it remains a fact that masks can do more harm than good in public.”
61) US mask guidance for kids is the strictest across the world, Skelding, 2021	“Kids need to see faces,” Jay Bhattacharya, a professor of medicine at Stanford University, told The Post. Youngsters watch people’s mouths to learn to speak, read and understand emotions, he said.“We have this idea that this disease is so bad that we must adopt any means necessary to stop it from spreading,” he said. “It’s not that masks in schools have no costs. They actually do have substantial costs.”
62) Masking young children in school harms language acquisition, Walsh, 2021	“This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development.”
63) The Case Against Masks for Children, Makary, 2021	“It’s abusive to force kids who struggle with them to sacrifice for the sake of unvaccinated adults… Do masks reduce Covid transmission in children? Believe it or not, we could find only a

	single retrospective study on the question, and its results were inconclusive. Yet two weeks ago the Centers for Disease Control and Prevention sternly decreed that 56 million U.S. children and adolescents, vaccinated or not, should cover their faces regardless of the prevalence of infection in their community. Authorities in many places took the cue to impose mandates in schools and elsewhere, on the theory that masks can't do any harm. That isn't true. Some children are fine wearing a mask, but others struggle. Those who have myopia can have difficulty seeing because the mask fogs their glasses. (This has long been a problem for medical students in the operating room.) Masks can cause severe acne and other skin problems. The discomfort of a mask distracts some children from learning. By increasing airway resistance during exhalation, masks can lead to increased levels of carbon dioxide in the blood. And masks can be vectors for pathogens if they become moist or are used for too long."
64) Face Covering Mandates, Peavey, 2021	"Face Covering Mandates And Why They AREN'T Effective."
65) Do masks work? A Review of the evidence, Anderson, 2021	"In truth, the CDC's, U.K.'s, and WHO's earlier guidance was much more consistent with the best medical research on masks' effectiveness in preventing the spread of viruses. That research suggests that Americans' many months of mask-wearing has likely provided little to no health benefit and might even have been counterproductive in preventing the spread of the novel coronavirus."
66) Most face masks won't stop COVID-19 indoors, study warns, Anderer, 2021	"New research reveals that cloth masks filter just 10% of exhaled aerosols, with many people not wearing coverings that fit their face properly."
67) How face masks and lockdowns failed/the face mask folly in retrospect, Swiss Policy Research, 2021	"Mask mandates and lockdowns have had no discernible impact."

68) CDC Releases School COVID Transmission Study But Buries One of the Most Damning Parts, Davis, 2021	"The 21% lower incidence in schools that required mask use among students was not statistically significant compared with schools where mask use was optional… With tens of millions of American kids headed back to school in the fall, their parents and political leaders owe it to them to have a clear-sighted, scientifically rigorous discussion about which anti-COVID measures actually work and which might put an extra burden on vulnerable young people without meaningfully or demonstrably slowing the spread of the virus…that a masking requirement of students failed to show independent benefit is a finding of consequence and great interest."
69) World Health Organization internal meeting, COVID-19 – virtual press conference – 30 March 2020, 2020	"This is a question on Austria. The Austrian Government has a desire to make everyone wear a mask who's going into the shops. I understood from our previous briefings with you that the general public should not wear masks because they are in short supply. What do you say about the new Austrian measures?… I'm not specifically aware of that measure in Austria. I would assume that it's aimed at people who potentially have the disease not passing it to others. In general WHO recommends that the wearing of a mask by a member of the public is to prevent that individual giving the disease to somebody else. We don't generally recommend the wearing to masks in public by otherwise well individuals because it has not been up to now associated with any particular benefit."
70) Face masks to prevent transmission of influenza virus: a systematic review, Cowling, 2010	"Review highlights the limited evidence base supporting the efficacy or effectiveness of face masks to reduce influenza virus transmission.""None of the studies reviewed showed a benefit from wearing a mask, in either HCW or community members in households (H)."
71) Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a	"Although N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings, our meta-analysis showed that there were insufficient data to determine

systematic review and meta-analysis, Smith, 2016	definitively whether N95 respirators are superior to surgical masks in protecting health care workers against transmissible acute respiratory infections in clinical settings."
72) Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis, Offeddu, 2017	"We found evidence to support universal medical mask use in hospital settings as part of infection control measures to reduce the risk of CRI and ILI among HCWs. Overall, N95 respirators may convey greater protection, but universal use throughout a work shift is likely to be less acceptable due to greater discomfort…Our analysis confirms the effectiveness of medical masks and respirators against SARS. Disposable, cotton, or paper masks are not recommended. The confirmed effectiveness of medical masks is crucially important for lower-resource and emergency settings lacking access to N95 respirators. In such cases, single-use medical masks are preferable to cloth masks, for which there is no evidence of protection and which might facilitate transmission of pathogens when used repeatedly without adequate sterilization… We found no clear benefit of either medical masks or N95 respirators against pH1N1…Overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power."
73) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	"Use of N95 respirators, compared with medical masks, in the outpatient setting resulted in no significant difference in the rates of laboratory-confirmed influenza."
Effectiveness of N95 respirators versus surgical masks againstinfluenza: A systematic review and meta-analysis74) Masks Don't Work: A Review of Science Relevant to COVID-19 Social Policy, Rancourt, 2020	The use of N95 respirators compared with surgical masks is not associated with alower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be rec-ommended for general public and nonhigh-risk medical staff those are not in close contact withinfluenza patients or suspected patients. "No RCT study with verified outcome shows a benefit for HCW or community members in households to wearing a mask or respirator. There is no such study. There are no exceptions.

	Likewise, no study exists that shows a benefit from a broad policy to wear masks in public (more on this below). Furthermore, if there were any benefit to wearing a mask, because of the blocking power against droplets and aerosol particles, then there should be more benefit from wearing a respirator (N95) compared to a surgical mask, yet several large meta-analyses, and all the RCT, prove that there is no such relative benefit."
75) More Than a Dozen Credible Medical Studies Prove Face Masks Do Not Work Even In Hospitals!, Firstenberg, 2020	"Mandating masks has not kept death rates down anywhere. The 20 U.S. states that have never ordered people to wear face masks indoors and out have dramatically lower COVID-19 death rates than the 30 states that have mandated masks. Most of the no-mask states have COVID-19 death rates below 20 per 100,000 population, and none have a death rate higher than 55. All 13 states that have death rates higher 55 are states that have required the wearing of masks in all public places. It has not protected them."
76) Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery?, Bahli, 2009	"From the limited randomized trials it is still not clear that whether wearing surgical face masks harms or benefit the patients undergoing elective surgery."
77) Peritonitis prevention in CAPD: to mask or not?, Figueiredo, 2000	"The current study suggests that routine use of face masks during CAPD bag exchanges may be unnecessary and could be discontinued."
78) The operating room environment as affected by people and the surgical face mask, Ritter, 1975	"The wearing of a surgical face mask had no effect upon the overall operating room environmental contamination and probably work only to redirect the projectile effect of talking and breathing. People are the major source of environmental contamination in the operating room."
79) The efficacy of standard surgical face masks: an investigation using "tracer particles, Ha'eri, 1980	"Particle contamination of the wound was demonstrated in all experiments. Since the microspheres were not identified on the

	exterior of these face masks, they must have escaped around the mask edges and found their way into the wound."
80) Wearing of caps and masks not necessary during cardiac catheterization, Laslett, 1989	"Prospectively evaluated the experience of 504 patients undergoing percutaneous left heart catheterization, seeking evidence of a relationship between whether caps and/or masks were worn by the operators and the incidence of infection. No infections were found in any patient, regardless of whether a cap or mask was used. Thus, we found no evidence that caps or masks need to be worn during percutaneous cardiac catheterization."
81) Do anaesthetists need to wear surgical masks in the operating theatre? A literature review with evidence-based recommendations, Skinner, 2001	"A questionnaire-based survey, undertaken by Leyland' in 1993 to assess attitudes to the use of masks, showed that 20% of surgeons discarded surgical masks for endoscopic work. Less than 50% did not wear the mask as recommended by the Medical Research Council. Equal numbers of surgeons wore the mask in the belief they were protecting themselves and the patient, with 20% of these admitting that tradition was the only reason for wearing them."
82) Mask mandates for children are not backed by data, Faria, 2021	"Even if you want to use the 2018-19 flu season to avoid overlap with the start of the COVID-19 pandemic, the CDC paints a similar picture: It estimated 480 flu deaths among children during that period, with 46,000 hospitalizations. COVID-19, mercifully, is simply not as deadly for children. According to the American Academy of Pediatrics, preliminary data from 45 states show that between 0.00%-0.03% of child COVID-19 cases resulted in death. When you combine these numbers with the CDC study that found mask mandates for students — along with hybrid models, social distancing, and classroom barriers — did not have a statistically significant benefit in preventing the spread of COVID-19 in schools, the insistence that we force students to jump through these hoops for their own protection makes no sense."

83) The Downsides of Masking Young Students Are Real, Prasad, 2021	"The benefits of mask requirements in schools might seem self-evident—they have to help contain the coronavirus, right?—but that may not be so. In Spain, masks are used in kids ages 6 and older. The authors of one study there examined the risk of viral spread at all ages. If masks provided a large benefit, then the transmission rate among 5-year-olds would be far higher than the rate among 6-year-olds. The results don't show that. Instead, they show that transmission rates, which were low among the youngest kids, steadily increased with age—rather than dropping sharply for older children subject to the face-covering requirement. This suggests that masking kids in school does not provide a major benefit and might provide none at all. And yet many officials prefer to double down on masking mandates, as if the fundamental policy were sound and only the people have failed."
84) Masks In Schools: Scientific American Fumbles Report On Childhood COVID Transmission, English/ACSH, 2021	"Masking is a low-risk, inexpensive intervention. If we want to recommend it as a precautionary measure, especially in situations where vaccination isn't an option, great. But that's not what the public has been told. "Florida governor Ron DeSantis and politicians in Texas say research does not support mask mandates," SciAm's sub-headline bellowed. "Many studies show they are wrong."If that's the case, demonstrate that the intervention works before you mandate its use in schools. If you can't, acknowledged what UC San Francisco hematologist-oncologist and Associate Professor of Epidemiology Vinay Prasad wrote over at the Atlantic:"No scientific consensus exists about the wisdom of mandatory-masking rules for schoolchildren … In mid-March 2020, few could argue against erring on the side of caution. But nearly 18 months later, we owe it to children and their parents to answer the question properly: Do the benefits of masking kids in school outweigh the downsides? The honest answer in 2021 remains that we don't know for sure."

85) Masks 'don't work,' are damaging health and are being used to control population: Doctors panel, Haynes, 2021	"The only randomized control studies that have ever been done on masks show that they don't work," began Dr. Nepute. He referred to Dr. Anthony Fauci's "noble lie," in which Fauci "changed his tune," from his March 2020 comments, where he downplayed the need and efficacy of mask wearing, before urging Americans to use masks later in the year. "Well, he lied to us. So if he lied about that, what else has he lied to you about?" questioned Nepute.Masks have become commonplace in almost every setting, whether indoors or outdoors, but Dr. Popper mentioned how there have been "no studies" which actually examine the "effect of wearing a mask during all your waking hours.""There's no science to back any of this and particularly no science to back the fact that wearing a mask twenty four-seven or every waking minute, is health promoting," added Popper."
86) Aerosol penetration through surgical masks, Chen, 1992	"The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the sub-micrometer-sized aerosols containing pathogens to which these health care workers are potentially exposed."
87) CDC: Schools With Mask Mandates Didn't See Statistically Significant Different Rates of COVID Transmission From Schools With Optional Policies, Miltimore, 2021	"The CDC did not include its finding that "required mask use among students was not statistically significant compared with schools where mask use was optional" in the summary of its report."
88) Horowitz: Data from India continues to blow up the 'Delta' fear narrative, Howorwitz, 2021	"Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the "Delta" variant — continues to refute every current premise of COVID fascism…Unless we do that, we must return to the very effective lockdowns and masks. In reality, India's experience proves the opposite true; namely:1) Delta is largely an attenuated

	version, with a much lower fatality rate, that for most people is akin to a cold.2) Masks failed to stop the spread there.3) The country has come close to the herd immunity threshold with just 3% vaccinated.
89) Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam, Chau, 2021	While not definitive in the LANCET publication, it can be inferred that the nurses were all masked up and had PPE etc. as was the case in Finland and Israel nosocomial outbreaks, indicating the failure of PPE and masks to constrain Delta spread.
90) Aerosol penetration through surgical masks, Willeke, 1992	“The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the submicrometer-size aerosols containing pathogens to which these health care workers are potentially exposed.”
91) The efficacy of standard surgical face masks: an investigation using “tracer particles”, Wiley, 1980	“Particle contamination of the wound was demonstrated in all aexperiments. Since the microspheres were not identified on the exterior of these face masks, they must have escped around the mask edges and found their way into the wound. The wearing of the mask beneath the headgear curtails this route of contamination.”
92) An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful, Meehan, 2020	“Decades of the highest-level scientific evidence (meta-analyses of multiple randomized controlled trials) overwhelmingly conclude that medical masks are ineffective at preventing the transmission of respiratory viruses, including SAR-CoV-2…those arguing for masks are relying on low-level evidence (observational retrospective trials and mechanistic theories), none of which are powered to counter the evidence, arguments, and risks of mask mandates.”

93) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	“Oral masks in healthy individuals are ineffective against the spread of viral infections.”
94) Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis, Long, 2020	“The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and nonhigh-risk medical staff those are not in close contact with influenza patients or suspected patients.”
95) Advice on the use of masks in the context of COVID-19, WHO, 2020	“However, the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses.”
96) Farce mask: it’s safe for only 20 minutes, The Sydney Morning Herald, 2003	“Health authorities have warned that surgical masks may not be an effective protection against the virus.”Those masks are only effective so long as they are dry,” said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney.”As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets.”Professor Cossart said that could take as little as 15 or 20 minutes, after which the mask would need to be changed. But those warnings haven’t stopped people snapping up the masks, with retailers reporting they are having trouble keeping up with demand.”
97) Study: Wearing A Used Mask Is Potentially Riskier Than No Mask At All, Boyd, 2020 Effects of mask-wearing on the inhalability and deposition of airborne SARS-CoV-2 aerosols in human upper airway	“According to researchers from the University of Massachusetts Lowell and California Baptist University, a three-layer surgical mask is 65 percent efficient in filtering particles in the air. That effectiveness, however, falls to 25 percent once it is used.“It is natural to think that wearing a mask, no matter new or old, should always be better than nothing,” said author Jinxiang Xi.“Our results show that this belief is only true for particles larger than 5

	micrometers, but not for fine particles smaller than 2.5 micrometers," he continued."
98) Unravelling the Role of the Mandatory Use of Face Covering Masks for the Control of SARS-CoV-2 in Schools: A Quasi-Experimental Study Nested in a Population-Based Cohort in Catalonia (Spain), Coma, 2022	"A recent study (Catalonia, Spain) done on face masks and their effectiveness was a retrospective population-based study among near 600,000 children aged 3 to 11 years attending preschool (3-5 years, without facial covering mandate) and primary education (6-11 years, with facial covering mandate); to assess the incidence of SARS-CoV-2, secondary attack rates (SAR) and the effective reproductive number (R*) for each grade during the first trimester of the 2021-2022 academic year, including an analysis of the differences between 5-year-old, without facial covering mandate, and 6 year-old children, with mandate. Researchers found that "the SARS-CoV-2 incidence was significantly lower in preschool than in primary education, and an age-dependent trend was observed. Children aged 3 and 4 showed lower outcomes for all the analyzed epidemiological variables, while children aged 11 had the higher values. Six-year-old children showed higher incidence than 5 year-olds (3·54% vs 3·1%; OR: 1·15 [95%CI: 1·08-1·22]) and slightly lower but not statistically significant SAR and R*: SAR were 4·36% in 6 year-old children, and 4·59% in 5 year-old (IRR: 0·96 [95%CI: 0·82-1·11]); and R* was 0·9 and 0·93 (OR: 0·96 [95%CI: 0·87-1·09]), respectively." Overall, facial covering mandates (face masks) in examined schools were not linked to lower SARS-CoV-2 incidence or spread, implying that these masks were not effective."
99) Correlation Between Mask Compliance and COVID-19 Outcomes in Europe, Spira, 2022	"The aim of this short study was to analyse the correlation between mask usage against morbidity and mortality rates in the 2020-2021 winter in Europe. Data from 35 European countries on morbidity, mortality, and mask usage during a six-month period were analysed and crossed. Mask usage was more homogeneous in Eastern Europe than in Western European countries. Spearman's correlation coefficients between mask usage and COVID-19 outcomes were either null or positive, depending on the

	subgroup of countries and type of outcome (cases or deaths). Positive correlations were stronger in Western than in Eastern European countries. These findings indicate that countries with high levels of mask compliance did not perform better than those with low mask usage."
100) The Foegen effect A mechanism by which facemasks contribute to the COVID-19 case fatality rate, Fögen, 2022	"The most important finding from this study is that contrary to the accepted thought that fewer people are dying because infection rates are reduced by masks, this was not the case. Results from this study strongly suggest that mask mandates actually caused about 1.5 times the number of deaths or ~50% more deaths compared to no mask mandates. This means that the risk for the individual wearing the mask should even be higher, because there is an unknown number of people in MMC who either do not obey mask mandates, are exempted for medical reasons or do not go to public places where mask mandates are in effect. These people do not have an increased risk and thus the risk on the other people under a mask mandate is actually higher."
101) Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota, Sood & Høeg, 2022	Unique study "of two adjacent K-12 school districts in Fargo, North Dakota, one which had a mask mandate and one which did not in the fall of the 2021-2022 academic year. In the winter, both districts adopted a masks-optional policy allowing for a partial crossover study design. We observed no significant difference between student case rates while the districts had differing masking policies (IRR 0.99; 95% CI: 0.92 to 1.07) nor while they had the same mask policies (IRR 1.04; 95% CI: 0.92 to 1.16). The IRRs across the two periods were also not significantly different (p = 0.40)." Researchers concluded that school-based mask mandates have "limited to no impact on the case rates of COVID-19 among K-12 students."
102) Medical Masks Versus N95 Respirators for Preventing COVID-19 Among Health Care Workers, Loeb, 2022	Researchers found that both the surgical masks and the N95 fitted COVID masks do not stop infection as in both trial arms (non-inferiority multi-center trial), participants got infected; moreover,

	there was no difference between the surgical masks and the N95 fitted masks in terms of stopping infection. “In the intention-to-treat analysis, RT-PCR–confirmed COVID-19 occurred in 52 of 497 (10.46%) participants in the medical mask group versus 47 of 507 (9.27%) in the N95 respirator group (hazard ratio [HR], 1.14 [95% CI, 0.77 to 1.69]). There were 47 (10.8%) adverse events related to the intervention reported in the medical mask group and 59 (13.6%) in the N95 respirator group.”
103) Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort, Chandra, 2022	“Successfully replicated the original result using 565 counties; non-masking counties had around 30 additional daily cases per 100,000 children after two weeks of schools reopening. However, after nine weeks, cases per 100,000 were 18.3 in counties with mandates compared to 15.8 in those without them ($p = 0.12$). In a larger sample of 1832 counties, between weeks 2 and 9, cases per 100,000 fell by 38.2 and 37.9 in counties with and without mask requirements, respectively ($p = 0.93$). The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are prone to multiple biases and provide insufficient evidence for recommending mask mandates.”
104) Physical interventions to interrupt or reduce the spread of respiratory viruses (Review), Jefferson, 2023	Ten studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask in the community studies only, wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (9 studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (6 studies; 13,919 people). Unwanted effects were rarely reported; discomfort was mentioned. **N95/P2 respirators** Four studies were in healthcare workers, and one small study was in the community. Compared with wearing medical or surgical masks, wearing N95/P2 respirators probably makes little to no

	difference in how many people have confirmed flu (5 studies; 8407 people); and may make little to no difference in how many people catch a flu-like illness (5 studies; 8407 people), or respiratory illness (3 studies; 7799 people). Unwanted effects were not well-reported; discomfort was mentioned.
MASK MANDATES	
1) Mask mandate and use efficacy for COVID-19 containment in US States, Guerra, 2021	"Calculated total COVID-19 case growth and mask use for the continental United States with data from the Centers for Disease Control and Prevention and Institute for Health Metrics and Evaluation. We estimated post-mask mandate case growth in non-mandate states using median issuance dates of neighboring states with mandates…did not observe association between mask mandates or use and reduced COVID-19 spread in US states."
2) These 12 Graphs Show Mask Mandates Do Nothing To Stop COVID, Weiss, 2020	"Masks can work well when they're fully sealed, properly fitted, changed often, and have a filter designed for virus-sized particles. This represents none of the common masks available on the consumer market, making universal masking much more of a confidence trick than a medical solution…Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated. The narrative says that if cases go down it's because masks succeeded. It says that if cases go up it's because masks succeeded in preventing more cases. The narrative simply assumes rather than proves that masks work, despite overwhelming scientific evidence to the contrary."
3) Mask Mandates Seem to Make CCP Virus Infection Rates Climb, Study Says, Vadum, 2020	"Protective-mask mandates aimed at combating the spread of the CCP virus that causes the disease COVID-19 appear to promote its spread, according to a report from RationalGround.com, a clearinghouse of COVID-19 data trends that's run by a grassroots group of data analysts, computer scientists, and actuaries."

4) Horowitz: Comprehensive analysis of 50 states shows greater spread with mask mandates, Howorwitz, 2020 Justin Hart	"How long do our politicians get to ignore the results?… The results: When comparing states with mandates vs. those without, or periods of times within a state with a mandate vs. without, there is absolutely no evidence the mask mandate worked to slow the spread one iota. In total, in the states that had a mandate in effect, there were 9,605,256 confirmed COVID cases over 5,907 total days, an average of 27 cases per 100,000 per day. When states did not have a statewide order (which includes the states that never had them and the period of time masking states did not have the mandate in place) there were 5,781,716 cases over 5,772 total days, averaging 17 cases per 100,000 people per day."
5) The CDC's Mask Mandate Study: Debunked, Alexander, 2021	"Thus, it is not surprising that the CDC's own recent conclusion on the use of nonpharmaceutical measures such as face masks in pandemic influenza, warned that scientific "evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission…" Moreover, in the WHO's 2019 guidance document on nonpharmaceutical public health measures in a pandemic, they reported as to face masks that "there is no evidence that this is effective in reducing transmission…" Similarly, in the fine print to a recent double-blind, double-masking simulation the CDC stated that "The findings of these simulations [supporting mask usage] should neither be generalized to the effectiveness …nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings."
6) Phil Kerpin, tweet, 2021 The Spectator	"The first ecological study of state mask mandates and use to include winter data: "Case growth was independent of mandates at low and high rates of community spread, and mask use did not predict case growth during the Summer or Fall-Winter waves."
7) How face masks and lockdowns failed, SPR, 2021	"Infections have been driven primarily by seasonal and endemic factors, whereas mask mandates and lockdowns have had no discernible impact"

8) Analysis of the Effects of COVID-19 Mask Mandates on Hospital Resource Consumption and Mortality at the County Level, Schauer, 2021	"There was no reduction in per-population daily mortality, hospital bed, ICU bed, or ventilator occupancy of COVID-19-positive patients attributable to the implementation of a mask-wearing mandate."
9) Do we need mask mandates, Harris, 2021	"But masks proved far less useful in the subsequent 1918 Spanish flu, a viral disease spread by pathogens smaller than bacteria. California's Department of Health, for instance, reported that the cities of Stockton, which required masks, and Boston, which did not, had scarcely different death rates, and so advised against mask mandates except for a few high-risk professions such as barbers….Randomized controlled trials (RCTs) on mask use, generally more reliable than observational studies, though not infallible, typically show that cloth and surgical masks offer little protection. A few RCTs suggest that perfect adherence to an exacting mask protocol may guard against influenza, but meta-analyses find little on the whole to suggest that masks offer meaningful protection. WHO guidelines from 2019 on influenza say that despite "mechanistic plausibility for the potential effectiveness" of masks, studies showed a benefit too small to be established with any certainty. Another literature review by researchers from the University of Hong Kong agrees. Its best estimate for the protective effect of surgical masks against influenza, based on ten RCTs published through 2018, was just 22 percent, and it could not rule out zero effect."
MASK HARMS	
1) Corona children studies: Co-Ki: First results of a German-wide registry on mouth and nose covering (mask) in children, Schwarz, 2021	"The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%)."

2) Dangerous pathogens found on children's face masks, Cabrera, 2021	"Masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and pneumonia-causing bacteria."
3) Masks, false safety and real dangers, Part 2: Microbial challenges from masks, Borovoy, 2020/2021	"Laboratory testing of used masks from 20 train commuters revealed that 11 of the 20 masks tested contained over 100,000 bacterial colonies. Molds and yeasts were also found. Three of the masks contained more than one million bacterial colonies… The outside surfaces of surgical masks were found to have high levels of the following microbes, even in hospitals, more concentrated on the outside of masks than in the environment. Staphylococcus species (57%) and Pseudomonas spp (38%) were predominant among bacteria, and Penicillium spp (39%) and Aspergillus spp. (31%) were the predominant fungi."
4) Preliminary report on surgical mask induced deoxygenation during major surgery, Beder, 2008	"Considering our findings, pulse rates of the surgeon's increase and SpO2 decrease after the first hour. This early change in SpO2 may be either due to the facial mask or the operational stress. Since a very small decrease in saturation at this level, reflects a large decrease in PaO2, our findings may have a clinical value for the health workers and the surgeons."
5) Mask mandates may affect a child's emotional, intellectual development, Gillis, 2020	"The thing is we really don't know for sure what the effect may or may not be. But what we do know is that children, especially in early childhood, they use the mouth as part of the entire face to get a sense of what's going on around them in terms of adults and other people in their environment as far as their emotions. It also has a role in language development as well… If you think about an infant, when you interact with them you use part of your mouth. They are interested in your facial expressions. And if you think about that part of the face being covered up, there is that possibility that it could have an effect. But we don't know because this is really an unprecedented time. What we wonder about is if this could play a role and how can we stop it if it would affect child development."

6) Headaches and the N95 face-mask amongst healthcare providers, Lim, 2006	"Healthcare providers may develop headaches following the use of the N95 face-mask."
7) Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021, Brooks, 2021	"Although use of double masking or knotting and tucking are two of many options that can optimize fit and enhance mask performance for source control and for wearer protection, double masking might impede breathing or obstruct peripheral vision for some wearers, and knotting and tucking can change the shape of the mask such that it no longer covers fully both the nose and the mouth of persons with larger faces."
8) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	"Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression."
9) Wearing a mask can expose children to dangerous levels of carbon dioxide in just THREE MINUTES, study finds, Shaheen/Daily Mail, 2021	"European study found that children wearing masks for only minutes could be exposed to dangerous carbon dioxide levels… Forty-five children were exposed to carbon dioxide levels between three to twelve times healthy levels."
10) How many children must die? Shilhavy, 2020	"How long are parents going to continue masking their children causing great harm to them, even to the point of risking their lives? Dr. Eric Nepute in St. Louis took time to record a video rant that he wants everyone to share, after the 4-year-old child of one of his patients almost died from a bacterial lung infection caused by prolonged mask use."
11) Medical Doctor Warns that "Bacterial Pneumonias Are on the Rise" from Mask Wearing, Meehan, 2021	"I'm seeing patients that have facial rashes, fungal infections, bacterial infections. Reports coming from my colleagues, all over the world, are suggesting that the bacterial pneumonias are on the rise…Why might that be? Because untrained members of the public are wearing medical masks, repeatedly… in a non-sterile

	fashion… They're becoming contaminated. They're pulling them off of their car seat, off the rear-view mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time."
12) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	"Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of an increased transmission of the virus in case of inappropriate use of the mask."
13) Face coverings for covid-19: from medical intervention to social practice, Peters, 2020	"At present, there is no direct evidence (from studies on Covid19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including Covid19. Contamination of the upper respiratory tract by viruses and bacteria on the outside of medical face masks has been detected in several hospitals. Another research shows that a moist mask is a breeding ground for (antibiotic resistant) bacteria and fungi, which can undermine mucosal viral immunity. This research advocates the use of medical / surgical masks (instead of homemade cotton masks) that are used once and replaced after a few hours."
14) Face masks for the public during the covid-19 crisis, Lazzarino, 2020	"The two potential side effects that have already been acknowledged are: (1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing. (2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and

	adopt other management measures, otherwise their risks and those of others may increase. Other potential side effects that we must consider are: (3) The quality and the volume of speech between two people wearing masks is considerably compromised and they may unconsciously come closer. While one may be trained to counteract side effect n.1, this side effect may be more difficult to tackle. (4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself."
15) Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers, Chughtai, 2019	"Respiratory pathogens on the outer surface of the used medical masks may result in self-contamination. The risk is higher with longer duration of mask use (>6 h) and with higher rates of clinical contact. Protocols on duration of mask use should specify a maximum time of continuous use, and should consider guidance in high contact settings."
16) Reusability of Facemasks During an Influenza Pandemic, Bailar, 2006	"After considering all the testimony and other information we received, the committee concluded that there is currently no simple, reliable way to decontaminate these devices and enable people to use them safely more than once. There is relatively little data available about how effective these devices are against flu even the first time they are used. To the extent they can help at all, they must be used correctly, and the best respirator or mask will do little to protect a person who uses it incorrectly. Substantial research must be done to increase our understanding of how flu spreads, to develop better masks and respirators, and to make it easier to decontaminate them. Finally, the use of face coverings is only one of many strategies that will be needed to slow or halt a pandemic, and people should not engage in activities that would increase their risk of exposure to flu just because they have a mask or respirator."

17) Exhalation of respiratory viruses by breathing, coughing, and talking, Stelzer-Braid, 2009	"The exhaled aerosols generated by coughing, talking, and breathing were sampled in 50 subjects using a novel mask, and analyzed using PCR for nine respiratory viruses. The exhaled samples from a subset of 10 subjects who were PCR positive for rhinovirus were also examined by cell culture for this virus. Of the 50 subjects, among the 33 with symptoms of upper respiratory tract infections, 21 had at least one virus detected by PCR, while amongst the 17 asymptomatic subjects, 4 had a virus detected by PCR. Overall, rhinovirus was detected in 19 subjects, influenza in 4 subjects, parainfluenza in 2 subjects, and human metapneumovirus in 1 subject. Two subjects were co-infected. Of the 25 subjects who had virus-positive nasal mucus, the same virus type was detected in 12 breathing samples, 8 talking samples, and in 2 coughing samples. In the subset of exhaled samples from 10 subjects examined by culture, infective rhinovirus was detected in 2."
18) [Effect of a surgical mask on six minute walking distance], Person, 2018	"Wearing a surgical mask modifies significantly and clinically dyspnea without influencing walked distance."
19) Protective masks reduce resilience, Science ORF, 2020	"The German researchers used two types of face masks for their study – surgical masks and so-called FFP2 masks, which are mainly used by medical personnel. The measurements were carried out with the help of spiroergometry, in which patients or in this case the test persons exert themselves physically on a stationary bicycle – a so-called ergometer – or a treadmill. The subjects were examined without a mask, with surgical masks and with FFP2 masks. The masks therefore impair breathing, especially the volume and the highest possible speed of the air when exhaling. The maximum possible force on the ergometer was significantly reduced."
20) Wearing masks even more unhealthy than expected, Coronoa transition, 2020	"They contain microplastics – and they exacerbate the waste problem…"Many of them are made of polyester and so you have a microplastic problem." Many of the face masks would contain

	polyester with chlorine compounds: “If I have the mask in front of my face, then of course I breathe in the microplastic directly and these substances are much more toxic than if you swallow them, as they get directly into the nervous system,” Braungart continues.”
21) Masking Children: Tragic, Unscientific, and Damaging, Alexander, 2021	“Children do not readily acquire SARS-CoV-2 (very low risk), spread it to other children or teachers, or endanger parents or others at home. This is the settled science. In the rare cases where a child contracts Covid virus it is very unusual for the child to get severely ill or die. Masking can do positive harm to children – as it can to some adults. But the cost benefit analysis is entirely different for adults and children – particularly younger children. Whatever arguments there may be for consenting adults – children should not be required to wear masks to prevent the spread of Covid-19. Of course, zero risk is not attainable – with or without masks, vaccines, therapeutics, distancing or anything else medicine may develop or government agencies may impose.”
22) The Dangers of Masks, Alexander, 2021	“With that clarion call, we pivot and refer here to another looming concern and this is the potential danger of the chlorine, polyester, and microplastic components of the face masks (surgical principally but any of the mass-produced masks) that have become part of our daily lives due to the Covid-19 pandemic. We hope those with persuasive power in the government will listen to this plea. We hope that the necessary decisions will be made to reduce the risk to our populations.”
23) 13-year-old mask wearer dies for inexplicable reasons, Corona Transition, 2020	“The case is not only causing speculation in Germany about possible poisoning with carbon dioxide. Because the student “was wearing a corona protective mask when she suddenly collapsed and died a little later in the hospital,” writes Wochenblick.Editor’s Review: The fact that no cause of death was communicated nearly three weeks after the girl’s death is indeed unusual. The carbon dioxide content of the air is usually about 0.04 percent. From a

	proportion of four percent, the first symptoms of hypercapnia, i.e. carbon dioxide poisoning, appear. If the proportion of the gas rises to more than 20 percent, there is a risk of deadly carbon dioxide poisoning. However, this does not come without alarm signals from the body. According to the medical portal netdoktor, these include “sweating, accelerated breathing, accelerated heartbeat, headaches, confusion, loss of consciousness”. The unconsciousness of the girl could therefore be an indication of such poisoning.”
24) Student Deaths Lead Chinese Schools to Change Mask Rules, that’s, 2020	“During the month of April, three cases of students suffering sudden cardiac death (SCD) while running during gym class have been reported in Zhejiang, Henan and Hunan provinces. Beijing Evening News noted that all three students were wearing masks at the time of their deaths, igniting a critical discussion over school rules on when students should wear masks.”
25) Blaylock: Face Masks Pose Serious Risks To The Healthy, 2020	“As for the scientific support for the use of face mask, a recent careful examination of the literature, in which 17 of the best studies were analyzed, concluded that, “ None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection.”[1] Keep in mind, no studies have been done to demonstrate that either a cloth mask or the N95 mask has any effect on transmission of the COVID-19 virus. Any recommendations, therefore, have to be based on studies of influenza virus transmission. And, as you have seen, there is no conclusive evidence of their efficiency in controlling flu virus transmission.”
26) The mask requirement is responsible for severe psychological damage and the weakening of the immune system, Coronoa Transition, 2020	“In fact, the mask has the potential to “trigger strong psychovegetative stress reactions via emerging aggression, which correlate significantly with the degree of stressful after-effects”. Prousa is not alone in her opinion. Several psychologists dealt with the mask problem — and most came to devastating results. Ignoring them would be fatal, according to Prousa.”

27) The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease, Kao, 2004	“Wearing an N95 mask for 4 hours during HD significantly reduced PaO2 and increased respiratory adverse effects in ESRD patients.”
28) Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?, Kisielinski, 2021	“We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.”“Here are the pathophysiological changes and subjective complaints: 1) Increase in blood carbon dioxide 2) Increase in breathing resistance 3) Decrease in blood oxygen saturation 4) Increase in heart rate 5) Decrease in cardiopulmonary capacity 6) Feeling of exhaustion 7) Increase in respiratory rate 8) Difficulty breathing and shortness of breath 9) Headache 10) Dizziness 11) Feeling of dampness and heat 12) Drowsiness (qualitative neurological deficits) 13) Decrease in empathy perception 14) Impaired skin barrier function with acne, itching and skin lesions”
29) Is N95 face mask linked to dizziness and headache?, Ipek, 2021	“Respiratory alkalosis and hypocarbia were detected after the use of N95. Acute respiratory alkalosis can cause headache, anxiety, tremor, muscle cramps. In this study, it was quantitatively shown that the participants’ symptoms were due to respiratory alkalosis and hypocarbia.”
30) COVID-19 prompts a team of engineers to rethink the humble face mask, Myers, 2020	“But in filtering those particles, the mask also makes it harder to breathe. N95 masks are estimated to reduce oxygen intake by anywhere from 5 to 20 percent. That’s significant, even for a healthy person. It can cause dizziness and lightheadedness. If you

	wear a mask long enough, it can damage the lungs. For a patient in respiratory distress, it can even be life threatening."
31) 70 doctors in open letter to Ben Weyts: 'Abolish mandatory mouth mask at school' – Belgium, World Today News, 2020	"In an open letter to the Flemish Minister of Education Ben Weyts (N-VA), 70 doctors ask to abolish the mandatory mouth mask at school, both for the teachers and for the students. Weyts does not intend to change course. The doctors ask that Minister Ben Weyts immediately reverses his working method: no mouth mask obligation at school, only protect the risk group and only the advice that people with a possible risk profile should consult their doctor."
32) Face masks pose dangers for babies, toddlers during COVID-19 pandemic, UC Davis Health, 2020	"Masks may present a choking hazard for young children. Also, depending on the mask and the fit, the child may have trouble breathing. If this happens, they need to be able to take it off," said UC Davis pediatrician Lena van der List. "Children less than 2 years of age will not reliably be able to remove a face mask and could suffocate. Therefore, masks should not routinely be used for young children…"The younger the child, the more likely they will be to not wear the mask properly, reach under the mask and touch potentially contaminated masks," said Dean Blumberg, chief of pediatric infectious diseases at UC Davis Children's Hospital. "Of course, this depends on the developmental level of the individual child. But I think masks are not likely to provide much potential benefit over risk until the teen years."
33) Covid-19: Important potential side effects of wearing face masks that we should bear in mind, Lazzarino, 2020	"Other potential side effects that we must consider, however, are 1) The quality and volume of speech between people wearing masks is considerably compromised and they may unconsciously come closer2) Wearing a mask makes the exhaled air go into the eyes. This generates an impulse to touch the eyes. 3) If your hands are contaminated, you are infecting yourself, 4) Face masks make breathing more difficult. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those phenomena increase breathing frequency and deepness, and they

	may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs, 5) The innate immunity's efficacy is highly dependent on the viral load. If masks determine a humid habitat where SARS-CoV-2 can remain active because of the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load (by re-inhaling exhaled viruses) and therefore they can cause a defeat of the innate immunity and an increase in infections."
34) Risks of N95 Face Mask Use in Subjects With COPD, Kyung, 2020	"Of the 97 subjects, 7 with COPD did not wear the N95 for the entire test duration. This mask-failure group showed higher British modified Medical Research Council dyspnea scale scores and lower FEV_1 percent of predicted values than did the successful mask use group. A modified Medical Research Council dyspnea scale score ≥ 3 (odds ratio 167, 95% CI 8.4 to >999.9; P = .008) or a $FEV_1 < 30\%$ predicted (odds ratio 163, 95% CI 7.4 to >999.9; P = .001) was associated with a risk of failure to wear the N95. Breathing frequency, blood oxygen saturation, and exhaled carbon dioxide levels also showed significant differences before and after N95 use."
35) Masks too dangerous for children under 2, medical group warns, The Japan Times, 2020	"Children under the age of 2 shouldn't wear masks because they can make breathing difficult and increase the risk of choking, a medical group has said, launching an urgent appeal to parents as the nation reopens from the coronavirus crisis…Masks can make breathing difficult because infants have narrow air passages," which increases the burden on their hearts, the association said, adding that masks also raise the risk of heat stroke for them."
36) Face masks can be problematic, dangerous to health of some Canadians: advocates, Spenser, 2020	"Face masks are dangerous to the health of some Canadians and problematic for some others…Asthma Canada president and CEO

	Vanessa Foran said simply wearing a mask could create risk of an asthma attack."
37) COVID-19 Masks Are a Crime Against Humanity and Child Abuse, Griesz-Brisson, 2020	"The rebreathing of our exhaled air will without a doubt create oxygen deficiency and a flooding of carbon dioxide. We know that the human brain is very sensitive to oxygen depravation. There are nerve cells for example in the hippocampus, that can't be longer than 3 minutes without oxygen – they cannot survive. The acute warning symptoms are headaches, drowsiness, dizziness, issues in concentration, slowing down of the reaction time – reactions of the cognitive system. However, when you have chronic oxygen depravation, all of those symptoms disappear, because you get used to it. But your efficiency will remain impaired and the undersupply of oxygen in your brain continues to progress. We know that neurodegenerative diseases take years to decades to develop. If today you forget your phone number, the breakdown in your brain would have already started 20 or 30 years ago…The child needs the brain to learn, and the brain needs oxygen to function. We don't need a clinical study for that. This is simple, indisputable physiology. Conscious and purposely induced oxygen deficiency is an absolutely deliberate health hazard, and an absolute medical contraindication."
38) Study shows how masks are harming children, Mercola, 2021	"Data from the first registry to record children's experiences with masks show physical, psychological and behavioral issues including irritability, difficulty concentrating and impaired learning.Since school shutdowns in spring 2020, an increasing number of parents are seeking drug treatment for attention deficit hyperactivity disorder (ADHD) for their children.Evidence from the U.K. shows schools are not the super spreaders health officials said they were; measured rates of infection in schools were the same as the community, not higher.A large randomized controlled trial showed wearing masks does not reduce the spread of SARS-CoV-2."

39) New Study Finds Masks Hurt Schoolchildren Physically, Psychologically, and Behaviorally, Hall, 2021 https://www.researchsquare.com/article/rs-124394/v2	"A new study, involving over 25,000 school-aged children, shows that masks are harming schoolchildren physically, psychologically, and behaviorally, revealing 24 distinct health issues associated with wearing masks…Though these results are concerning, the study also found that 29.7% of children experienced shortness of breath, 26.4% experienced dizziness, and hundreds of the participants experiencing accelerated respiration, tightness in chest, weakness, and short-term impairment of consciousness."
40) Protective Face Masks: Effect on the Oxygenation and Heart Rate Status of Oral Surgeons during Surgery, Scarano, 2021	"In all 20 surgeons wearing FFP2 covered by surgical masks, a reduction in arterial O_2 saturation from around 97.5% before surgery to 94% after surgery was recorded with increase of heart rates. A shortness of breath and light-headedness/headaches were also noted."
41) Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity, Fikenzer, 2020	"Ventilation, cardiopulmonary exercise capacity and comfort are reduced by surgical masks and highly impaired by FFP2/N95 face masks in healthy individuals. These data are important for recommendations on wearing face masks at work or during physical exercise."
42) Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19, Ong, 2020	"Most healthcare workers develop de novo PPE-associated headaches or exacerbation of their pre-existing headache disorders."
43) Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media, The American Institute of Stress, 2020	"Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems, and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even

	warn of increased transmission of the virus in case of inappropriate use of the mask."
44) Reusing masks may increase your risk of coronavirus infection, expert says, Laguipo, 2020	"For the public, they should not wear facemasks unless they are sick, and if a healthcare worker advised them."For the average member of the public walking down a street, it is not a good idea," Dr. Harries said."What tends to happen is people will have one mask. They won't wear it all the time, they will take it off when they get home, they will put it down on a surface they haven't cleaned," she added.Further, she added that behavioral issues could adversely put themselves at more risk of getting the infection. For instance, people go out and don't wash their hands, they touch parts of the mask or their face, and they get infected."
45) What's Going On Under the Masks?, Wright, 2021	"Americans today have pretty good chompers on average, at least relative to most other people, past and present. Nevertheless, we do not think enough about oral health as evidenced by the almost complete lack of discussion regarding the effect of lockdowns and mandatory masking on our mouths."
46) Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Healthy ChildrenA Randomized Clinical Trial, Walach, 2021	"A large-scale survey in Germany of adverse effects in parents and children using data of 25 930 children has shown that 68% of the participating children had problems when wearing nose and mouth coverings."
47) NM Kids forced to wear masks while running in 100-degree heat; Parents are striking back, Smith, 2021	"Nationally, children have a 99.997% survival rate from COVID-19. In New Mexico, only 0.7% of child COVID-19 cases have resulted in hospitalization. It is clear that children have an extremely low risk of severe illness or death from COVID-19, and mask mandates are placing a burden upon kids which is detrimental to their own health and well-being."
48) Health Canada issues advisory for disposable masks with graphene, CBC, 2021	"Health Canada is advising Canadians not to use disposable face masks that contain graphene. Health Canada issued the notice on Friday and said wearers could inhale graphene, a single layer of

	carbon atoms. Masks containing the toxic particles may have been distributed in some health-care facilities."
49) COVID-19: Performance study of microplastic inhalation risk posed by wearing masks, Li, 2021 Is graphene safe?	"Wearing masks considerably reduces the inhalation risk of particles (e.g., granular microplastics and unknown particles) even when they are worn continuously for 720 h. Surgical, cotton, fashion, and activated carbon masks wearing pose higher fiber-like microplastic inhalation risk, while all masks generally reduced exposure when used under their supposed time (<4 h). N95 poses less fiber-like microplastic inhalation risk. Reusing masks after they underwent different disinfection pre-treatment processes can increase the risk of particle (e.g., granular microplastics) and fiber-like microplastic inhalation. Ultraviolet disinfection exerts a relatively weak effect on fiber-like microplastic inhalation, and thus, it can be recommended as a treatment process for reusing masks if proven effective from microbiological standpoint. Wearing an N95 mask reduces the inhalation risk of spherical-type microplastics by 25.5 times compared with not wearing a mask."
50) Manufacturers have been using nanotechnology-derived graphene in face masks — now there are safety concerns, Maynard, 2021	"Early concerns around graphene were sparked by previous research on another form of carbon — carbon nanotubes. It turns out that some forms of these fiber-like materials can cause serious harm if inhaled. And following on from research here, a natural next-question to ask is whether carbon nanotubes' close cousin graphene comes with similar concerns.Because graphene lacks many of the physical and chemical aspects of carbon nanotubes that make them harmful (such as being long, thin, and hard for the body to get rid of), the indications are that the material is safer than its nanotube cousins. But safer doesn't mean safe. And current research indicates that this is not a material that should be used where it could potentially be inhaled, without a good amount of safety testing first…As a general rule of thumb, engineered nanomaterials should not be used in products where

	they might inadvertently be inhaled and reach the sensitive lower regions of the lungs."
51) Masking young children in school harms language acquisition, Walsh, 2021	"This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development."Studies show that by age four, kids from low-income households will hear 30 million less words than their more affluent counterparts, who get more quality face-time with caretakers." (https://news.stanford.edu/news/2014/november/language-toddlers-fernald-110514.html)."
52) Dangerous pathogens found on children's face masks, Rational Ground, 2021	"A group of parents in Gainesville, FL, sent 6 face masks to a lab at the University of Florida, requesting an analysis of contaminants found on the masks after they had been worn. The resulting report found that five masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and pneumonia-causing bacteria. Although the test is capable of detecting viruses, including SARS-CoV-2, only one virus was found on one mask (alcelaphine herpesvirus 1)…Half of the masks were contaminated with one or more strains of pneumonia-causing bacteria. One-third were contaminated with one or more strains of meningitis-causing bacteria. One-third were contaminated with dangerous, antibiotic-resistant bacterial pathogens. In addition, less dangerous pathogens were identified, including pathogens that can cause fever, ulcers, acne, yeast infections, strep throat, periodontal disease, Rocky Mountain Spotted Fever, and more."
53) Face mask dermatitis" due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care	"The duration of wearing masks showed a significant impact on the prevalence of symptoms ($p < 0.001$). Type IV hypersensitivity was significantly more likely in participants with symptoms

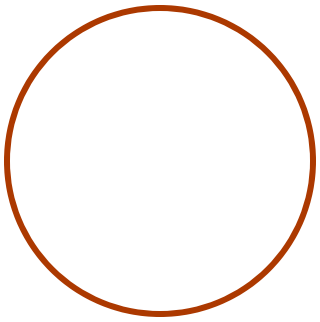
and non-health care workers in Germany, Niesert, 2021	compared to those without symptoms (p = 0.001), whereas no increase in symptoms was observed in participants with atopic diathesis. HCWs used facial skin care products significantly more often than non-HCWs (p = 0.001)."
54) Effect of Wearing Face Masks on the Carbon Dioxide Concentration in the Breathing Zone, AAQR/Geiss, 2020	"Detected carbon dioxide concentrations ranged from 2150 ± 192 to 2875 ± 323 ppm. The concentrations of carbon dioxide while not wearing a face mask varied from 500–900 ppm. Doing office work and standing still on the treadmill each resulted in carbon dioxide concentrations of around 2200 ppm. A small increase could be observed when walking at a speed of 3 km h–1 (leisurely walking pace)…concentrations in the detected range can cause undesirable symptoms, such as fatigue, headache, and loss of concentration."
55) Surgical masks as source of bacterial contamination during operative procedures, Zhiqing, 2018	"The source of bacterial contamination in SMs was the body surface of the surgeons rather than the OR environment. Moreover, we recommend that surgeons should change the mask after each operation, especially those beyond 2 hours."
56) The Damage of Masking Children Could be Irreparable, Hussey, 2021	"When we surround children with mask-wearers for a year at a time, are we impairing their face barcode recognition during a period of hot neural development, thus putting full development of the FFA at risk? Does the demand for separation from others, reducing social interaction, add to the potential consequences as it might in autism? When can we be sure that we won't interfere with visual input to the face recognition visual neurology so we don't interfere with brain development? How much time with stimulus interference can we allow without consequences? Those are all questions currently without answers; we don't know. Unfortunately, the science implies that if we mess up brain development for faces, we may not currently have therapies to undo everything we've done."
57) Masks can be Murder, Grossman, 2021	"Wearing masks can create a sense of anonymity for an aggressor, while also dehumanizing the victim. This prevents empathy,

	empowering violence, and murder." Masking helps remove empathy and compassion, allowing others to commit unspeakable acts on the masked person."
58) London high school teacher calls face masks an 'egregious and unforgivable form of child abuse, Butler, 2020	"In his email, Farquharson called the campaign to legislate mask wearing a "shameful farce, a charade, an act of political theatre" that's more about enforcing "obedience and compliance" than it is about public health. He also likened children wearing masks to "involuntary self-torture," calling it "an egregious and unforgivable form of child abuse and physical assault."
59) UK Government Advisor Admits Masks Are Just "Comfort Blankets" That Do Virtually Nothing, ZeroHedge, 2021	"As the UK Government heralds "freedom day" today, which is anything but, a prominent government scientific advisor has admitted that face masks do very little to protect from coronavirus and are basically just "comfort blankets…the professor noted that "those aerosols escape masks and will render the mask ineffective," adding "The public were demanding something must be done, they got masks, it is just a comfort blanket. But now it is entrenched, and we are entrenching bad behaviour…all around the world you can look at mask mandates and superimpose on infection rates, you cannot see that mask mandates made any effect whatsoever," Axon further noted, adding that "The best thing you can say about any mask is that any positive effect they do have is too small to be measured."
60) Masks, false safety and real dangers, Part 1: Friable mask particulate and lung vulnerability, Borovoy, 2020	"Surgical personnel are trained to never touch any part of a mask, except the loops and the nose bridge. Otherwise, the mask is considered useless and is to be replaced. Surgical personnel are strictly trained not to touch their masks otherwise. However, the general public may be seen touching various parts of their masks. Even the masks just removed from manufacturer packaging have been shown in the above photos to contain particulate and fiber that would not be optimal to inhale… Further concerns of macrophage response and other immune and inflammatory and fibroblast response to such inhaled particles specifically from

	facemasks should be the subject of more research. If widespread masking continues, then the potential for inhaling mask fibers and environmental and biological debris continues on a daily basis for hundreds of millions of people. This should be alarming for physicians and epidemiologists knowledgeable in occupational hazards."
61) Medical Masks, Desai, 2020	"Face masks should be used only by individuals who have symptoms of respiratory infection such as coughing, sneezing, or, in some cases, fever. Face masks should also be worn by health care workers, by individuals who are taking care of or are in close contact with people who have respiratory infections, or otherwise as directed by a doctor. Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."

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Author



Paul Elias Alexander

Dr. Paul Alexander is an epidemiologist focusing on clinical epidemiology, evidence-based medicine, and research methodology. He has a master's in epidemiology from University of Toronto, and a master's degree from Oxford University. He earned his PhD from McMaster's Department of Health Research Methods, Evidence, and Impact. He has some background training in Bioterrorism/Biowarfare from John's

I oppose school masking regulation." Title 216-RICR-30-30-4

Cristina Oliveira <mboliveira09@gmail.com>
Mon 3/11/2024 8:39 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

"I oppose the proposed school masking regulation."
Title 216-RICR-30-30-4
I have two children and refuse to put a mask on them.

On the regulation section 4.3 part B, it states the following…..
"An absence of scientific evidence regarding the effectiveness of face masks .

Masks came off our kids in February 2022 due to over 400 people testifying opposing the mask mandate. It was proven that this caused irreparable harm !

Our children have a God-given right to breathe freely without restrictions!!!!!

Thank you ,
Cristina Oliveira

Pawtucket , RI

Sent from my iPhone

Unmask the children

Elton Taylor <yepitsej73@gmail.com>

Mon 3/11/2024 8:47 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Masking the Children of R.I. again will increase the psychological and physical strain on our Children even more than the last time...They were submitted to such mandates

mask mandate hearing written testimony

Lisa Daft <lisadaftdmd@gmail.com>

Mon 3/11/2024 8:54 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Mr. Garceau,

I am writing in opposition of any language included in RIDOH policy giving the RIDOH the authority to mandate masks on minors. Living and working through the pandemic, it is easy to see that children were greatly affected by being forced to wear masks and being around others wearing masks. There has been an increase in speech delays, socializing has been affected, and we have seen an increase in mental health issues with adolescents. The science is clear that masking has more risks than the threat of a virus. I suspect when updated data from 2020-2023 regarding mental health episodes is finally released, government agencies will not be able to hide behind the "science". I find it interesting that government agencies have not updated any statistics since 2020.

I ask that no changes to RIDOH policy be made until updated data is released so a risk vs benefit analysis can be done.

Masking should always be optional. There are many other precautions that can be taken to help keep students and employees healthy in a school setting. In fact the science that does exist already proves masking is not very effective in preventing the spread of respiratory viruses.

Thank you for the opportunity to write in on this topic.

Sincerely,

Dr. Lisa Daft

unmask our children

christine carr <carr401@hotmail.com>

Mon 3/11/2024 10:25 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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I oppose any further mask mandates in RI

Opposition to the mask regulation

Sarah <sazza724@yahoo.com>

Mon 3/11/2024 11:20 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I oppose this regulation to put masks on again !! Hi my name is Sarah and I live in north Attleboro . I think this regulation is absurd considering there is no grounds to re mask our children or ourselves!! It's not safe nor effective!

Sarah Roque
401-742-0354
P.O. BOX 144 North Attleboro MA.02761

Stop permanent mask mandate regulations testimony

Nellie roque <nroque1122@gmail.com>

Mon 3/11/2024 1:55 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hi, I am a mother of 4 children, and I am against the mandate regulation.
I have lost confidence in our supposed experts that were stating the safety of masks during COVID. I am a nurse, and capable of making decisions for my children. Experts have sneaked their way into families saying they know best when they don't.

3 of my children have mitochondrial disease. Their doctor recommended that they should not have masks on all day. We received a medical note, but my children were stressed because they were different from the other kids. Our other daughter, we placed in an amazing Christian school that let parents decide for themselves. This school could not provide the needs for my other 3 children so we were stuck.

Please leave it up to the parents to decide what is best for their children, it is not right what is happening in this country. God bless.

Nelia Roque
33 Ferncrest drive
Cumberland, RI 02864
Sent from my iPhone

(No subject)

Goretta Borges <gorettab.gb@icloud.com>

Mon 3/11/2024 4:05 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

UNMASK OUR CHILDREN

Sent from my iPhone

(No subject)

Goretta Borges <gorettab.gb@icloud.com>

Mon 3/11/2024 4:07 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I oppose any further mask mandates in Rhode Island

Unmask our children

3/15/24 hearing for mask mandate

Jackie <jdaley24@gmail.com>

Mon 3/11/2024 4:13 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4ri@hotmail.com <consent4ri@hotmail.com>

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Report Suspicious

Hello,
I am writing to add my testimony to the hearing this Friday 3/15 regarding future mask mandates.

I will never allow my children to wear masks again. They do not work, they provide a false sense of security to those who wear them, and they limit my children's ability to breathe. Not to mention how unsanitary it is, and how limiting to their socialization and education it is to be so confined in masks around peers and teachers.

If there are future mask mandates, you better believe there will be a herd behind it to oppose.... It is not normal, and never will be.

Jackie Brousseau
80 Carue dr, Scituate RI

Mask Mandate!

EarthMoma <EarthMoma@protonmail.com>

Mon 3/11/2024 6:35 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Good afternoon Zachary,

I am writing with vehement opposition to mask mandate the RIDOH and the state are looking to impose on RI's school children with no end in sight and no state of emergency.

RIDOH's mask mandate hurt our children. Prolonged, constant, and forced mask use impeded communication, socialization, education, connection, breathing, language acquisition, mental health, and any number of core human functions.

Further more, the Superior Court judge in the Parents United case ruled that the masking policy cause "Irreparable Harm" to our children.
It has been proven that masking defy' s science and common sense over and over again.

Compassion for the children of this state must take top priority!

Sincerely,
Very concerned parents

Sent with Proton Mail [proton.me] secure email.

Regulations for mask mandates

Amy Vadney <amy.vadney@warwickschools.org>

Tue 3/12/2024 8:05 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Good morning,
I would like my testimony IN OPPOSITION to the regulations you are trying to put forth in Rhode Island regarding masking our school children.

As a mother of a 4th grader, a teacher, and a professional I strongly implore you not to pass these new regulations for masking our children. Science has proven how harmful they have been to the students.

Mrs. Amy Vadney
Special Education B.S.
Elementary Education, B.S.
School Counseling, M.A.
Toll Gate High School
(401) 734-3208
amy.vadney@warwickschools.org

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Mask in school

aroberio20@gmail.com <aroberio20@gmail.com>

Tue 3/12/2024 8:50 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I think that the children have had enough of these mask. They are hot, hard to breathe & they wore them long enough. All Covid mandates have been lifted so why make them wear them. Enough..
Sent from my iPhone

Opposition to Face mask Mandates

Julie Romano <julieromano70@gmail.com>

Tue 3/12/2024 10:43 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I hope this letter finds you well. I am writing to express my concerns and opposition to the face mask mandate bill 216-RICR-30-05-4 currently being proposed. While I understand the importance of public health measures, I believe these mandates infringe upon individual freedoms.

It is crucial to acknowledge that personal liberty is a fundamental principle in our society. Mandating face masks is perceived as an overreach of government authority, and many individuals are deeply concerned about the erosion of our rights.

Furthermore, I argue that these mandates are not supported by conclusive evidence regarding their effectiveness in preventing the spread of respiratory illnesses. There is a need for transparent communication and a thorough examination of the scientific basis behind such measures to ensure that they are proportionate and well-founded.

Moreover, some individuals face difficulties wearing masks due to various health conditions or find them uncomfortable, potentially leading to negative consequences .

I urge you to consider a balanced approach that respects individual freedoms while addressing public health concerns. A collaborative effort to educate the public about the importance of voluntary measures and fostering a sense of personal responsibility could be a more effective strategy.

Thank you for your attention to this matter, and I trust that you will carefully consider the diverse perspectives on this issue.

Julie Romano

Barrington RI

Opposition to Mask Mandates

Julie Romano <julieromano70@gmail.com>

Tue 3/12/2024 10:44 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I hope this letter finds you well. I am writing to express my concerns and opposition to the mandatory face mask mandate bill 216-RICR-30-05-4 currently being proposed. While I understand the importance of public health measures, I believe these mandates infringe upon individual freedoms.

It is crucial to acknowledge that personal liberty is a fundamental principle in our society. Mandating face masks is perceived as an overreach of government authority, and many individuals are deeply concerned about the erosion of our rights.

Furthermore, I argue that these mandates are not supported by conclusive evidence regarding their effectiveness in preventing the spread of respiratory illnesses. There is a need for transparent communication and a thorough examination of the scientific basis behind such measures to ensure that they are proportionate and well-founded.

Moreover, some individuals face difficulties wearing masks due to various health conditions or find them uncomfortable, potentially leading to negative consequences .

I urge you to consider a balanced approach that respects individual freedoms while addressing public health concerns. A collaborative effort to educate the public about the importance of voluntary measures and fostering a sense of personal responsibility could be a more effective strategy.

Thank you for your attention to this matter, and I trust that you will carefully consider the diverse perspectives on this issue.

Julie Romano

Barrington RI

Opposition of mask mandate regulation proposal

Lucia Roque <lroque1951@yahoo.com>

Tue 3/12/2024 12:56 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I am a grandmother of many children and have seen first hand my grandchildren suffered wearing masks for 8 hours a day. And to find out now that there was no scientific evidence backing up this mask mandate, infuriates me. This proposal is absolute nonsense. This state better revise this proposal or there are going to be a lot of parents, aunties, uncles, and grandparents that are not going to allow this to happen!!!

Lucia Roque
33 Ferncrest Drive
Cumberland.
Sent from my iPhone

Mask Hearing

Heather Vye <vyeheather@gmail.com>

Tue 3/12/2024 1:35 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good afternoon,

I won't be able to attend the hearing on Friday, unfortunately. Please accept this email as my opposition to the proposed mask regulation. No child should be forced to wear a mask at school. We lived through enough unnecessary masking during Covid. Both my children were impacted negatively- especially my son who has a speech impediment.

Thank you,
Heather Vye
Portsmouth, RI

Concerning legislation on masking

Shannon Laiho <slaiho9@gmail.com>

Tue 3/12/2024 5:07 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Zachary,

I am reaching out because I am in opposition to allowing anyone to mask our children ever again.
The harm is real. The science in favor of masking is shaky at best.
We are Australian citizens as well as RI residents and NEVER during the entire pandemic did they mask anyone under the age of 12, due to the OBVIOUS harms.
We have young children that will never fully recover from the harm done to them from masking.
This is an article published 18 years ago with regards to how effective masks are.... Masks have not changed. The science has not changed.
May rational thinking prevail. Thank you for your time.
Best regards,
Shannon Laiho
Middletown RI



[smh.com.au]Farce mask: it's safe for only 20 minutes [smh.com.au]
smh.com.au [smh.com.au]

Sent from my iPhone

The Sydney Morning Herald

National Health

This was published 21 years ago

Farce mask: it's safe for only 20 minutes

April 27, 2003 — 10.00am

Retailers who cash in on community fears about SARS by exaggerating the health benefits of surgical masks could face fines of up to $110,000.

NSW Fair Trading Minister Reba Meagher yesterday warned that distributors and traders could be prosecuted if it was suggested the masks offered unrealistic levels of protection from the disease.

"I'm sure everyone would agree that it is un-Australian to profiteer from people's fears and anxieties," Ms Meagher said.

"There appears to be some debate about whether surgical masks are able to minimise the effects of SARS."

Ms Meagher said her department would investigate any complaints about false mask claims which concerned the public.

"Penalties can range from fines of up to $22,000 for an individual or $110,000 for a corporation," she said.

Health authorities have warned that surgical masks may not be an effective protection against the virus.

"Those masks are only effective so long as they are dry," said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney.

"As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets."

Professor Cossart said that could take as little as 15 or 20 minutes, after which the mask would need to be changed. But those warnings haven't stopped people snapping up the masks, with retailers reporting they are having trouble keeping up with demand.

John Bell from the Pharmaceutical Society of Australia, who owns a pharmacy in Woollahra, Sydney, said mask supplies were running low.

"At the moment we don't have any because we haven't been able to get any in the last few days," MrBell said. "In the early stages it was unbelievable; we'd get people coming in all the time."

Mr Bell agreed with Professor Cossart's assessment regarding the effectiveness of the masks. "I think they're of marginal benefit," he said. "In a way they give some comfort to people who think they're doing as much as they can do to prevent the infection."

That seems to be the mentality of travellers to Asian destinations, who are buying and wearing the masks while overseas.

Rosemary Taylor, of Kirribilli, arrived in Sydney from Shanghai last week after a two-week holiday in China. Ms Taylor and travelling companion Joan Switzer had worn the masks during the trip home, even though they had been warned they were of little value.

"We were told you need 16 layers on your mask for it to offer 95per cent protection," Ms Taylor said.

Mask Mandate hearing on March 15th 216-RICR-30-05-4

Ladd Meyer <ladd.meyer@gmail.com>

Wed 3/13/2024 6:16 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello,
I am unable to attended in person the Mask Mandate hearing on March 15th for 216-RICR-30-05-4. However I am admittedly opposed to it. The mask were not effective at all and the damage done to learning and speech during this time to children outweigh the "benefit". It should NEVER happen again. For example my son was in 2019 so was raised during the lock downs and forced masking. He didn't learn to walk until he was almost three since every place he could go to play was closed and his speech was delayed, which the pediatrician believes is due to people's faces being covered while speaking. My oldest daughter, who was school age during this time (started Kindergraten in 2020) also developed a skin bacterial infection from wearing masks all day at school.
Don't attempt this again, the negatives far outweigh the positives.
thank you,
Ladd J Meyer
39 Cady Rd
Barrington, RI 02806

OPPOSITION TESTIMONY: RIDOH PROPOSED RULE - MASKING IN SCHOOL

Kristine-E.A. <i.yell.o@gmail.com>

Wed 3/13/2024 9:40 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Dear Mr. Zachary Garceau,

I am writing in OPPOSITION to the RIDOH Proposed rule for masking in school.

RIDOH is proposing to give themselves power over our children by issuing mandates that are not backed by scientific evidence.

I suggest a revision as follows: "RIDOH will not implement a mask mandate because RIDOH cannot support its regulation with quality science." I request the required response explaining why RIDOH would consider such a step without fully assessing the effects mask mandates have on:

1. social connections?
2. On language acquisition?
3. On reading?
4. On speech development?
5. On learning?
6. On mental health?
7. On connections?
8. On oxygen levels and heart rates?
9. On facial recognition?
10. On social development?

The truth that both RIDOH and parents know is that science clearly demonstrated before COVID that masks do not stop the transmission of respiratory illness. We have even more science backing that up in the aftermath of the catastrophe that was RIDOHs handling of COVID. Additionally, we now have science showing that masking has long standing harmful ramifications for our children.

RIDOH does not want to honor science because this is not about the health and wellbeing of our children. This is about power and control over our children.

I oppose the RIDOH proposed masking rule and ask that you disengage from this endeavor.

Sincerely,
Kristine Cahir

--
Kristine Cahir (Aiello)

(No subject)

Michelle Hawes <mhawes420@yahoo.com>

Wed 3/13/2024 10:25 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4ri@hotmail.com <consent4ri@hotmail.com>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

Do not mandate masks for our kids in school. This is ridiculous.

Yahoo Mail: Search, Organize, Conquer [mail.onelink.me]

Stop permanent mask mandate regulation

Christine Patricio <cpatricio143@me.com>

Wed 3/13/2024 11:12 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

I Christine Patricio reside at 9 Charpentier Avenue Pawtucket, RI 02861. I OPPOSE MASK MANDATE REGULATIONS!!

Thank you! 😊

Opposition to Permanent Mask Regulation

Michelle Miller <odelia85@hotmail.com>

Wed 3/13/2024 11:19 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Representatives,

As an educator I couldn't for the life of me understand why students were being required to wear a mask in a school setting during the COVID 19 pandemic especially when children have a 99.97% survival rate according to the CDC. Young children especially rely on verbal cues when learning to read and sounding out letters. Mask wearing hinders facial expression, facial recognition, and language acquisition. That's just common sense.

RI General Law 16.81.1 requires students, teachers, and administrators the right to a safe and secure environment however it also needs to be conducive to learning. It's simply not conducive/ possible for children to learn in a mask. Schools are institutions of learning, of education, and the Rhode Island Department of Health should allow them to operate as such. Schools are not hospitals, clinics or healthcare providers yet they've been required to mandate a medical device(masks) for a virus that no child in RI has died from according to your own data.

The Rhode Island Department of Health have not been able to provide the data to show any long-term effects of masking and whether they even stop transmission. When my daughter was in kindergarten two years ago, she was hurt by the mask mandates in her reading skills, her ears hurting by the pulling from the masks, and breakouts on her face from her eczema and the masks further irritating her skin. Therefore, I strongly oppose future masks mandates in schools.

Thank You

Michelle Miller

OPPOSE 216 RICR 30-05-4 MASKING

Tracy Tellier <tracy.tellier@yahoo.com>

Wed 3/13/2024 12:17 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Rhode Island Department of Health,

Here is my written testimony in opposition to 216 RICR 30-05-4 Masking:

NEVER AGAIN!

While I could be brief and keep it at that, I also feel the need to let this department know how I really feel and I welcome this opportunity.

You messed with our kids.

The Rhode Island Department of Health lost all credibility and trust during Covid and has never regained that credibility or trust back.

The State nor Rhode Island Department of Health will never be allowed to abuse my children ever again with any face diaper dictorial orders. I will repeat, this department or the state will never ever be allowed to abuse my children ever again.

Masking does not work. They've never worked. The State of Rhode Island & The Rhode Island Department of Health had every opportunity in (Southwell v. McKee) to prove the effectiveness of masking in a court of law but they failed to do so. Not only did they fail to do so, they couldn't & wouldn't. The state & this department had zero data to prove the effectiveness. None. Nada. Zilch.

As a reminder, "Masks Work" is a slogan not demonstrable evidence.

This department still has never addressed the harms in masking. You cannot deny there are harms. I've I witnessed them with my own children. I want this department to address the "irreparable harm" from Southwell v McKee. (Crickets).

We're told that children's brains don't fully develop until their mid 20s yet this department, the department of supposedly "health" masked kids & continues to advocate for masked kids in schools for 6+ hours/day and even while doing sporting activities . I'm being totally serious when I'm asking this department if they know anything about health? I'm asking that because you're advocating for children who do not have fully developed brains, you're advocating to cut off true oxygen to children's developing brains. That is sick and that is twisted and until the folks in this department can reconcile that this department has zero credibility unless proven otherwise.

I'm also here to tell you if for any reason this ridiculous draconian regulation passes (as this state is as corrupt as it gets) I would pull my kids out of public school so fast should u ever mandate face diapers again. We all know it's all about the money since the state got a lot of $$$$ from the federal government to mask our kids.

Signed an angry & pissed off parent
Tracy Tellier

NO MASK MANDATE!!!

Paul Gagnon <pgagnon8484@gmail.com>

Wed 3/13/2024 1:32 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

This email is to show my opposition on your new rules you are trying to set in place for OUR children. The fact that the masks don't work or prevent the spread of any airborne illness should be more than enough proof that this new "rule" you're trying to put in place, it just bologna!....Leave the kids alone and knock off trying to push your liberal agenda on mine and other people's kids. Let us make the decision whether or not our child should be in school just like it has been since the beginning instead of you and the teachers trying to tell us what's best for our kids!

Masks

Cindy Chaves <cinderleela@cox.net>

Wed 3/13/2024 5:06 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

I oppose any mask mandates for my grandchildren in the state of RI. Please remove any such policies.
Thank you
Cindy chaves
Sent from my iPhone

OPPOSE proposed Regulation 216-RICR30-05-04

Melanie Charpentier <melaniecharpentier5@gmail.com>

Wed 3/13/2024 5:27 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

I'm sending this email in opposition of regulation 216-RICR30-05-04.

Masks are not proven to stop the spread of an infectious disease. There are many types of masks and not all work and cost the same amount of money.

My son never use to get sick before. Now that he's had the vaccination and forced to wear a mask, he is sick constantly. This nonsense needs to stop. Germs are good for people and help us build up our resistance.

Best,
Melanie Charpentier
Concerned parent
Sent from my iPhone

Mask proposal

kerri senerchia <kerriasenerchia@hotmail.com>
Wed 3/13/2024 8:54 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good evening,

I'm appalled that this mask mandate regulation is even being proposed. Although I'm not surprised that RI is the ONLY state in the country proposing such a bill.

As a mom and teacher I am more than opposed to the idea of EVER forcing my children or my students in masks again.

Are you simply ignoring the data that shows the damage that COVID restrictions caused children or are you choosing to have your head in the sand?

Negative educational and emotional damage was done to our children and it will take years to "catch up".

My children suffered emotionally by not being able to be social with their peers and when they were it was very awkward with masks on. Teenagers everywhere are suffering to adapt in social situations as those important formative years were disrupted by Covid restrictions.

As an MLL teacher, the effect of masks on language development has been grave.
My students who have been in this country 3-4 years can barely speak English. And, when they do, their sounds and mouth formation are incorrect. I have spent most of my instructional time on phonics and language development with my middle school children who have repeatedly told me:

"I can't hear the ending sounds of words."

"Those sounds are the same."

" I don't like how I sound in English."

In my twenty nine years of teaching I have never had students struggle this much with following directions in English and distinguishing between sounds. Usually students who have been here several years are good at listening and speaking and we are focusing on reading and writing. With masks having such a negative effect, they are behind in all four areas of language acquisition.

A colleague of mine who works in the Child Outreach portion of our district has never had more speech and language referrals.

You have ruined a generation of children.

Forcing masks on children was detrimental and did nothing to stop the spread of viruses as countless studies have proven. Yet, you are continuing to try to impose masks whenever you deem fit.

It is not YOUR job to tell us how to care for our children or any of us for that matter.

I will never wear a mask again, I will never put one on my children again and I will never ask my

students to wear one.

You are fighting a fight you will NOT win.

Are you choosing to ignore the lawsuits in which the teachers in Barrington won their case? Or, the parents who opposed the mask mandate and won?

End this charade. Now.
We have had enough.

Kerri Lapierre
Mom and teacher

Sent from my iPhone

RI mask mandate

Sherry Cucca <sherrycucca@gmail.com>

Thu 3/14/2024 6:50 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello,

I am opposing the bill to mandate masks on children for future diseases. It is ridiculous. Kids, nor adults, should need to wear a mask ever. We have dealt with diseases throughout history before COVID and we didn't mask anyone. Instead of masking, we need to promote healthy eating, lifestyle, and how to take care of our immune system and make it strong to fight off disease. NO MASKING OUR CHILDREN!!!

Thank you,
Sherry Cucca

Opposition to mask mandate

Jennifer Lambert <jlambert2123@gmail.com>

Thu 3/14/2024 7:47 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good morning,

I'm strongly opposed to masking our children. We've learned that there is no science behind this and it has done irreparable harm to our children. It's unbelievable that this is even a consideration in 2024.

Respectfully,

Jennifer

OPPOSITION TESTIMONY: RIDOH PROPOSED RULE - MASKING IN SCHOOL

Justin Cahir <j.cahir@gmail.com>

Thu 3/14/2024 8:23 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Mr. Zachary Garceau,

I am writing in OPPOSITION to the RIDOH Proposed rule for masking in school.

RIDOH is proposing to give themselves power over our children by issuing mandates that are not backed by scientific evidence.

I suggest a revision as follows: "RIDOH will not implement a mask mandate because RIDOH cannot support its regulation with quality science." I request the required response explaining why RIDOH would consider such a step without fully assessing the effects mask mandates have on:

1. social connections?
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8. On oxygen levels and heart rates?
9. On facial recognition?
10. On social development?

The truth that both RIDOH and parents know is that science clearly demonstrated before COVID that masks do not stop the transmission of respiratory illness. We have even more science backing that up in the aftermath of the catastrophe that was RIDOHs handling of COVID. Additionally, we now have science showing that masking has long standing harmful ramifications for our children.

RIDOH does not want to honor science because this is not about the health and wellbeing of our children. This is about power and control over our children.

I oppose the RIDOH proposed masking rule and ask that you disengage from this endeavor.

Sincerely,
Justin Cahir

I oppose 216-RICR-30-05-4

Miriam Iri <miriamandkitty3@gmail.com>

Thu 3/14/2024 10:51 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I am a concerned resident from the state of Connecticut, I'm writing to oppose 216-RICR-30-05-04. Masks should not be forced on the public any longer and it's the individual's right to decide on choosing what is right for their health. Thank you.

Sincerely,

Miriam Irizarry, Sterling Connecticut

(No subject)

Mary Daley <msbdaley@gmail.com>

Thu 3/14/2024 11:25 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Superintendent and School Committee Members,

Please be advised that Rhode Island Department of Health has proposed a permanent regulation for future mask mandates. [google.com] It would give RIDOH the power to impose masks on our children for *any* infectious

disease (RSV, flu, chicken pox), *without* declaring a state of emergency. Rhode Island is the *only* state to attempt to implement mask mandates as a *permanent* executive power over children. Please protect our children from this.

I invite you to attend RIDOH´s mask mandate regulation hearing on [google.com]March 15 [google.com]th [google.com] at 9am [google.com] at One Capitol Hill (Conference rooms A, B &C), Providence, RI 02908.

RIDOH's mask mandate hurt our children. Prolonged, constant, forced mask use impeded communication, socialization, education, connection, breathing, language acquisition, and any number of core human functions. I urge you to oppose mandates that harm children while defying [google.com]science [google.com], [google.com]common sense [google.com], real world experience (remember that states with mask mandate had comparable Covid rates to those without mask mandates), decency, and compassion for children.

Thank you for your time and your service to our community.

Mary Daley

I oppose your regulation for mask mandates

maddalena cirignotta <mcirignotta@yahoo.com>

Thu 3/14/2024 11:25 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Good morning,

I'm Anwen Daley and I'm 11 years old. Your mask mandates hurt me. They made it hard to breathe and I couldn't hear anyone. For second and third grade, I couldn't understand my teachers and they couldn't understand me. I never got breaks from hours of masking and I was bullied by adults when I tried to give myself one. I hated school.

I couldn't make friends because I couldn't even see my friend. You forced us to cover our faces.

I had to exercise in a mask. It hurt my body and it made it even harder to breathe.
Have you tried to have gym in a mask when it's 95 degrees out?

I do not ever want to have to wear a mask again. Now I can never trust you because you hurt children.

I oppose your horrible mask mandates.

Anwen Daley
South Kingstown

Proposed Rule/Regulation- Masking in School

Barbara Lardner <avalon1357@msn.com>

Thu 3/14/2024 12:33 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Hello Mr. Garceau,

Thank you for your service at RIDOH. I am writing to you in opposition to the proposed rule 216-RICR-30-05-04 Masking in School. As a former public school teacher who taught throughout the entire COVID Pandemic, I saw how detrimental masks were to the children. They caused irreparable harm to the children's language skills, social skill and education. Mask mandates also effected the children's emotional stability by frightening them in a place where they should feel safe. The mask mandates were unnecessary and ineffective and imposed on society by a political tyranny that ignored science, as they had no effect on stopping the spread. To have our government agencies to want to start imposing medical mandates again because of another "pandemic emergency' is showing that our government has learned nothing from the COVID pandemic. The government needs to stay out of all personal medical decisions and abandon all health mandates. Please don't harm and frighten our children again with more masking mandates. Leave our kids alone!! Please oppose 216-RICR-30-05-04.

Barbara Lardner
Riverside, RI

Sent from my iPad

Testimony for mask regulation hearing 3/15

Suzanne Salomon <suzannepsalomon@gmail.com>
Thu 3/14/2024 12:58 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.
Report Suspicious

Dear Zachary,
Please see my testimony below

Children have suffered from anxiety, depression, learning loss during the state mandated mask requirement. My children included and have documentation if needed. I strongly oppose any future mask mandate in the state of Rhode Island. Our children are just beginning to heal from the past mistakes of RIDOH. A time when our children were forced to wear masks in school. It's appalling that RIDOH would even consider approving such a regulation again.

Maybe we need to take stroll down memory lane since it appears RIDOH has forgotten the damage inflicted on the children of Rhode Island.

-The Rhode Island Superior Court has established that mask mandates are inflicting "irreparable harm on children"

-Forcibly masking children during school hours and against parents' wishes is unacceptable.
One-way masking using a N95 works and individuals are free to wear one. Forced masking of children is detrimental to their emotional/social well being.

Therefore -

RIDOH will implement a mask mandate on children when it can demonstrate with numerous randomized control trials that masks prevent infection and transmission. There will be no regulation requiring masking in schools for the alleged prevention of respiratory viral infections until evidence of their effectiveness has been demonstrated convincingly by

multiple, rigorous randomized, controlled clinical trials. RIDOH will not implement a mask mandate because RIDOH cannot support its regulation with quality science.

1. cloth masks have been proven to be ineffective in the transmission of Covid and respiratory viruses. The CDC now concedes that cloth masks do not provide protection as previously purported. Masks impede literacy learning because children cannot see others' expressions, mouth-movement. Sound is muffled.

2. "Kids need to see faces," Jay Bhattacharya, a professor of medicine at Stanford University. Youngsters watch people's mouths to learn to speak, read and understand emotions, he said.

3. "The impact of Covid on children has caused a strain on their mental health, emotional well being and academic success" - Jeffrey Riley Masachussetts education Commissioner

4. The Rhode Island Superior Court has established that mask mandates are inflicting "irreparable harm" on children.

5. The most vulnerable can protect themselves with N95 masks if they so choose.

Thank you,
Suzanne Salomon

No masks

HEATHER BREN <hjd922@verizon.net>

Thu 3/14/2024 1:13 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Masking has not been proven to be effective and has actually been proven to be harmful to the respiratory and immune systems! Use facts and stop the madness

Sent from Yahoo Mail for iPhone [overview.mail.yahoo.com]

Masking Mandates in Rhode Island hearing 3/14

Marlene Kiernan <mkiernan1@cox.net>

Thu 3/14/2024 1:17 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
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Report Suspicious

Dear Mr. Garceau and R.I Department of Health,

I am writing to express my deep concerns regarding the mandates implemented by the Department of Health during the Covid-19 pandemic, particularly in relation to masking in schools. As a parent of children who were in the 3rd and 7th grade during this challenging time, I have witnessed firsthand the significant loss of learning and crucial mental and social development experienced by our youth.

Teachers across the country have echoed the sentiment that the impact of these losses on our children has been catastrophic. The classroom environment, where peer interaction and hands-on learning are essential, was irreplaceable during those formative years. Yet, masking became a central component of the measures imposed, despite evidence suggesting its ineffectiveness.

It is disheartening to note that recommendations from figures such as Dr. Fauci and the CDC have indicated that masking did not provide the intended protection. In light of this knowledge, it raises serious questions as to why the Rhode Island Department of Health feels it necessary to enact measures to be able to once again establish mandates based on flawed premises.

Should another pandemic occur, it is imperative that decisions be made based on the current scientific understanding and tailored to the specific circumstances of the situation. Blanket rules and unchecked authorities only serve to undermine trust and exacerbate tensions within our communities.

Our children's well-being and future development should be at the forefront of any decision-making process, learn from the mistakes of Covid, of which masking was one.

Thank you for considering my perspective on this matter.

Sincerely,

Marlene C. Johnson

Re: Testimony for mask mandate

Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Thu 3/14/2024 1:32 PM
To:Kiela Daley <sassa419@hotmail.com>

Good Afternoon,

Thank you for submitting your comments. Please note that we were not able to be opened and therefore, they cannot be added to the rulemaking record unless they are submitted in a different file format.

Best,

Zachary J. Garceau (he/him/his)
Chief Program Development
Office: 401-222-7884
Cell: 401-408-2747
Zachary.Garceau@health.ri.gov

From: Kiela Daley <sassa419@hotmail.com>
Sent: Thursday, March 14, 2024 1:14 PM
To: Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Subject: Testimony for mask mandate

This Message Is From an External Sender
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Report Suspicious

Kiela Daley

OPPOSE MASK REGULATION

Cherico3@hotmail.com <Cherico3@hotmail.com>
Thu 3/14/2024 1:41 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
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Report Suspicious

Hello- I would like you to know I OPPOSE the regulation for masking here in Rhode Island as a permanent use to mandate. Most other countries of the world do NOT mask young children under 12 and for good reason. We will never truly understand the impacts of these harsh mandates until we are able to reflect back on these past few years.

As a mother of 3 children in public school, I have seen this negatively affect their social- emotional well-being first hand. And in RI, our legislators refused to listen to our concerns. As parents, We are the experts on our own children. And yet- the department of health and RIDE were able to supersede us in the decision making process. This will have lasting consequences. I urge you to to please start listening to us parents and let's ask the kids how the impacts affected them and have RIDOH and RIDE conduct a comprehensive analysis of the risk/benefits of mandating masks in schools. This should have been done the moment they were mandated. And now we have evidence and data coming out of states where districts NEVER enforced masking.

Trust in our legislators and government regulatory agencies like RIDOH will have to be earned back. This is one way we can start paving the road for healing and moving forward. If parents don't have a say and masks are mandated for school children going forward, I think it will have lasting impacts to this generation of children, and it will not be good. I hope you listen to what us parents and teachers witnessed firsthand in schools. This will be a moment in time where RIDOH could do the right thing.

Thank you for your consideration,
Cherie D. Waluk
Portsmouth Parent

Testimony in Opposition to Regulation

Stephen Skoly <sskoly@affiliatesri.com>

Thu 3/14/2024 1:55 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4RI@hotmail.com <consent4RI@hotmail.com>

1 attachments (599 KB)

BP-50M31_20240314_144724.pdf;

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This message came from outside your organization.

Report Suspicious

America's response to the COVID-19 pandemic and its misguided strategies failed on many levels. While not to minimize the tragic and unavoidable deaths associated with a pandemic, many formally trusted public health agencies including the CDC, WHO and NIH failed to follow the many years of trusted science.

While the COVID cover-up began in China, COVID chaos continued in the United States. Unchecked government tyranny can never happen again. On many levels even the Rhode Island Department of Health failed to "follow the science". Pseudoscience and unlawfully enacted mandates can never again be imposed on the citizens of Rhode Island.
Finally, a pandemic does not preclude the United States Constitution. It is imperative that false government narratives be appropriately challenged.

With permission I have included Chapter 10 of the Norfolk Group's questions for a COVID-19 Commission recently presented to Congress. This Chapter reviews the science of masking mandates.

Please feel free to contact me should any questions remain.

Respectfully Submitted,

Dr. Stephen T. Skoly

Oral and Maxillofacial Surgeon

https://www.norfolkgroup.org/

Chapter Ten | Masks

Background

Public mask use was rare in the United States before the COVID-19 pandemic. On April 3, 2020, the CDC began recommending face coverings, including both cloth and surgical masks, for everyone two years old and up. The CDC cited no evidence for the efficacy of masks and the previous lack of evidence on efficacy of mask wearing for other respiratory viruses was ignored or distorted. During the pandemic, universal and school-masking became increasingly controversial and polarized.

In supporting mask mandates for people ages 2 and up, the CDC and other government officials: 1) Exaggerated the benefits of masks based on pre-pandemic studies, 2) Promoted studies that supported masking recommendations/mandates, while ignoring or censoring those that did not, 3) Did not fund randomized controlled trials to determine the efficacy of masking, 4) Failed to explain why masking recommendations were not aligned with many European countries, especially for children, and 5) Failed to acknowledge potential harms of masking, especially for children.

Randomized Mask Studies

Randomized controlled trials (RCTs) are the gold standard in medical research.

Prior to the COVID-19 pandemic, the evidence that masks did little if anything to stop the spread of respiratory viruses was uncontroversial. A meta-analysis of 14 randomized controlled trials *"did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility."* A Cochrane analysis of nine trials stated that *"the pooled results of randomized trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."* RCTs conducted in healthcare workers found that surgical masks provided questionable benefit against respiratory pathogens, including the common cold. Another RCT published in 2010 investigating the use of masks as source control found no difference in infection rates of household contacts between masked and unmasked groups. In light of this research, why did public health officials and agencies promote the idea that masks would be effective against SARS-CoV2? Why did they start recommending and mandating surgical masks to prevent SARS-CoV2 transmission?

Few RCTs have evaluated the effectiveness of cloth masks. The results from the first concluded that *"cloth masks should not be recommended for health care workers"*. If they are not effective for hospital staff, why were they recommended for the public?

In March 2021, a research team in Denmark published the first RCT of mask effectiveness against SARS-CoV2 transmission. To the extent that the study was powered, there was no significant reduction in SARS-CoV2 and other respiratory viral infections for those wearing surgical masks compared to unmasked controls. Why was this study ignored or dismissed by the CDC and other U.S. public health agencies?

In August, 2021, a second randomized mask study was published, eventually appearing in Science. Rural Bangladeshi villagers were randomized to wear cloth masks, surgical masks or no masks. With a p-value slightly below 0.05, masks reduced short-term transmission by between 0% and 18% (95% confidence intervals), suggesting that the masks had marginal or no impact on COVID-19 transmission. A

subsequent reanalysis of the data found an even weaker effect. Why was this study used to justify the continuation of mask policies? Why did mainstream media outlets exaggerate the results of this study to claim that masks are highly effective against SARS-CoV-2 transmission?

Why did neither CDC nor NIH/NIAID conduct or fund large RCTs to compare transmission rates between masked individuals, households, schools and/or workplaces to unmasked controls groups and to groups wearing different mask types? This would have provided strong evidence as to whether masks prevent viral transmission in different community settings, which masks (if any) were most effective, and whether mask wearing was warranted.

Observational Mask Studies

Observational studies of individuals can provide valuable information when they are well conducted and properly adjust for potential confounders. Non-randomized research studies based on geographically related groups (ecological data) rather than individuals are prone to bias, and more suitable for hypothesis generation than hypothesis evaluation.

Before the pandemic, there was not much evidence that cloth masks were effective against respiratory viruses. One study concluded that *"the use of fabric materials may provide only minimal levels of respiratory protection to a wearer against virus-size submicron aerosol particles (e.g. droplet nuclei). This is partly because fabric materials show only marginal filtration performance against virus-size particles when sealed around the edges. Face seal leakage will further decrease the respiratory protection offered by fabric materials."* Despite such evidence, why were cloth masks encouraged rather than discouraged as protection against Covid-19?

In a May 2020 paper about masking in hospital settings, Dr. Mike Klompas, a Harvard professor and hospital epidemiologist, wrote that *"we know that wearing a mask outside health care facilities offers little, if any, protection from infection…In many*

cases, the desire for wide spread masking is a reflexive reaction to anxiety over the pandemic." Why did Dr. Anthony Fauci and the CDC come to a different conclusion? Did they recommend and mandate masks to reduce anxiety amongst the public?

In July, 2020, CDC published its first study on mask efficacy against COVID-19. In this study, two hairstylists tested positive for SARS-CoV2 yet did not infect any of their patrons. The authors concluded that the lack of transmission was due to consistent adherence to masking on the part of the hairstylists. However, viral loads were not tested, and in an early study of household transmission, the secondary attack rate was only 19%. Therefore, regardless of masking, there was a low probability of spread and, despite the positive test, it is possible that viral levels were too low to be infectious. Furthermore, this study consisted of a sample size of two and no control group. Why was this report considered strong evidence of mask effectiveness?

In January 2021, the CDC published a study from Wood County, Wisconsin, which found lower transmission rates in schools, where masks were commonly used, compared to the community at large. Despite the lack of a comparative unmasked control group, why did the CDC and the Secretary of Education use this study as evidence that masks are effective? Schools in Norway that did not mask students <12 also saw similarly low transmission levels during the same time period. Was the possibility that children transmit less frequently than adults, rather than mask mandates, considered as an explanation to why schools had relatively low transmission rates?

In the summer of 2021, Duke University produced a report claiming that *"widespread use of masks in schools can effectively prevent COVID-19 transmission"*, which was then promoted by *The New York Times*. The study found that within-school transmission was very low, which the authors concluded was due to universally implemented mask mandates. However, the study had no control group of schools that did not mandate masks. Considering that Sweden had very low in-school transmission without masking children, a more plausible explanation is that children

are less prone to spread COVID-19 than adults. Why did Duke University and *The New York Times* promote such a fundamentally flawed study?

In September 2021, the CDC published a mask study conducted in Arizona, comparing school districts with and without mask mandates. The study was not randomized and did not control for important confounders such as vaccination rates in the community; it used a longer period of data collection time for masked districts (14% longer); and, it used an inappropriate definition of "outbreak" (2 or more cases in 14 days) that biased numbers against large school districts, of which only 11% had mask mandates, and in favor of small district, of which 52% had mask mandates. Despite its obvious and serious methodological flaws, why did Dr. Walensky and the media use this study to claim that unmasked districts had higher rates of COVID?

A CDC study published in October, 2021, compared U.S. counties with and without school mask mandates, concluding that masking reduced pediatric infection rates. Such ecological studies are very prone to bias, since both mask mandates and the seasonality of COVID-19 are regional. Therefore, it was not surprising that a follow up study that used the same methodology as the original study, but simply extended the study period and included more counties, concluded that masks did not affect pediatric case rates. Why did the CDC publish this heavily flawed study and base public health policy on it? When the extended follow-up study was published, why did CDC ignore it?

In November 2021, the British Medical Journal published a systematic review of observational mask studies conducted during the pandemic. From their meta-analysis, the authors concluded that mask wearing reduced COVID-19 infection by 53%. However, this conclusion was based on six studies with moderate to critical bias because they did not control for variables such as simultaneous changes in behavior, activities, and the use of other mitigation measures. Why were these studies frequently used as support for implementing mask mandates?

Ecological studies are slightly better when comparing neighboring districts, such as (i) an earlier CDC study conducted in the fall of 2020 in Georgia that showed that student

masking did not significantly reduce transmission in school, or (ii) a 2022 study in Fargo, North Dakota, that *"suggests school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students."* Did the CDC set masking policies based on cherry-picked studies while ignoring others that did not have the desired outcome?

The best observational study of masks in children was published in March 2022. Using a quasi-experimental design, Spanish researchers compared school children aged 6, who were subject to a mask mandate, with children aged 5, for whom masks were not mandated. They found no significant difference in COVID-19 rates and concluded that *"mask mandates in schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective."* In April 2022, in another study looking at mask mandates, in Finland, there was no difference in pediatric case rates between children in communities with and without mask mandates. Why did the CDC ignore these studies?

In May 2022, another Duke University study evaluated whether schools with or without mask mandates had a higher proportion of secondary (school acquired) versus primary (community acquired) COVID infections. The classification of primary versus secondary transmission was conducted by school health staff. Masked school districts, however, did not generally consider masked students to be potential contacts during tracing because of CDC guidelines which stated that *"the close contact definition excludes students who were between 3 to 6 feet of an infected student if both the infected student and the exposed student(s) correctly and consistently wore well-fitting masks the entire time."* This would lead to in-school transmission cases in districts with mask mandates being overlooked by contact tracers and incorrectly considered community transmission, giving falsely low rates of secondary transmission in districts with mask requirements. Despite its obvious and serious methodological flaws, why did the NIH promote this study, claiming that mandatory masking in schools reduced COVID-19 cases?

In November 2022, the New England Journal of Medicine published a study claiming that the lifting of masking requirements was associated with additional COVID-19 cases. The study compared COVID-19 incidence in two school districts with sustained mask mandates throughout the school year, with 70 school districts that ended mask mandates during the first, second or third week of March, 2022. Districts that ended mask mandates on the second week (n=17) had many more cases than those ending mandates on the first (n=46) or third week (n=7) of March, which in turn had more than the two districts that kept mandates in place (n=2). The difference between the 2nd and 1st/3rd week can only be explained by confounding, and in the presence of such major confounding, no reliable conclusions can be made about the districts with continued mask mandates. While the authors' difference in difference technique can be useful to adjust for covariates that remain constant over time to infer causality, it does not adjust for critical time-varying confounders such as population immunity levels, which have different temporal patterns in different locations in this study. Further, since observations within the same school district are dependent, the statistical analysis should have been done at the district level rather than individual student/staff level. With n=2 city districts still masking and n=70 more suburban districts no longer masking, it was epidemiologically inappropriate to conclusively attribute district case rate differences to a change in mask policy. Why did the journal publish such a flawed study? Why did media promote this flawed research study uncritically?

Exaggerating Mask Effectiveness

In February-March 2020, mask use began to increase among the general public. Unless they had COVID-19, public health officials were quick to discourage this trend, including CDC Director Robert Redfield, NIH/NIAID Director Anthony Fauci and the U.S. Surgeon General Jerome Adams. Dr. Anthony Fauci gave the same advice to close associates in private, saying that *"the typical mask you buy in the drug store is not really effective in keeping out*

virus, which is small enough to pass through the material." In April 2020, the official public health message suddenly changed.

On April 3rd, 2020, CDC recommended face masks for people who were confirmed or suspected to have COVID-19: *"You should wear a facemask when you are around other people (e.g., sharing a room or vehicle) or pets and before you enter a healthcare provider's office. If you are not able to wear a facemask (for example, because it causes trouble breathing), then people who live with you should not stay in the same room with you, or they should wear a facemask if they enter your room."* Why did they make this recommendation without citing any high quality evidence in support of the efficacy of face masks for prevention or transmission of respiratory viral infections?

CDC information guidance provided to healthcare workers continued to contradict recommendations for the general public, for example stating that *"face masks protect the wearer from splashes and sprays."* while *"respirators, which filter inspired air, offer respiratory protection."* Why did the CDC recommend surgical and cloth face masks for the general public while at the same time informing healthcare workers that facemasks do little to filter inspired air or offer protection from respiratory viral infection?

On September 17, 2020, CDC director Robert Redfield said *"I might even go so far as to say that this face mask is more guaranteed to protect me against COVID than when I take a COVID vaccine"*. Why did Dr. Redfield exaggerate the benefits of masks? Why did the CDC Director lower confidence in COVID-19 vaccines before vaccine trial data were even available?

Double masking was endorsed by NIH/NIAID Director Anthony Fauci and CDC Director Rochelle Walensky, presumably based on a single study published by CDC in March, 2021, in which the authors cautioned that *"the findings of these simulations should neither be generalized to the effectiveness of all medical procedure masks or cloth masks nor interpreted as being representative of the effectiveness of these*

masks when worn in real-world settings." Why did Drs. Fauci and Walensky recommend double masking based only on simulated rather than real-world data?

On October 29, 2021, CDC director Rochelle Walensky stated that *"the evidence is clear"* that masking *"can reduce your chance of infection by more than 80%, whether it's from the flu, the coronavirus or even just the common cold."* What evidence did she use to make this conclusion, which appears to greatly exaggerate the benefits of masks?

CDC promoted a 350% reduction in "outbreaks" based on their flawed Arizona school mask mandate study whereas other positive studies have shown at most a 2% to 25% reduction in transmission rates. Why did health officials continue to cite low quality studies instead of citing the only two randomized COVID mask trials from Denmark and Bangladesh, both conducted pre-vaccination, which showed zero or minimal efficacy of public mask use against SARS-CoV2?

Why were some studies showing masks as not effective at curbing viral spread, such as Cochrane influenza studies, censored?

Did people engage in behavior that increased their chances of contracting the virus because they had a false sense of security that they would be fully protected by masking?

Mask Mandates

In addition to mask recommendations, many governments, schools, universities, and businesses instituted mask mandates.

Why did some American schools mandate masks for children two and up, while WHO recommended against masking children under the age 6 and the European Centers for Disease Control recommended against masks for children 12 and under?

Why did Head Start, a federal program serving preschool-age children from low-income families, maintain a mask requirement longer than any other setting?

Why were masks mandated on public transportation such as buses, trains and airplanes without any scientific studies showing their efficacy in such settings?
Were there any discussions about the ethics and wisdom of imposing mask mandates based on weak studies while ignoring higher quality studies showing that masks made little or no difference in COVID-19 spread?
When the legality of Connecticut school mask mandates were questioned in court, the State argued and the Connecticut Supreme Court "wrestled" over whether the legal challenge was moot since the governor had subsequently ended the mandate. Will State Governments continue to attempt to dismiss legal challenges to pandemic restrictions on the grounds that the restrictions are no longer in place?

Harms of Masking Children

Mitigations that limit children's observations of faces due to masking of teachers and peers should not be discounted as harmless, especially in young children and those with special needs. We know from studies of children who are blind that language and emotional development may be hindered by lack of visual cues, though this may be multifactorial. Without specific interventions, blind children are slower to learn language and emotional fluency unrelated to level of intelligence. Evidence suggests young children learn basic emotions and interact with others by focusing on faces. Lip reading and visual cues can be particularly important to children with developmental challenges in language and speech development.

Seeing faces is crucial for communication in children with hearing loss, who may have hampered word recognition in settings where people are masked. Children without hearing impairment may also have reduced word identification, particularly in noisy environments when the speaker is masked. Face masks also appear to impair recognition of emotions, trustworthiness and perceived closeness and may "undermine the success of our social

interactions." Another study found mask use limits the ability to read facially expressed emotions in people of all ages, particularly in 3-5- years-old.

WHO recommended against masking children ages 5 and younger, because this age group is at low risk of illness, because masks are not "in the overall interest of the child," and because many children are unable to wear masks properly. Even for children ages 6 to 11, the WHO did not routinely recommend masks, because of the "potential impact of wearing a mask on learning and psychosocial development."

Why did the CDC recommend masks for all children two and up?
An Italian study published in March 2021, found that masking is a barrier to speech recognition, hearing, and communication, and that masks impede children's ability to decode facial expressions, dampening children's perceived trustworthiness of faces. Why was this not considered when implementing mask mandates in children?
Research has suggested that hearing-impaired children have difficulty discerning individual sounds; opaque masks, of course, prevent lip-reading. Why were masks frequently used on these children and their teachers?
Some teachers, parents, and speech pathologists have reported that masks can make learning difficult for some of America's most vulnerable children, including those with cognitive delays, speech issues, and autism. Masks may also hinder language and speech development—especially important for students who do not speak English at home. Why were masks frequently used on these children and their teachers?
Masks may impede emotion recognition, even in adults, but particularly in children. When children were asked, many said that prolonged mask wearing is uncomfortable and that they dislike it. By the summer of 2022, babies and young children were suffering developmental delays, behavioral issues, and speaking less which some experts have attributed, at least partially, to mask wearing of children and their teachers. Why were masks used on very young children under the age of five?

Mask wearing may cause physiological harm, including breathing difficulties, headaches, dermatitis, and general discomfort which may have several negative downstream effects, including reduced time and intensity of exercise, additional sick days, reduced learning capacity, and increased anxiety. Were these factors considered when implementing mask mandates?

Public health interventions with clear downsides in children were implemented for long periods of time in the absence of high quality evidence such as randomized trials in children. There were also no clear endpoints or metrics given to end mandates. Why were known, expected and potential harms to children from masking not taken into account in the recommendation and implementation process?

Children face the least risk of COVID-19 and face the highest risk of harm from prolonged masking. Why were the youngest and most vulnerable children in the Head Start programs, overseen by the Department of Health and Human Services, some of the very last to be allowed to remove their masks in the Fall of 2022?

RIDOH MASK REGULATION HEARING

Suzanne Rei <zqrei63@gmail.com>

Thu 3/14/2024 2:19 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Zachary

I'm not sure if I am able to make the meeting tomorrow, but I would like to voice my statement against mask mandates on our children.

Mandatory is not Law it becomes law only if you allow it….I will not allow it…
Required is not law
God gave us the right to breath here on Earth….Man does not and will not take it from us..you want to wear a mask wear one, but do not force people to wear a mask, especially our children

I was never an anti vaxxer until covid 19 hit, since then I've opened my eyes to not trusting

1. Our government
2. So called elected {selected} officials
3. Science
4. CDC
5. FDA
6. Hospitals
7. Doctors

I have not seen a doctor for a few years now, and what I see is that they need to sell a product that health insurance pays them for every medicine, or procedure they provide, which big pharmaceuticals pays the health insurance…it a money scam that goes down the line.

Mask wearing is another medical induced procedure for doctors and big pharma to cash in on… mask hurts your health not protects your health…
Main symptons of CARBON DIOXIDE TOXICITY

1. Causes
    b. drowsiness
    c. mild narcosis
    d. confusion
    e. headache

3. Respiratory- shortness of breath
4. rash on covered area where the mask is worn
5. increases heart rate
6. slows your immune system
7. scientifically wearing a mask is inaccurate, because virologist measure covid 19 to be 80-180mm in size making the weave of material masks to be the equivalent of a chain-link fence to a mosquito.

Enough is Enough, stop with the fear mongering nonsense, this is a crime against humanity, and your trying to start with our children….
Gods children are not for Sale…

Thank you

Suzanne Rei

If you need additional information please feel free to email back anytime…

Proposed Mask Regulation for Schools

Carissa M <colink401@gmail.com>
Thu 3/14/2024 2:32 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (258 KB)
Stephen Petty Affidavit.pdf;

This Message Is From an External Sender
This message came from outside your organization.
Report Suspicious

I have to be honest when covid first showed up in March 2020 I would wear a mask to go to the grocery store, etc. Shortly after, I started to have some negative effects and so did my child. Such as exacerbated asthma symptoms, fainting and chronic rhinitis. This made me look into the pros and cons of masking. I scoured scientific medical journals and credible experts to see what evidence there was on the effectiveness of masking to mitigate viruses and if there were any potential harms.

What I found, and that I have attached to my testimony, was that masks are not an effective means and can even make one more likely to catch the flu or other viruses. One of the mentioned attachments comes from Industrial Hygienist Stephen Petty who has 30+ years experience regarding PPE and has been an expert witness in over 400 legal cases. He explains that a tight fitting N95 mask is at best 12% effective against covid and other viruses. The effectiveness of a cloth facial covering falls to 0 when there is a 3% of more open area in the edges around the sides. Did you really expect children as young as 2 yrs old to wear masks and not touch them? On average, per the CDC, an adult touches their face 23 times. When I tried to discuss this with decision makers, I was met with animosity instead of an open conversation.

I find it disheartening that the agency whose mission is to prevent disease and protect and promote the health and safety for Rhode Islanders, is not basing its decisions on all available scientific evidence. The preposterous language in the original proposed masking regulation stated in Section 4.3B, "An absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the Department from considering a face mask requirement." That sounds absolutely absurd and I'm thankful we had legal representation that forced the removal of this language. The new proposed regulation says it will take into account the "effectiveness, disadvantages and side effects of masking". Let the record show parents did receive a ruling from Judge Lanphear that masking our children caused irreparable harm. I'm sure many can agree that the impression RIDOH is giving us is of an agency that is inept. Employees making decisions affecting the population should be critical thinkers and researchers. I'm not so sure that is the case after the testimony received in court from the previous, acting Director, Dr McDonald, who admitted that he just took orders from the CDC without reading any of the primary sources and data. If any future mask mandate for schools is going to be the final decision of the Director for RIDOH as referenced in Section 4.3C, then they better review the available information firsthand. Parents should not have had to go through the trouble and financial burden of obtaining a lawyer to have a public agency do their job and follow the proper regulatory process. We were expected to follow all of the rules yet those in leadership didn't. I hope going forward this will change but we are ready to unite and protect our kids again if need be.

Carissa Moglia

https://www.sciencedaily.com/releases/2015/04/150422121724.htm [sciencedaily.com]

https://www.cdc.gov/hygiene/personal-hygiene/face.html [cdc.gov]

EXHIBIT O

AFFIDAVIT OF STEPHEN E. PETTY, P.E., C.I.H., C.S.P.

Before me, the undersigned authority, on this day personally appeared STEPHEN E. PETTY ("Affiant") who, being by me first duly sworn, deposes and says:

1. I am an adult in sound mind and body and have personal knowledge of the fact averred herein.

2. Since April 14, 1996, I have owned and operated EES Group, Inc., a consultancy corporation specializing in health and safety and forensics.

3. I hold relevant industry certifications including board certifications as a C.I.H. (Certified Industrial Hygienist), a C.S.P. (Certified Safety Professional), and a P.E. (Professional Engineer) in six states (Florida, Kentucky, Ohio, Pennsylvania, Texas, and West Virginia). My curriculum is attached hereto as **Exhibit i**.

4. I have served as an expert in personal protective equipment and related disciplines in approximately 400 legal cases. I am certified in and have provided testimony as an expert in these areas. My list of representative cases is attached hereto as **Exhibit ii**.

5. For example, I am currently serving as an expert in the Monsanto Roundup and 3M PFAS litigation. Recently I testified in four trials for the DuPont C8 litigation.

6. I taught Environmental and Earth Sciences as an adjunct professor at Franklin University.

7. I hold nine U.S. patents relating to heating, ventilation and air conditioning (HVAC) systems.

8. I am a current member in good standing of the following relevant associations: American Industrial Hygiene Association (AIHA), American Board of Industrial Hygiene (ABIH), American Conference of Governmental Industrial Hygienists (ACGIH), American Institute of Chemical Engineers (AIChE), American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE); Member ASHRAE 40 Std. and TC 2.3, and Sigma Xi.

9. I am an expert in the field of Industrial Hygiene, which is the science and art devoted to the anticipation, recognition, evaluation, and control of those environmental factors or stressors — including viruses — arising in or from the workplace, which may cause sickness, impaired health and well-being, or significant discomfort among workers or among the citizens of the community.

10. Industrial Hygiene is fundamentally concerned with the proper methods of mitigating airborne/dermal hazards and pathogens, as well as with the design and use of engineering controls, administrative controls, and personal protective equipment, among other things.

Affidavit of Stephen E. Petty, P.E., C.I.H., C.S.P.

11. Medical doctors, virologists, immunologists, and many public health professionals are not qualified experts in these areas by virtue of those aforementioned credentials.

12. On May 7, 2021, the Centers for Disease Control (CDC) updated its guidance, providing that the primary mechanism for transmission of Covid-19 is through airborne aerosols, and not, as previously stated, by touching contaminated surfaces or through large respiratory droplets, as also stated during previous periods of the pandemic.

13. Airborne viral aerosols can consist of a single viral particle or multiple viral particles clumped together, and usually smaller than 5 μ (microns) in size. By comparison, droplets are >5 μ to >10 μ in size.

14. The area of a micron by a micron is approximately 1/4,000th of the area of the cross-section of a human hair and 1/88th the diameter of a human hair. Covid particles are 1/10 of a micron or ~1/40,000th of the area of a cross section of a human hair and ~1/880th the diameter of a human hair.

15. A recent University of Florida study capturing air samples within an enclosed automobile cabin occupied by a Covid-positive individual showed that the only culturable Covid-19 virus samples obtained were between 0.25μ to 0.5μ in size. Particles smaller than 5μ are considered very small and/or very fine or aerosols.

16. Very small particles do not fall by gravity in the same rate that larger particles do and can stay suspended in still air for a long time, even days to weeks.

17. Because they stay suspended in concentration in indoor air, very small particles can potentially accumulate and become more concentrated over time indoors if the ventilation is poor.

18. Very small airborne aerosols pose a particularly great risk of exposure and infection because, since they are so small, they easily reach deep into the lung. This explains in part why Covid-19 is so easily spread, and why so little Covid-19 is required for infection.

19. Exposure to airborne aerosols is a function of two primary parameters: concentration and time. Less is better regarding both parameters.

20. For many reasons, personal protective equipment (PPE) is the least desirable way to protect people from very small airborne aerosols. Moreover, masks are not PPE since they cannot be sealed and do not meet the provisions of the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard (RPS), namely 29 CFR 1910.134.

21. Regarding PPE, facial coverings do not effectively protect individuals from exposure to very small airborne aerosols. A device referred to as a respirator is required to provide such protection.

Affidavit of Stephen E. Petty, P.E., C.I.H., C.S.P.

22. The AIHA, in their September 9, 2020 Guidance Document for COVID-19 (**Exhibit iii**) noted that the acceptable relative risk reduction methods must be ≥90%; masks were shown to be only 10% and 5% (see Exhibit iii - Figure 2) and far below the required 90% level.

23. Similarly, Shah et al, 2021 (**Exhibit iv**), using ideally sealed masks and particles 1 micron in size, reported efficiencies for the more commonly used cloth masks and surgical masks of 10% and 12% respectively. No mask can be perfectly sealed, thus "real world" effectiveness would be even lower.

24. Industrial hygienists refer to a "Hierarchy of Controls" that are typically implemented to minimize exposures, including exposures to very small airborne aerosols like Covid-19.

25. Regarding practical or "engineering" controls, industrial hygienists focus on practices that dilute, destroy, or contain airborne hazards (or hazards in general).

26. PPE — especially facial coverings — do not dilute, destroy, or contain airborne hazards. Therefore, facial coverings are not contained in the Industrial Hygiene (IH) Hierarchy of Controls. Even respirators (part of the PPE Category and not masks) are in the last priority on the Hierarchy of Controls.

27. Facial coverings are not comparable to respirators. Leakage occurs around the edges of ordinary facial coverings. Thus, ordinary facial coverings do not provide a reliable level of protection against inhalation of very small airborne particles and are not considered respiratory protection.

28. For example, during the seasonal forest fires in the summer of 2020, the CDC issued public guidance warning that facial coverings provide no protection against smoke inhalation. That is because facial coverings do not provide a reliable level of protection against the small particles of ash contained in smoke. Ash particles are substantially larger than Covid-19 aerosolized particles.

29. I have reviewed the Mayfield City School District (MCSD) "Protective Facial Covering Policy During Pandemic/Endemic Events" as set forth in the Policy Manual of the MCSD Board of Education.

30. Ordinary facial coverings like the ones required by the MCSD facial covering policy do not meet any of the several key OSHA Respiratory Protection Standards for respirators.

31. Because of the gaps around the edges of facial coverings required by MCSD's policy, they do not filter out Covid-19 aerosols. The policy stating masks will be worn without gaps defies known science that masks worn today cannot be sealed and always have gaps.

32. The effectiveness of a cloth facial covering falls to zero when there is a 3% or more open area in the edges around the sides of the facial covering.

33. Most over-the-counter disposable facial coverings have edge gaps of 10% or more. When adult-sized facial coverings are used by children, edge gaps will usually greatly exceed 10%.

Affidavit of Stephen E. Petty, P.E., C.I.H., C.S.P.

32. Even short breaks (e.g. to eat) expose individuals to Covid-19 aerosols in indoor spaces.

33. Ordinary cloth facial coverings like the ones required by the MCSD mask requirement do not provide any filtering benefit relative to particles smaller than 5μ if not sealed.

34. Substantial mitigation of Covid-19 particles could be immediately achieved by:

a. opening windows and using fans to draw outdoor air into indoor spaces (diluting the concentration of aerosols),

b. setting fresh air dampers to maximum opening on HVAC systems,

c. overriding HVAC energy controls,

d. increasing the number of times indoor air is recycled,

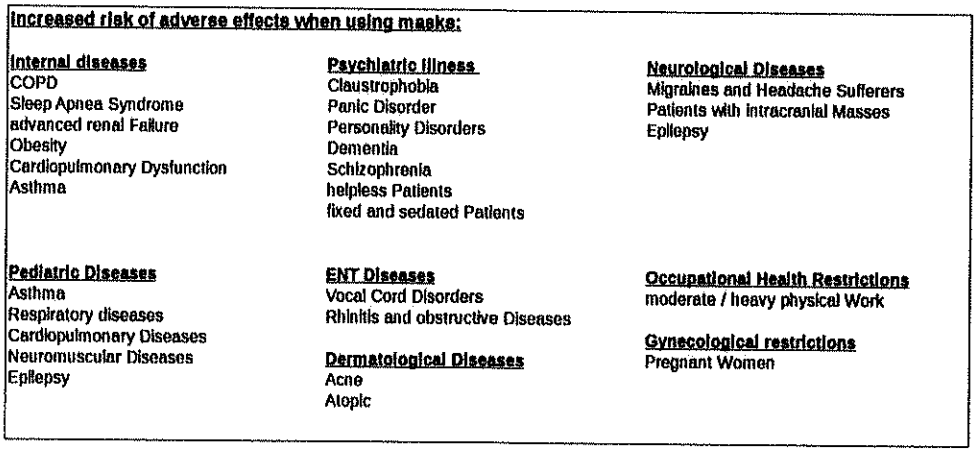
e. installing needlepoint ionization technology to HVAC intake fans, and

f. installing inexpensive ultraviolet germicide devices into HVAC systems.

35. All of the above-referenced techniques are more effective and meet standard industrial hygiene hierarchy of controls (practices) for controlling exposures in place for nearly 100 years. The use of cloth facial coverings do not fit within these basic hierarchy of controls since masks are not PPE and cannot be sealed. There are no OSHA standards for facial coverings (masks) as respiratory protection.

36. Extended use of respiratory PPE is not indicated without medical supervision.

37. As explained in an article titled "Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?" that was published on April 20, 2021, in the *International Journal of Environmental Research and Public Health* and that is attached to this Affidavit as **Exhibit v**, the following negative effects from wearing masks was reported in the literature:



Increased risk of adverse effects when using masks:

Internal diseases
COPD
Sleep Apnea Syndrome
advanced renal Failure
Obesity
Cardiopulmonary Dysfunction
Asthma

Psychiatric illness
Claustrophobia
Panic Disorder
Personality Disorders
Dementia
Schizophrenia
helpless Patients
fixed and sedated Patients

Neurological Diseases
Migraines and Headache Sufferers
Patients with intracranial Masses
Epilepsy

Pediatric Diseases
Asthma
Respiratory diseases
Cardiopulmonary Diseases
Neuromuscular Diseases
Epilepsy

ENT Diseases
Vocal Cord Disorders
Rhinitis and obstructive Diseases

Dermatological Diseases
Acne
Atopic

Occupational Health Restrictions
moderate / heavy physical Work

Gynecological restrictions
Pregnant Women

Figure 5. Diseases/predispositions with significant risks, according to the literature found, when using masks. Indications for weighing up medical mask exemption certificates.

Example statements made in the paper include the following: "The overall possible resulting measurable drop in oxygen saturation (O2) of the blood on the one hand and the increase in carbon dioxide (CO2) on the other contribute to an increased noradrenergic stress response, with heart rate increase and respiratory rate increase, in some cases also to a significant blood pressure increase." Exhibit v, p. 25. In fact, "Neither higher level institutions such as the WHO or the European Centre for Disease Prevention and Control (ECDC) nor national ones, such as the Centers for Disease Control and Prevention, GA, USA (CDC) or the German RKI, substantiate with sound scientific data a positive effect of masks in the public (in terms of a reduced rate of spread of COVID-19 in the population)." Exhibit v, p. 24, for these reasons, students who are required to wear masks pursuant to a mandate suffer immediate and irreparable injury, loss, or damage.

38. In summary:

a. PPE is the least desirable way to protect people from very small airborne aerosols.

b. Facial coverings as required by the MCSD policy are not recognized as PPE since they cannot be sealed and are not covered by the OSHA RPS.

c. If PPE were to be used for protection, respirators, not facial coverings as required by the MCSD policy are needed to provide any effective protection from very small airborne aerosols.

d. Very small aerosol particles are more likely to be a greater cause of disease than respiratory droplets because they can evade PPE and reach deep into the lungs, whereas respiratory droplets have to work against gravity in order to travel up a person's nose into the sinus.

Affidavit of Stephen E. Petty, P.E., C.I.H., C.S.P.

e. Much better alternatives to controlling exposure are available (i.e., engineering controls of dilution – ventilation with increased fresh air and destruction), and should be used to minimize exposures as opposed to masks.

f. Individuals who are required to wear masks pursuant to a mandate suffer immediate and irreparable injury, loss, and damage due to the overall possible resulting measurable drop in oxygen saturation of the blood on one hand and the increase in carbon dioxide on the other, which contributes to an increased noradrenergic stress response, with heart rate increase and respiratory rate increase and, in some cases, a significant blood pressure increase.

Stephen Petty

Stephen Petty, P.E., C.I.H., C.S.P.

STATE OF OHIO

COUNTY OF FRANKLIN

Sworn to and subscribed before me this 1st day of September, 2021, by Stephen Petty, ( ) who is personally known to me or ( ) who produced FL! drivers license as identification.

Lori A. Jones

NOTARY PUBLIC, State of Ohio

Commission No.

My commission expires: 2-3-2026

LORI A JONES
Notary Public
State of Ohio
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Cloth masks: Dangerous to your health?

Date: April 22, 2015

Source: University of New South Wales

Summary: Respiratory infection is much higher among healthcare workers wearing cloth masks compared to medical masks, research shows. Cloth masks should not be used by workers in any healthcare setting, authors of the new study say.

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FULL STORY

The widespread use of cloth masks by healthcare workers may actually put them at increased risk of respiratory illness and viral infections and their global use should be discouraged, according to a UNSW study.

The results of the first randomized clinical trial (RCT) to study the efficacy of cloth masks were published in the journal *BMJ Open*.

The trial saw 1607 hospital healthcare workers across 14 hospitals in the Vietnamese capital, Hanoi, split into three groups: those wearing medical masks, those wearing cloth masks and a control group based on usual practice, which included mask wearing.

Workers used the mask on every shift for four consecutive weeks.

The study found respiratory infection was much higher among healthcare workers wearing cloth masks.

The penetration of cloth masks by particles was almost 97% compared to medical masks with 44%.

Professor Raina MacIntyre, lead study author and head of UNSW's School of Public Health and Community Medicine, said the results of the study caution against the use of cloth masks.

"Masks are worn to protect from infection during pandemics and outbreaks, especially when there are no drugs or vaccines available for protection," Professor MacIntyre said.

"Masks are especially important for frontline doctors and nurses, as their protection from infection is key to maintaining the ability to tackle a pandemic effectively.

"We should be cautious about cloth mask use in healthcare settings, particularly high-risk situations such as emergency departments, intensive care, paediatric or respiratory wards."

Cloth masks remain widely used globally because they are a cheaper option especially in areas where there are shortages of protective equipment, including in Asian countries, which have historically been affected by emerging infectious diseases, as well as in West Africa, which was the epicentre of the recent Ebola epidemic.

The authors speculate that the cloth masks' moisture retention, their reuse and poor filtration may explain the increased risk of infection.

Professor MacIntyre, who has completed the largest body of clincial trial research on respiratory protection in health workers internationally, said emerging infectious diseases are not constrained within geographical borders.

"Effective controls of outbreaks and pandemics at the origin impacts us directly, so it is important for global disease control that the use of cloth masks be discouraged in high-risk situations," she said.

"Despite more than half the world using cloth masks, global disease control guidelines, including those from the World Health Organisation, fail to clearly specify conditions of their use.

"These guidelines need to be updated to reflect the higher infection risk posed by cloth masks, as found in our study."

Professor MacIntyre said the study's results pointed to the effectiveness of medical masks, in addition to the harm caused by cloth masks.

"Additional research is urgently needed to build on our study's findings."

The trial was a collaboration between researchers in Australia and the National Institute for Hygiene and Epidemiology in Vietnam and was funded by an Australian Research Council Linkage Grant.

A separate expert review by Professor MacIntyre published in the *British Medical Journal* earlier this month found that the lack of research on facemasks and respirators is reflected in varied and sometimes conflicting global policies and guidelines.

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Story Source:

Materials provided by **University of New South Wales**. Original written by Dan Wheelahan. *Note: Content may be edited for style and length.*

Journal Reference:

1. C. R. MacIntyre, H. Seale, T. C. Dung, N. T. Hien, P. T. Nga, A. A. Chughtai, B. Rahman, D. E. Dwyer, Q. Wang. **A cluster randomised trial of cloth masks compared with medical masks in healthcare workers**. *BMJ Open*, 2015; 5 (4): e006577 DOI: 10.1136/bmjopen-2014-006577

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University of New South Wales. "Cloth masks: Dangerous to your health?." ScienceDaily. ScienceDaily, 22 April 2015. <www.sciencedaily.com/releases/2015/04/150422121724.htm>.

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Water, Sanitation, and Environmentally Related Hygiene (WASH)

APRIL 16, 2024

Healthy Habits: Facial Cleanliness

KEY POINTS

- Washing your face regularly prevents disease.
- Use soap and clean, running water to remove dirt, oil, and more from your face.



Overview

Many diseases and conditions can be prevented or controlled through appropriate personal hygiene and by frequently washing the face. Appropriate facial hygiene practices include not only washing the face, but also properly caring for teeth, mouth, eyes, contact lenses, and ears.

Think before touching your face

Your hands can make your face dirty. Thinking before touching your face can help stop the spread of germs. On average, people touch their faces 23 times per hour. Unwashed hands can easily spread germs to your face after touching contaminated surfaces or objects.

Protect yourself by:

- Washing your hands at key times (such as before touching your face or putting in contact lenses)
- Using a tissue for your nose
- Using a tissue to scratch or rub your eyes or to adjust your glasses.

You can also prevent itchiness by using facial moisturizer for dry skin and eye drops for dry eyes.

Keep your face clean to help prevent some diseases

Respiratory illnesses can be caused by many different bacteria and viruses. Typically, respiratory infections like the common cold, flu, and COVID-19 can spread through droplets in the air when an infected person coughs or sneezes. They can also be spread by direct contact with bacteria, viruses, and other disease-causing germs. When you touch your face, the germs on your hands can enter your body through your nose, eyes, and mouth, making you sick. Protect yourself by washing your hands before touching your face and by washing your face regularly.

Pink eye (conjunctivitis) spreads easily from person to person. Good hygiene practices, such as handwashing, face washing, and not touching or rubbing eyes, are important for limiting the spread of pink eye.

SOURCES

CONTENT SOURCE:

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

No Mask Mandates

Corey Newkirk <corey.newkirk@gmail.com>

Thu 3/14/2024 2:33 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Hello,

Your mask mandates were extremely unhealthy and violated my personal freedom. I could not breathe in masks. I got dizzy and felt panicked. When I went without a mask to preserve my personal health, others, who had seemingly lost their sense of humanity from all of the talk of distancing and shut downs, and were rude and cruel to me citing your misinformation, or perhaps disinformation, as the case may be.

My kids suffered because of them. They felt alienated. My neighbor's young children came home from school with rashes on their faces and had no opportunity to heal because they had to live in masks at school week after week.

I implore you not to ever attempt to impose a mask mandate again. It is not in the public's best interest, and there is no genuine argument citing true data that can be made to say that it is. Do the right thing.

Corey Newkirk
South Kingstown

My name is Kiela Daley and I am a mother of five children, currently 17,15,13,11 and 8 years old. I have wanted to be a Mom for as long as I can remember. I dreamt of having a large family. I am beyond blessed that my husbands hard work and sacrifice has allowed me to stay home and my full time job has been raising them. I have taken this job very seriously. I was only 25 years old having my first child and it hit hard coming home from the hospital realizing that I was in charge of this precious child's life. I still felt like a kid myself and the weight and responsibility of this Childs wellbeing was on my shoulders, I knew I was going to do everything in my power to keep this child safe, protected, loved and well cared for. I was blessed to have 4 more children and the sentiment was the same for all of them. They are 5 very different children. Their personalities , temperaments, wants, needs are so vastly different. I had one child wean off breast-feeding at 10 months old and another not until she was 4.5 years old. I have tried to cater to their own individual needs since infancy. I have tried to do what is best for each of my children based on their needs and based on what I believe to be in their best interest.

I would always discuss their health with our trusted pediatrician whose been in our family forever . I chose not to give every vaccine they offered. I chose to hold off on antibiotics numerous times. We constantly discussed pros and cons, facts, evidence and I took all this science into account when making any health decisions for my children and then…Covid hits.

Covid hits and then all science, evidence, facts, reasoning, logic goes out the window for those in the Government. For you the RIDOH.

BUT not for me. My parenting and philosophies remanded the same. However my rights were now being stripped from me. My children's heath and wellness was now supposed to be handled by you? THE RIDOH.

Facts: Covid was not affecting children, no children were dying, no children were even being hospitalized ! I spoke in great length to my pediatrician throughout all of Covid times and not once did he or anyone in his entire practice send a child to ER due to covid.

The regulations and mandates put in place by the RIDOH did not follow any science. You did not follow any regular rule making legal procedures. You chose to impose masking on school aged children with zero scientific evidence that masking even worked . Your first publication of the rule proposed, stated (and I quote)

"An absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the Department from considering a face mask requirement"

EVEN after all that we know now, you are STILL choosing to not use SCIENCE?

Im sorry , what? If the RIDOH isn't going to use SCIENCE based evidence to make decisions what ARE you using and basing your mandates on?? You have demonstrated your ability to abuse your power and take zero responsibility and accountability . At the the expense of MY CHILDREN. It is very clear that the RIDOH has never had safety or evidence based science justifying the abuse that was put upon children.
MY CHILDREN. The same 5 kids that I have literally spent every waking moment of my life caring for. The same 5 that no one knows more deeply than their own mother. The same 5 that I had to watch handle wearing a mask affect them all so differently but NONE being in a positive light. I had to chose the lesser of two evils. To go against what I knew was right and make them mask and go to school /sports so they could have some sense normalcy and socializing or I had to keep them home and isolated and they were miserable! Their mental health was deteriorating at such a rapid pace that caused such internal turmoil and anxiety that

I had daily panic attacks. In the end I chose to allow them to go to school/sports and we had many many discussions about how we all had to “play the game’ for now until TRUTH won over government control. They saw for themselves how they were NEVER in danger with Covid. A Virus so deadly you don’t even have any symptoms ?? hmmmm A virus so contagious that you wear a mask to enter a restaurant but take it off after sitting 5ft away at your table? A virus that comes out at 10pm? A virus so awful that an old navy mask worn around your chin helps protect?
They knew that their MOM had their well-being in mind, that I had demonstrated for years that my job was to protect them and to keep them safe. They knew that what I was protecting them from wasn’t some virus but instead it was for their freedom. It was protecting their bodily rights. It was preserving the parental voice and ability to care for your own children. They knew I would never stop fighting for them. I will never stop fighting for my children .I will protect them with everything that I have. I will continue to use logic and science and research and PRAYER to help guide my decisions when it comes to my children’s physical and mental health. I will NEVER EVER again put a mask on my child, especially KNOWING that the RIDOH and the government DO NOT use scientific evidence to decide what’s best for my children.

Testimony pdf

Kiela Daley <sassa419@hotmail.com>

Thu 3/14/2024 2:44 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (22 KB)

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ASSOCIATES in Oral & Maxillofacial Surgery

Stephen T. Skoly, Jr., DMD

America's response to the COVID-19 pandemic and its misguided strategies failed on many levels. While not to minimize the tragic and unavoidable deaths associated with a pandemic, many formally trusted public health agencies including the CDC, WHO and NIH failed to follow the many years of trusted science.

While the COVID cover-up began in China, COVID chaos continued in the United States. Unchecked government tyranny can never happen again. On many levels even the Rhode Island Department of Health failed to "follow the science". Pseudoscience and unlawfully enacted mandates can never again be imposed on the citizens of Rhode Island.
Finally, a pandemic does not preclude the United States Constitution. It is imperative that false government narratives be appropriately challenged.

With permission I have included Chapter 10 of the Norfolk Group's questions for a COVID-19 Commission recently presented to Congress. This Chapter reviews the science of masking mandates.

Please feel free to contact me should any questions remain.

Respectfully Submitted,

Dr. Stephen T. Skoly

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Chapter Ten | Masks

Background

Public mask use was rare in the United States before the COVID-19 pandemic. On April 3, 2020, the CDC began recommending face coverings, including both cloth and surgical masks, for everyone two years old and up. The CDC cited no evidence for the efficacy of masks and the previous lack of evidence on efficacy of mask wearing for other respiratory viruses was ignored or distorted. During the pandemic, universal and school-masking became increasingly controversial and polarized.

In supporting mask mandates for people ages 2 and up, the CDC and other government officials: 1) Exaggerated the benefits of masks based on pre-pandemic studies, 2) Promoted studies that supported masking recommendations/mandates, while ignoring or censoring those that did not, 3) Did not fund randomized controlled trials to determine the efficacy of masking, 4) Failed to explain why masking recommendations were not aligned with many European countries, especially for children, and 5) Failed to acknowledge potential harms of masking, especially for children.

Randomized Mask Studies

Randomized controlled trials (RCTs) are the gold standard in medical research.

Prior to the COVID-19 pandemic, the evidence that masks did little if anything to stop the spread of respiratory viruses was uncontroversial. A meta-analysis of 14 randomized controlled trials *"did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility."* A Cochrane analysis of nine trials stated that *"the pooled results of randomized trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."* RCTs conducted in healthcare workers found that surgical masks provided questionable benefit against respiratory pathogens, including the common cold. Another RCT published in 2010 investigating the use of masks as source control found no difference in infection rates of household contacts between masked and unmasked groups. In light of this research, why did public health officials and agencies promote the idea that masks would be effective against SARS-CoV2? Why did they start recommending and mandating surgical masks to prevent SARS-CoV2 transmission?

Few RCTs have evaluated the effectiveness of cloth masks. The results from the first concluded that *"cloth masks should not be recommended for health care workers"*. If they are not effective for hospital staff, why were they recommended for the public?

In March 2021, a research team in Denmark published the first RCT of mask effectiveness against SARS-CoV2 transmission. To the extent that the study was powered, there was no significant reduction in SARS-CoV2 and other respiratory viral infections for those wearing surgical masks compared to unmasked controls. Why was this study ignored or dismissed by the CDC and other U.S. public health agencies?

In August, 2021, a second randomized mask study was published, eventually appearing in Science. Rural Bangladeshi villagers were randomized to wear cloth masks, surgical masks or no masks. With a p-value slightly below 0.05, masks reduced short-term transmission by between 0% and 18% (95% confidence intervals), suggesting that the masks had marginal or no impact on COVID-19 transmission. A

subsequent reanalysis of the data found an even weaker effect. Why was this study used to justify the continuation of mask policies? Why did mainstream media outlets exaggerate the results of this study to claim that masks are highly effective against SARS-CoV-2 transmission?

Why did neither CDC nor NIH/NIAID conduct or fund large RCTs to compare transmission rates between masked individuals, households, schools and/or workplaces to unmasked controls groups and to groups wearing different mask types? This would have provided strong evidence as to whether masks prevent viral transmission in different community settings, which masks (if any) were most effective, and whether mask wearing was warranted.

Observational Mask Studies

Observational studies of individuals can provide valuable information when they are well conducted and properly adjust for potential confounders. Non-randomized research studies based on geographically related groups (ecological data) rather than individuals are prone to bias, and more suitable for hypothesis generation than hypothesis evaluation.

Before the pandemic, there was not much evidence that cloth masks were effective against respiratory viruses. One study concluded that *"the use of fabric materials may provide only minimal levels of respiratory protection to a wearer against virus-size submicron aerosol particles (e.g. droplet nuclei). This is partly because fabric materials show only marginal filtration performance against virus-size particles when sealed around the edges. Face seal leakage will further decrease the respiratory protection offered by fabric materials."* Despite such evidence, why were cloth masks encouraged rather than discouraged as protection against Covid-19?

In a May 2020 paper about masking in hospital settings, Dr. Mike Klompas, a Harvard professor and hospital epidemiologist, wrote that *"we know that wearing a mask outside health care facilities offers little, if any, protection from infection…In many*

cases, the desire for wide spread masking is a reflexive reaction to anxiety over the pandemic." Why did Dr. Anthony Fauci and the CDC come to a different conclusion? Did they recommend and mandate masks to reduce anxiety amongst the public?

In July, 2020, CDC published its first study on mask efficacy against COVID-19. In this study, two hairstylists tested positive for SARS-CoV2 yet did not infect any of their patrons. The authors concluded that the lack of transmission was due to consistent adherence to masking on the part of the hairstylists. However, viral loads were not tested, and in an early study of household transmission, the secondary attack rate was only 19%. Therefore, regardless of masking, there was a low probability of spread and, despite the positive test, it is possible that viral levels were too low to be infectious. Furthermore, this study consisted of a sample size of two and no control group. Why was this report considered strong evidence of mask effectiveness?

In January 2021, the CDC published a study from Wood County, Wisconsin, which found lower transmission rates in schools, where masks were commonly used, compared to the community at large. Despite the lack of a comparative unmasked control group, why did the CDC and the Secretary of Education use this study as evidence that masks are effective? Schools in Norway that did not mask students <12 also saw similarly low transmission levels during the same time period. Was the possibility that children transmit less frequently than adults, rather than mask mandates, considered as an explanation to why schools had relatively low transmission rates?

In the summer of 2021, Duke University produced a report claiming that *"widespread use of masks in schools can effectively prevent COVID-19 transmission"*, which was then promoted by *The New York Times.* The study found that within-school transmission was very low, which the authors concluded was due to universally implemented mask mandates. However, the study had no control group of schools that did not mandate masks. Considering that Sweden had very low in-school transmission without masking children, a more plausible explanation is that children

are less prone to spread COVID-19 than adults. Why did Duke University and *The New York Times* promote such a fundamentally flawed study?

In September 2021, the CDC published a mask study conducted in Arizona, comparing school districts with and without mask mandates. The study was not randomized and did not control for important confounders such as vaccination rates in the community; it used a longer period of data collection time for masked districts (14% longer); and, it used an inappropriate definition of "outbreak" (2 or more cases in 14 days) that biased numbers against large school districts, of which only 11% had mask mandates, and in favor of small district, of which 52% had mask mandates. Despite its obvious and serious methodological flaws, why did Dr. Walensky and the media use this study to claim that unmasked districts had higher rates of COVID?

A CDC study published in October, 2021, compared U.S. counties with and without school mask mandates, concluding that masking reduced pediatric infection rates. Such ecological studies are very prone to bias, since both mask mandates and the seasonality of COVID-19 are regional. Therefore, it was not surprising that a follow up study that used the same methodology as the original study, but simply extended the study period and included more counties, concluded that masks did not affect pediatric case rates. Why did the CDC publish this heavily flawed study and base public health policy on it? When the extended follow-up study was published, why did CDC ignore it?

In November 2021, the British Medical Journal published a systematic review of observational mask studies conducted during the pandemic. From their meta-analysis, the authors concluded that mask wearing reduced COVID-19 infection by 53%. However, this conclusion was based on six studies with moderate to critical bias because they did not control for variables such as simultaneous changes in behavior, activities, and the use of other mitigation measures. Why were these studies frequently used as support for implementing mask mandates?

Ecological studies are slightly better when comparing neighboring districts, such as (i) an earlier CDC study conducted in the fall of 2020 in Georgia that showed that student

masking did not significantly reduce transmission in school, or (ii) a 2022 study in Fargo, North Dakota, that *"suggests school-based mask mandates have limited to no impact on the case rates of COVID-19 among K-12 students."* Did the CDC set masking policies based on cherry-picked studies while ignoring others that did not have the desired outcome?

The best observational study of masks in children was published in March 2022. Using a quasi-experimental design, Spanish researchers compared school children aged 6, who were subject to a mask mandate, with children aged 5, for whom masks were not mandated. They found no significant difference in COVID-19 rates and concluded that *"mask mandates in schools were not associated with lower SARS-CoV-2 incidence or transmission, suggesting that this intervention was not effective."* In April 2022, in another study looking at mask mandates, in Finland, there was no difference in pediatric case rates between children in communities with and without mask mandates. Why did the CDC ignore these studies?

In May 2022, another Duke University study evaluated whether schools with or without mask mandates had a higher proportion of secondary (school acquired) versus primary (community acquired) COVID infections. The classification of primary versus secondary transmission was conducted by school health staff. Masked school districts, however, did not generally consider masked students to be potential contacts during tracing because of CDC guidelines which stated that *"the close contact definition excludes students who were between 3 to 6 feet of an infected student if both the infected student and the exposed student(s) correctly and consistently wore well-fitting masks the entire time."* This would lead to in-school transmission cases in districts with mask mandates being overlooked by contact tracers and incorrectly considered community transmission, giving falsely low rates of secondary transmission in districts with mask requirements. Despite its obvious and serious methodological flaws, why did the NIH promote this study, claiming that mandatory masking in schools reduced COVID-19 cases?

In November 2022, the New England Journal of Medicine published a study claiming that the lifting of masking requirements was associated with additional COVID-19 cases. The study compared COVID-19 incidence in two school districts with sustained mask mandates throughout the school year, with 70 school districts that ended mask mandates during the first, second or third week of March, 2022. Districts that ended mask mandates on the second week (n=17) had many more cases than those ending mandates on the first (n=46) or third week (n=7) of March, which in turn had more than the two districts that kept mandates in place (n=2). The difference between the 2nd and 1st/3rd week can only be explained by confounding, and in the presence of such major confounding, no reliable conclusions can be made about the districts with continued mask mandates. While the authors' difference in difference technique can be useful to adjust for covariates that remain constant over time to infer causality, it does not adjust for critical time-varying confounders such as population immunity levels, which have different temporal patterns in different locations in this study. Further, since observations within the same school district are dependent, the statistical analysis should have been done at the district level rather than individual student/staff level. With n=2 city districts still masking and n=70 more suburban districts no longer masking, it was epidemiologically inappropriate to conclusively attribute district case rate differences to a change in mask policy. Why did the journal publish such a flawed study? Why did media promote this flawed research study uncritically?

Exaggerating Mask Effectiveness

In February-March 2020, mask use began to increase among the general public. Unless they had COVID-19, public health officials were quick to discourage this trend, including CDC Director Robert Redfield, NIH/NIAID Director Anthony Fauci and the U.S. Surgeon General Jerome Adams. Dr. Anthony Fauci gave the same advice to close associates in private, saying that *"the typical mask you buy in the drug store is not really effective in keeping out*

virus, which is small enough to pass through the material." In April 2020, the official public health message suddenly changed.

On April 3rd, 2020, CDC recommended face masks for people who were confirmed or suspected to have COVID-19: *"You should wear a facemask when you are around other people (e.g., sharing a room or vehicle) or pets and before you enter a healthcare provider's office. If you are not able to wear a facemask (for example, because it causes trouble breathing), then people who live with you should not stay in the same room with you, or they should wear a facemask if they enter your room."* Why did they make this recommendation without citing any high quality evidence in support of the efficacy of face masks for prevention or transmission of respiratory viral infections?

CDC information guidance provided to healthcare workers continued to contradict recommendations for the general public, for example stating that *"face masks protect the wearer from splashes and sprays."* while *"respirators, which filter inspired air, offer respiratory protection."* Why did the CDC recommend surgical and cloth face masks for the general public while at the same time informing healthcare workers that facemasks do little to filter inspired air or offer protection from respiratory viral infection?

On September 17, 2020, CDC director Robert Redfield said *"I might even go so far as to say that this face mask is more guaranteed to protect me against COVID than when I take a COVID vaccine"*. Why did Dr. Redfield exaggerate the benefits of masks? Why did the CDC Director lower confidence in COVID-19 vaccines before vaccine trial data were even available?

Double masking was endorsed by NIH/NIAID Director Anthony Fauci and CDC Director Rochelle Walensky, presumably based on a single study published by CDC in March, 2021, in which the authors cautioned that *"the findings of these simulations should neither be generalized to the effectiveness of all medical procedure masks or cloth masks nor interpreted as being representative of the effectiveness of these*

masks when worn in real-world settings." Why did Drs. Fauci and Walensky recommend double masking based only on simulated rather than real-world data?

On October 29, 2021, CDC director Rochelle Walensky stated that *"the evidence is clear"* that masking *"can reduce your chance of infection by more than 80%, whether it's from the flu, the coronavirus or even just the common cold."* What evidence did she use to make this conclusion, which appears to greatly exaggerate the benefits of masks?

CDC promoted a 350% reduction in "outbreaks" based on their flawed Arizona school mask mandate study whereas other positive studies have shown at most a 2% to 25% reduction in transmission rates. Why did health officials continue to cite low quality studies instead of citing the only two randomized COVID mask trials from Denmark and Bangladesh, both conducted pre-vaccination, which showed zero or minimal efficacy of public mask use against SARS-CoV2?

Why were some studies showing masks as not effective at curbing viral spread, such as Cochrane influenza studies, censored?

Did people engage in behavior that increased their chances of contracting the virus because they had a false sense of security that they would be fully protected by masking?

Mask Mandates

In addition to mask recommendations, many governments, schools, universities, and businesses instituted mask mandates.

Why did some American schools mandate masks for children two and up, while WHO recommended against masking children under the age 6 and the European Centers for Disease Control recommended against masks for children 12 and under?

Why did Head Start, a federal program serving preschool-age children from low-income families, maintain a mask requirement longer than any other setting?

Why were masks mandated on public transportation such as buses, trains and airplanes without any scientific studies showing their efficacy in such settings?
Were there any discussions about the ethics and wisdom of imposing mask mandates based on weak studies while ignoring higher quality studies showing that masks made little or no difference in COVID-19 spread?
When the legality of Connecticut school mask mandates were questioned in court, the State argued and the Connecticut Supreme Court "wrestled" over whether the legal challenge was moot since the governor had subsequently ended the mandate. Will State Governments continue to attempt to dismiss legal challenges to pandemic restrictions on the grounds that the restrictions are no longer in place?

Harms of Masking Children

Mitigations that limit children's observations of faces due to masking of teachers and peers should not be discounted as harmless, especially in young children and those with special needs. We know from studies of children who are blind that language and emotional development may be hindered by lack of visual cues, though this may be multifactorial. Without specific interventions, blind children are slower to learn language and emotional fluency unrelated to level of intelligence. Evidence suggests young children learn basic emotions and interact with others by focusing on faces. Lip reading and visual cues can be particularly important to children with developmental challenges in language and speech development.

Seeing faces is crucial for communication in children with hearing loss, who may have hampered word recognition in settings where people are masked. Children without hearing impairment may also have reduced word identification, particularly in noisy environments when the speaker is masked. Face masks also appear to impair recognition of emotions, trustworthiness and perceived closeness and may "undermine the success of our social

interactions." Another study found mask use limits the ability to read facially expressed emotions in people of all ages, particularly in 3-5- years-old.

WHO recommended against masking children ages 5 and younger, because this age group is at low risk of illness, because masks are not "in the overall interest of the child," and because many children are unable to wear masks properly. Even for children ages 6 to 11, the WHO did not routinely recommend masks, because of the "potential impact of wearing a mask on learning and psychosocial development."

Why did the CDC recommend masks for all children two and up?

An Italian study published in March 2021, found that masking is a barrier to speech recognition, hearing, and communication, and that masks impede children's ability to decode facial expressions, dampening children's perceived trustworthiness of faces.

Why was this not considered when implementing mask mandates in children?

Research has suggested that hearing-impaired children have difficulty discerning individual sounds; opaque masks, of course, prevent lip-reading. Why were masks frequently used on these children and their teachers?

Some teachers, parents, and speech pathologists have reported that masks can make learning difficult for some of America's most vulnerable children, including those with cognitive delays, speech issues, and autism. Masks may also hinder language and speech development—especially important for students who do not speak English at home. Why were masks frequently used on these children and their teachers?

Masks may impede emotion recognition, even in adults, but particularly in children. When children were asked, many said that prolonged mask wearing is uncomfortable and that they dislike it. By the summer of 2022, babies and young children were suffering developmental delays, behavioral issues, and speaking less which some experts have attributed, at least partially, to mask wearing of children and their teachers. Why were masks used on very young children under the age of five?

Mask wearing may cause physiological harm, including breathing difficulties, headaches, dermatitis, and general discomfort which may have several negative downstream effects, including reduced time and intensity of exercise, additional sick days, reduced learning capacity, and increased anxiety. Were these factors considered when implementing mask mandates?

Public health interventions with clear downsides in children were implemented for long periods of time in the absence of high quality evidence such as randomized trials in children. There were also no clear endpoints or metrics given to end mandates. Why were known, expected and potential harms to children from masking not taken into account in the recommendation and implementation process?

Children face the least risk of COVID-19 and face the highest risk of harm from prolonged masking. Why were the youngest and most vulnerable children in the Head Start programs, overseen by the Department of Health and Human Services, some of the very last to be allowed to remove their masks in the Fall of 2022?

(No subject)

Stephen Skoly <sskoly@affiliatesri.com>

Thu 3/14/2024 2:45 PM

To:consent4RI@hotmail.com <consent4RI@hotmail.com>;Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (610 KB)

BP-50M31_20240314_154247.pdf;

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Report Suspicious

mask mandates

Chris Eldridge <spinloop@gmail.com>

Thu 3/14/2024 3:04 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good Afternoon,

I am writing to let you know that I am strongly opposed to mask mandates without declaring a state of emergency. RI should not be able to implement mask mandates as a permanent executive power.

Best Regards,
Chris

School mask mandates

Lee Papa <leepapa524@gmail.com>

Thu 3/14/2024 3:25 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I am a grandparent of elementary age boys and am opposed to masks! It affects the children in a negative way, socially and with reading, writing etc..
Also the virtual learning proved to be a big failure.
We all hope this never happens again but if it does, a much better plan is in place! Thank you!

Sent from my iPhone

OPPOSE 216-RICR-30-05-4

Karen Papa <12.kpapa.53@gmail.com>

Thu 3/14/2024 3:29 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I strongly oppose this proposed Masking in School regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially in relation to children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data.

Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority.

Karen Papa
4480 Old Post Rd, Charlestown, RI 02813

216-RICR-30-05-4 Public Hearing

Adam Muccino <adammuccino@gmail.com>

Thu 3/14/2024 3:37 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (15 KB)

RICR-30-05-4 Testimony.docx;

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Report Suspicious

Good afternoon Mr. Garceau,

Attached please find a word document that contains my commentary on 216-RICR-30-05-4 - Masking in Schools in advance of the Public Hearing scheduled for tomorrow morning.

At your earliest convenience, please reply to this email confirming that my correspondence has or will be entered into the record.

Thank you,

Adam Muccino
North Scituate, RI

Title of Rule: Masking in School
Rule Identifier: 216-RICR-30-05-4
Rulemaking Action: Proposed Adoption
Important Dates:
Date of Public Notice: February 2, 2024
Hearing Date: March 15, 2024
End of Public Comment: March 20, 2024

DO NOT ADOPT 216-RICR-30-05-4 - Masking in School

My children narrowly escaped the draconian masking requirements foisted upon LEAs by the State, Department of Health, and the Department of Education as they were thankfully too young at the time. However, should there be a need to return to a discussion of masking children in schools, I want the decision to put a mask on my children's face during school hours to lie with an elected member of my community not an unelected bureaucrat. State Leaders can advocate and communicate their recommendations to parents and families through multiple channels and parents and families can make their own choice.

That this public hearing is occurring today after the COVID-19 pandemic has long since passed is yet another example of how the trust between the people of RI and its government has been eroded. That this hearing is occurring today, after the State tried forcing the masking issue via executive fiat as opposed to following policy and State Law is yet another example of why a decision of the magnitude to require masking of children in schools should not lie with one unelected individual but with the elected School Committees in each District.

Finally, it should not take private citizens to hire an attorney to take the State to court to force this body to follow Rhode Island State law and its own policies and procedures. If this body has any sense of propriety you would apologize to the children, parents and families of Rhode Island and drop this issue by refusing to adopt RICR-30-05-4.

Respectfully,

Adam R. Muccino
North Scituate, RI

Oppose 216 RICR 30-05-4 Masking

steven.tellier <steven.tellier@yahoo.com>

Thu 3/14/2024 3:37 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I fully oppose this proposed masking regulation

Sincerely,

Steven Tellier

Sent from my Verizon, Samsung Galaxy smartphone

OPPOSE Masking in Schools 216-RICR-30-05-4

Tom Papa <tjpapa151@gmail.com>

Thu 3/14/2024 3:40 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I strongly oppose this proposed Masking in School regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially in relation to children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data.

Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority.

Thomas Papa
4480 Old Post Rd
Charlestown, RI 02813

Mask Mandates

acdaukas <acdaukas@protonmail.com>

Thu 3/14/2024 3:42 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Dear Mr Garceau,

I am strongly opposed to any future mask mandates being forced on our children!. I have seen the unpleasant results within my own family.

There are no scientific facts this action, only negative reports of acute discomfort, social isolation, and increased respiratory illnesses.

I sincerely hope you will do the right thing, and not allow such dreadful mandates ever to be repeated!

Sincerely.

Angela Daukas, RN, MN

Westerly, Rhode Island

Sent from Proton Mail [proton.me] for iOS

Masking in schools

Eileen Keenan <keenan700@aol.com>

Thu 3/14/2024 3:59 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Our daughter is a teacher and was astonished how many special needs students had more difficulty understanding the teacher when masks were required. These were not hearing impaired students. Right now there are no mandates and we really have to learn to live with Covid in the winter months because it seems here to stay.
Eileen Keenan
Sent from my iPhone

OPPOSE 216-RICR-30-05-4

Linda Pearson <linpearson@gmail.com>

Thu 3/14/2024 4:24 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Hello Mr Garceau

I strongly oppose this proposed “Masking in School” regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially in relation to children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data.

Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority.

Thank you for your attention to this very important matter.

Linda Pearson
74 Woodsia Rd, Saunderstown, RI 02874

I strongly oppose masking in schools

Tom Pearson <tompearson7474@gmail.com>

Thu 3/14/2024 4:28 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Hello Mr Garceau

I strongly oppose this proposed “Masking in School” regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially in relation to children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data.

Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority.

Thank you for your attention to this very important matter.
Thomas Pearson
74 Woodsia Rd, Saunderstown, RI 02874

(No subject)

District 2 RIAFG <district2.riafg@gmail.com>

Thu 3/14/2024 4:35 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I oppose the mask mandate!!!

Opposition to masking in school 216-RICR-30-30-4

Jackie O <jornazianrn@gmail.com>

Thu 3/14/2024 4:38 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I am writing to you to oppose masking regulations 216-RICR-30-30-4. There is no scientific research explaining any benefits of using masks. This is an extreme overreach in power within our govt. My child will never wear one! I will pull her out of the school system and homeschool her if need be! These non science backed mandates imposed upon young students by RIDOH not only are unnecessary and ineffective, but as the Superior Court judge in the case ruled…the masking policy caused "irreparable harm" to our children. My child will not participate in anything like this and I will make sure that all of my friends, colleagues and family members across the state will not mask their children!

Sincerely,
Jaclyn Ornazian

PDF file that contains my slide presentation for tomorrow (3/15/24) on 216-RICR-30-05-4, Masking in Schools, & related pdf documents, for entry into the permanent written record

Andrew Bostom <andrewgbostom@gmail.com>

Thu 3/14/2024 4:45 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

10 attachments (13 MB)

Mar 15 2024 Hearing Slides.pdf; Ludvigsson 2020 Swedish children nejm.pdf; Hajj pilgrims flu etc masking null 2020.pdf; Flu Meta 2020.pdf; Guinea-Bissau.pdf; Face Mask disruptive in children.pdf; Rao_ Harms SARSCOV1.pdf; N95 trial in children.pdf; Jefferson_et_al-2023-Cochrane_Database_of_Systematic_Reviews (1).pdf; Hoeg et al_FULL_MMWR_absurd masking studies_2023.pdf;

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

3/14/2024

Dear Mr. Garceau,

Attached please find a pdf document that contains my slide presentation for tomorrow (3/15/24) on 216-RICR-30-05-4, Masking in Schools, which will also be presented in person during the Public Hearing scheduled for tomorrow morning.

In addition, I have attached a number of key direct sources (in their entirety, also as pdfs) I will be discussing tomorrow, in summary, which I would also like to have incorporated into the permanent record

Please reply to this email at your earliest convenience confirming that my correspondence including all the attachments, have, or will be entered into the permanent record.

Sincerely,

Andrew G. Bostom, MD, MS

Retired Brown University Associate Professor of Medicine and Family Medicine

Cellphone: 401-447-7217

CLINICAL RESEARCH STUDY

THE AMERICAN JOURNAL of MEDICINE®

An Analysis of Studies Pertaining to Masks in *Morbidity and Mortality Weekly Report*: Characteristics and Quality of Studies through 2023

Tracy Beth Høeg, MD, PhD,[a,b] Alyson Haslam, PhD,[a] Vinay Prasad, MD, MPH[a]

[a]Department of Epidemiology and Biostatistics, University of California San Francisco; [b]Department of Clinical Research, University of Southern Denmark, Odense, Denmark.

ABSTRACT

BACKGROUND: The purpose of this study was to describe and evaluate the nature and methodology of reports and appropriateness of conclusions in *The Morbidity and Mortality Weekly Report* (MMWR) pertaining to masks. Because MMWR has substantial influence on United States health policy and is not externally peer-reviewed, it is critical to understand the scientific process within the journal. Mask policies have been highly influenced by data published in the MMWR.

METHODS: Retrospective cross-sectional study of MMWR publications pertaining to masks through 2023. Outcomes included study design, whether the study was able to assess mask effectiveness, if results were statistically significant, if masks were concluded to be effective, if randomized evidence or conflicting data were mentioned or cited, and appropriateness of causal statements.

RESULTS: There were 77 studies, all published after 2019, that met our inclusion criteria. The most common study design was observational without a comparator group: 22/77 (28.6%); 0/77 were randomized; 23/77 (29.9%) assessed mask effectiveness; 11/77 (14.3%) were statistically significant, but 58/77 (75.3%) stated that masks were effective. Of these, 41/58 (70.7%) used causal language. One mannequin study used causal language appropriately (1.3%). None cited randomized data; 1/77 (1.3%) cited conflicting evidence.

CONCLUSIONS: MMWR publications pertaining to masks drew positive conclusions about mask effectiveness >75% of the time despite only 30% testing masks and <15% having statistically significant results. No studies were randomized, yet over half drew causal conclusions. The level of evidence generated was low and the conclusions were most often unsupported by the data. Our findings raise concern about the reliability of the journal for informing health policy.

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KEYWORDS: Centers for Disease Control and Prevention; Health policy; Masks; Medical evidence; Public health

INTRODUCTION

Prior to the COVID-19 pandemic, pooled randomized data[1] on surgical and N95 respirator masks in the community and health care setting failed to demonstrate evidence of efficacy against influenza or influenza-like illness. In March of 2020, the Centers for Disease Control and Prevention

Funding: None.

Conflicts of Interest: TBH and AH have no conflicts to disclose. VP discloses research funding from Arnold Ventures; royalties from Johns Hopkins Press, Medscape, and MedPage; consulting fees from UnitedHealthcare and OptumRx; honoraria from various universities, medical centers, professional societies, and nonprofits; and subscriber fees from Patreon, YouTube, and Substack.

Authorship: All authors had access to the data and all authors contributed to writing and revising the manuscript.

Requests for reprints should be addressed to Vinay Prasad, MD, MPH, Department of Epidemiology and Biostatistics, University of California San Francisco, UCSF Mission Bay Campus, Mission Hall: Global Health & Clinical Sciences Building, 550 16th St, 2nd Fl, San Francisco, CA 94158.

E-mail addresses: thoeg@health.sdu.dk vinayak.prasad@ucsf.edu

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https://doi.org/10.1016/j.amjmed.2023.08.026

(CDC) did not generally recommend mask wearing for healthy people,[2] consistent with the advice from the US Surgeon General.[3] Over several weeks in March and early April 2020, a coordinated social media campaign to recommend masks began.[4] Then on April 3, 2020, the CDC recommended that people ages 2 years and older wear a cloth face covering in public.[5] On July 15th, 2020, the CDC Director recommended all Americans start wearing masks as a way to "get the epidemic under control,"[5,6] citing a *Morbidity and Mortality Weekly Report* (MMWR) study involving 2 hairstylists in Missouri.[7] That coming Fall of 2020, universal masking in schools and daycares was recommended by the CDC[8] and widespread mandates were enacted at the state, district, and county levels for children as young as 2 years. Masking on public transportation was required by federal mandate starting January of 2021.[9]

CLINICAL SIGNIFICANCE

- We identified a strong tendency for *Morbidity and Mortality Weekly Report* (MMWR) publications to make causal claims about mask effectiveness that were unsupported by the data.
- Over 60% of the included studies concluded that masks were effective without statistically significant evidence to support this.
- For clinicians, simply reading the report conclusions pertaining to masks in MMWR may be misleading for advising patients and making health policy recommendations.

MMWR is a weekly scientific journal without external peer review overseen by the CDC to publish data on nationally notifiable infectious diseases, which can then be used for program planning, evaluation, and policy development.[10] It is considered their primary avenue for disseminating scientific information and is often referred to as "the voice of CDC."[10] The review and publication process at this journal, the levels of evidence generated, and the extent to which the studies published in this journal represent and advance current international scientific understanding remain largely opaque to the general public.

The aim of the present study was to evaluate all studies published in MMWR pertaining to masks, looking specifically at what conclusions were drawn about mask effectiveness and whether or not the conclusions were appropriate given the data presented. If causality was inferred, we determined whether or not this was appropriate, given the study's methodology. Secondary aims included describing multiple study characteristics, including study type, number of authors, if some or all of the authors were from the CDC, and whether or not studies cited randomized or conflicting data.

METHODS

Study Identification and Data Abstraction

We sought to assess MMWR face mask studies by searching PubMed using 2 search strategies: 1) ("MMWR. Morbidity and mortality weekly report"[Journal]) AND ("face covering") AND (covid); 2) ("MMWR. Morbidity and mortality weekly report"[Journal]) AND (mask) AND (covid). The searches were done on June 8, 2023. For the initial search, we included all studies, regardless of study design or publication date, and we did not have any restriction criteria in the search. After reviewing articles, we removed guidance documents and an article that was a figure only (eg, no methods).

From each study, we abstracted the study design, setting, general age of participants (children, adolescents, adults, older adults), number of people in the analysis, number of study authors, if there was a control or comparator group (yes or no) and if yes, how many were masked vs unmasked, the geographic region, whether the study tested masks, whether there was a conclusion made about mask effectiveness, if causal language was used, and if yes, whether it was used appropriately (methodology permitted causal inference); if the conclusions matched with the study findings (ie, the conclusions about masks were supported by the results); whether the study pointed to other evidence of mask efficacy/effectiveness and the source of evidence; if randomized data on masking were cited; and if conflicting data were cited or mentioned. Information was also obtained on the number of authors per study and whether or not any of the authors were affiliated with the CDC.

We defined geographic region of the United States as such: Far West (Wash, Ore, Calif, Nev, Alaska, Hawaii), Rocky Mountain (Mont, Idaho, Wyo, Utah, Colo), Plains (ND, SD, Minn, Iowa, Neb, Kan, Mo), Southwest (Ariz, NM, Okla, Texas), Great Lakes (Wis, Mich, Ill, Ind, Ohio), Southeast (Ark, La, Miss, Ala, Ga, Fla, Ky, Tenn, WVa, Va, NC, SC), Mideast (NY, Pa, NJ, Md, Del), and New England (VT, NH, Mass, Conn, Maine, RI).

Multicomponent mitigation strategy studies were considered as testing masks, if masks were specifically identified as being one of the components. We coded each study as testing masks or not if it included any type of control or comparison group or time period. We coded study results as being indeterminate for studies that did not test masking, no difference/negative if masking was no better, and positive if numbers were more favorable for masking, even if there were no formal statistical tests conducted. We then determined whether or not the studies testing masks had statistically significant results.

We coded the study's conclusions about masking, according to the authors' conclusion statements at the end of the abstract/discussion as favorable for masking or neutral (no difference). This coding was done independently by 2 people (AH and TBH). Causal language was defined as using terms such as "can," "likely," "led to," or otherwise

drawing definitive conclusions about mask effectiveness that was not based on references to other studies. We defined "appropriate" use of causal language as those that had a randomized design or observational methodology, which permitted causal inference.

Statistical Analysis

We presented descriptive characteristics and compared frequencies of study characteristics between studies testing mask efficacy or effectiveness and those that do not test mask efficacy or effectiveness. We used Chi-square and Wilcoxon rank sum test to determine differences between groups. We conducted all statistical analysis in R statistical software (version 4.6.1). Using package 'irr', we calculated a kappa statistic to measure the amount of agreement in whether the study determined a mask to be effective or not (including not determined). We also calculated a kappa statistic to determine whether the study authors used causal language in describing their results.

Ethics Approval

In accordance with 45 CFR §46.102(f), this study was not submitted for University of California, San Francisco institutional review board approval because it involved publicly available data and did not involve individual patient data.

Patient and Public Involvement

Patients or the public were not involved in the design, conduct, or reporting, or dissemination plans of our research.

RESULTS

Our search identified 83 MMWR published studies on PubMed, all of which were published after 2019. We excluded 5 guidance documents and a search result that was a stand-alone figure. Of the included 77 studies, 23 (29.9%) studies were graded as assessing mask effectiveness, with the remaining 54 (70.1%) not having the methodology to do so. Seventy-two studies (93.5%) pertained to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), one pertained to SARS-CoV-2 and influenza co-infection, 3 studies pertained mainly to influenza, and one pertained to rhino- and enteroviruses.

No studies met our inclusion criteria through 2019. Thirty studies were published in 2020; 33 were published in 2021; and 14 were published in 2022. The median number of participants was 558 (interquartile range [IQR] 171, 2964). The median number of authors was 13 (IQR 9, 26); total listed authors, including duplicates, was 1544. Seventy studies (90.9%) had one or more authors affiliated with the CDC.

The kappa statistic for intra-author agreement in the determination of whether studies made a conclusion about masks was 0.69 ($P < .0001$), and the kappa statistic for the use of causal language was 0.66 ($P < .0001$). These numbers suggest that the agreement was substantial for both.

Study characteristics, stratified by whether or not masks were tested for effectiveness, are shown in Table 1 and described in detail in the Supplementary Material (available online). Seventy-five of 77 studies (97.4%) were from the United States alone, one was from Chile, and one was from multiple countries. All geographic regions were represented, with 32/77 (41.6%) using multi-state data. The most common study design was observational, without a control or comparator group (22/77; 28.6%). All age groups were represented. The most common setting was community (35/77; 45.5%), followed by kindergarten through high school (13/77; 16.9%). The characteristics of the 77 studies, by whether or not they had appropriate methodology to test masks, are described in the Supplementary Material.

In the Figure, we show a total of 23/77 (29.9%) identified studies that assessed the effectiveness of masks, however, 58/77 (75.3%) stated that masks were effective. Of these 58 studies, 41 (70.7%) used causal language and 40 (69.0%) used causal language inappropriately. One mannequin study allowed causal inference. Eleven of 77 (14.3%) found a statistically significant inverse relationship between masking and cases. No studies (0/77; 0%) were randomized. Four of 77 (5.2%) had a numerically higher number of cases in the mask group than the comparator group, but all 4/4 (100%) concluded that masks were effective. Of all publications included, 0/77 (0.0%) cited a randomized study or review of only randomized studies. Of all 58 studies stating that masks were effective, only one (1.7%), which mainly focused on influenza,[11] mentioned conflicting data on mask effectiveness.

Table 2[7,12–21] shows examples of language used in multiple MMWR studies that did not have appropriate methodology to draw conclusions about the effectiveness of masking.

Table 3 shows the data characteristics of the included MMWR studies, overall and stratified by the testing of masks or not.

As shown in Table 4, of the studies that evaluated masks, 22/22 (100%) concluded that masks were effective; 18/22 (81.8%) reported results favoring masks; 13/22 (59.1%) tested for statistical differences; and 12/22 (54.5%) were statistically significant.

Details about the included studies and grading of subjective endpoints are publicly available at the following GitHub repository: https://github.com/tracybethhoeg/mmwrmasks under an MIT license.

DISCUSSION

We found that, among the 77 studies identified pertaining to masks published in MMWR, 30% tested the effectiveness of masks, with 14% having statistically significant results, yet over 75% of all 77 studies concluded that masks were effective. Of the 5% that reported *higher* case rates in the masked group than the comparator group, all concluded that masks were effective. MMWR studies consistently drawi conclusions about mask effectiveness without

Table 1 Study Characteristics of *Morbidity and Mortality Weekly Report* Studies Mentioning Masks or Face Coverings, Stratified by Whether Mask Effectiveness Was Tested

	All Studies (N = 77)	Studies Not Assessing the Effectiveness of Masks (n = 54)	Studies Assessing the Effectiveness of Masks (n = 23)	*P* Value, Chi-Square or Wilcoxon Rank Sum
Age group, n (%)				.55
Adolescents	2 (2.6)	1 (1.9)	1 (4.3)	
Adults	24 (31.2)	17 (31.5)	7 (30.4)	
All	26 (33.8)	17 (31.5)	9 (39.1)	
Children/adolescents	12 (15.6)	9 (16.7)	3 (13.0)	
Children/adults	5 (6.5)	5 (9.3)	0 (0.0)	
Children	6 (7.8)	3 (5.6)	3 (13.0)	
Older adults	2 (2.6)	2 (3.7)	0 (0.0)	
Sample size, median (IQR)	558 (171, 2964)	584 (158, 2493)	390 (261, 2893)	.85
Geographical region, n (%)				.12
Far West	6 (7.8)	5 (9.3)	1 (4.3)	
Great Lakes	9 (11.7)	9 (16.7)	0 (0.0)	
Mideast	5 (6.5)	2 (3.7)	3 (13.0)	
Multistate/National	32 (41.6)	23 (42.6)	9 (39.1)	
New England	3 (3.9)	3 (5.6)	0 (0.0)	
Non-US	1 (1.3)	1 (1.9)	0 (0.0)	
Plains	5 (6.5)	3 (5.6)	2 (8.7)	
Rocky Mountain	3 (3.9)	2 (3.7)	1 (4.3)	
Southeast	8 (10.4)	4 (7.4)	4 (17.4)	
Southwest	4 (5.2)	1 (1.9)	3 (13.0)	
US and non-US	1 (1.3)	1 (1.9)	0 (0.0)	
Setting, n (%)				.5
Childhood early care and education settings	2 (2.6)	2 (3.7)	0 (0.0)	
College campus	3 (3.9)	2 (3.7)	1 (4.3)	
Community	35 (45.5)	23 (42.6)	12 (52.2)	
Event	10 (13.0)	8 (14.8)	2 (8.7)	
Health care workers	2 (2.6)	1 (1.9)	1 (4.3)	
Homeless	1 (1.3)	1 (1.9)	0 (0.0)	
Hospitalized patients	3 (3.9)	3 (5.6)	0 (0.0)	
Older adult residence	2 (2.6)	2 (3.7)	0 (0.0)	
Outpatient	2 (2.6)	0 (0.0)	2 (8.7)	
Kindergarten through high school	13 (16.9)	9 (16.7)	4 (17.4)	
Specialty group/navy/sport	4 (5.2)	3 (5.6)	1 (4.3)	
Study design, n (%)				< .001
Case-control	7 (9.1)	2 (3.7)	5 (21.7)	
Cross-sectional	11 (14.3)	10 (18.5)	1 (4.3)	
Mannequin	2 (2.6)	0 (0.0)	2 (8.7)	
Modeling	2 (2.6)	1 (1.9)	1 (4.3)	
Observational - comparative time period	4 (5.2)	0 (0.0)	4 (17.4)	
Observational -comparator/ control group	10 (13.0)	3 (5.6)	7 (30.4)	
Observational — no comparator/control group	22 (28.6)	22 (40.7)	0 (0.0)	
Observational - pre/post	2 (2.6)	0 (0.0)	2 (8.7)	
Outbreak investigation	17 (22.1)	16 (29.6)	1 (4.3)	
Number of authors; median (IQR)	13 (9, 26)	13 (10, 25)	12 (9, 31)	.91
Authors affiliated with the CDC = yes (%)	70 (90.9)	49 (90.7)	21 (91.3)	1

CDC = Centers for Disease Control and Prevention; IQR = interquartile range.

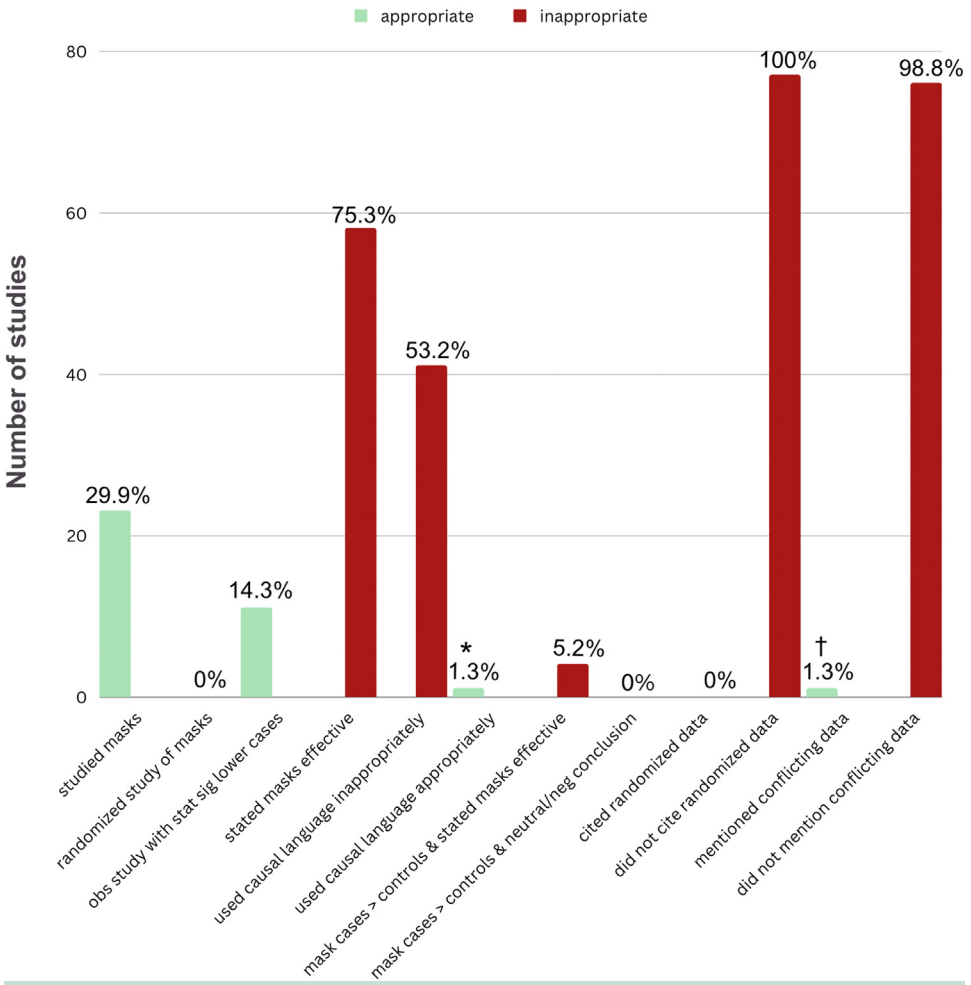


Figure Select characteristics of the 77 *Morbidity and Mortality Weekly Report* (MMWR) publications pertaining to masks.

supporting evidence. This is particularly problematic and difficult to justify considering that the totality of randomized evidence about the use of surgical or N95 masks to prevent the spread of respiratory viruses has been negative.[1,22]

Over 50% of the identified studies used causal language in their conclusions about mask effectiveness. Only one of these studies, which was a mannequin study, had methodology that permitted causal inference. In other words, the remaining 40 studies used language that indicated with certainty that masks lower transmission rates despite the fact that their results found, at most, a correlation. Twenty-five of these 40 studies, however, did not even test mask effectiveness. We have provided examples of study conclusions, which stated that masks resulted in case reductions, despite the fact that none of the studies had the appropriate methodology to assess mask effectiveness (Table 2). There were a total of 25 studies that did not evaluate masks but made causal claims about their effectiveness. It is important to note that the one identified study, which permitted causal inference, was a study of particle filtration on mannequins,[23] with unknown relevance for human health.

The inappropriate use of causal language used in MMWR studies was also adopted directly by the CDC director when she cited an observational phone survey, which also happened to be included in the present analysis,[24] stating to the public, "Masks can help reduce your chance of #COVID19 infection by more than 80%."[25] This referenced study found an association between respondents' recollection about mask wearing and self-reported COVID-19 tests, which was nonsignificant for cloth masks.

A number of studies that were particularly influential in shaping policy recommendations around masking in the public and schools were not even among the studies that attempted to properly evaluate masks, as they had no control group or comparative time period. These studies included the investigation of 2 Missouri hairdressers,[7] the Georgia overnight camp outbreak investigation,[16] and the Marin County, California school outbreak investigation.[17] None of these had methodology that permitted an evaluation of mask effectiveness, but they nonetheless drew conclusions about mask effectiveness (Table 2), which were then rapidly communicated to the public via the CDC.

Table 2 Select Conclusion Statements Indicating a Causal Relationship Between Mask Wearing and Decreased Case Rates/Transmission from MMWR Mask Studies that Failed to Find Evidence of Mask Effectiveness

Study and Date	Conclusion Statement	Control Group/Time Period	Provided Evidence of Mask Effectiveness
Outbreak investigation of 2 Missouri hairdressers 7/14/2020[7]	"Consistent and correct use of face coverings, when appropriate, is an important tool for minimizing spread of SARS-CoV-2."	No	No
Georgia camp outbreak investigation 8/7/2020[16]	"Consistent and correct use of cloth masks should be emphasized as important strategies for mitigating transmission."	No	No
Investigation of university soccer team outbreaks 10/30/2022[12]	"Improved strategies to promote mask use and social distancing among college-aged adults need to be implemented."	No	No
Hopi Tribe outbreak investigation 11/6/2020[13]	"This investigation highlights the need for. . . encouraging consistent mask wearing."	No	No
Household transmission in Wisconsin and Tennessee 11/6/2020[14]	"All household members wearing a mask in shared spaces, can reduce the probability of household transmission."	No	No
Georgia school outbreak investigation 3/12/2021[15]	"Correct mask use and physical distancing, even after educators are vaccinated, will be critical."	No	No
Transmission in Salt Lake City, Utah Elementary Schools 3/26/2021[18]	"Schools can be opened safely with minimal in-school transmission when critical prevention strategies including mask use are implemented."	No	No
Outbreaks at a youth camp and men's conference 9/3/2021[19]	"This investigation underscores the impact of secondary SARS-CoV-2 transmission during large events such as camps and conferences when COVID-19 prevention strategies, including vaccination, masking, physical distancing, and screening testing, are not implemented."	No	No
Marin County Elementary School outbreak 9/3/2021[17]	"Strict adherence to multiple nonpharmaceutical prevention strategies, including masking, are important to ensure safe school instruction."	No	No
Evaluation of a test to stay (TTS) strategy in Lake County, Ill 12/31/2021[20]	"TTS strategy with multiple prevention components, including masking and physical distancing, resulted in low secondary transmission of SARS-CoV-2 in K-12 schools in Lake County, Illinois."	No	No
Antigen test positivity after COVID-19 isolation 2/25/2022[21]	"The high percentage of positive antigen test results during the 5-9 days after symptom onset reinforces the importance of correct and consistent mask use during this period."	No	No

MMWR = *Morbidity and Mortality Weekly Report*; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Table 3 Data Characteristics of *Morbidity and Mortality Weekly Report* Publications Mentioning Mask or Face Covering (n = 77)

	All Studies (N = 77)	Studies Not Assessing the Effectiveness of Masks (n = 54)	Studies Assessing the Effectiveness of Masks (n = 23)	*P* Value, Chi-Square
Conclusion supportive of masks = yes (%)	58 (75.3)	36 (66.7)	23 (100.0)	.016
Results (%)				< .001
Positive	19 (24.7)	1 (1.9)	18 (78.3)	
Indeterminate	54 (70.1)	53 (98.1)	1 (4.3)	
No difference	4 (5.2)	0 (0.0)	4 (17.4)	
Tested for statistical difference (%)				< .001
Yes	15 (19.5)	0 (0.0)	15 (65.2)	
No	10 (13.0)	2 (3.7)	8 (34.8)	
Not applicable	52 (67.5)	52 (96.3)	0 (0.0)	
Use of causal language (%)				.009
Yes	41 (53.2)	25 (46.3)	16 (69.6)	
No	19 (24.7)	12 (22.2)	7 (30.4)	
Not applicable	17 (22.1)	17 (31.5)	0 (0.0)	
Appropriate use of causal language (%)				.011
Yes	1 (1.3)	0 (0.0)	1 (4.3)	
No	40 (51.9)	25 (46.3)	15 (65.2)	
Not used	19 (24.7)	12 (22.2)	7 (30.4)	
Not applicable	17 (22.1)	17 (31.5)	0 (0.0)	
Cited other mask effectiveness studies = yes (%)	40 (51.9)	23 (42.6)	17 (73.9)	.023
Cited randomized mask data = yes (%)	1 (1.3)	1 (1.9)	0 (0.0)	1
Cited conflicting mask data = yes (%)	1 (1.3)	1 (1.9)	0 (0.0)	1

Commensurate with the existing randomized data prior to 2020,[1] the CDC had previously recommended against wearing masks to prevent respiratory infections.[2,6] A shift in messaging for the public to wear masks to control the pandemic came July 15 from the CDC director. This change came following the report of 2 hairdressers wearing masks while working, which concluded that masks were "likely a contributing factor in preventing transmission of SARS-CoV-2 during the close-contact interactions between stylists and clients."[6] In this instance, public health recommendations shifted largely based on anecdotal data in MMWR.

Table 4 Characteristics of *Morbidity and Mortality Weekly Report* Publications Evaluating Studies Testing Masks (n = 23)

	Yes	No/Not Applicable
Concluded masks were effective	23 (100.0)	0 (0.0)
Reported favorable results	18 (78.3)	5 (21.7)
Used statistical testing	14 (60.9)	9 (39.1)
Statistical tests positive	11 (47.8)	12 (52.2)
Use of causal language	16 (69.6)	7 (30.4)
Use of causal language and appropriate	1 (4.3)	22 (95.7)
Cite randomized mask data	0 (0.0)	23 (100.0)
Cite conflicting mask data	0 (0.0)	23 (100.0)
Cite other efficacy/effectiveness studies	17 (73.9)	6 (26.1)

Randomized studies are the most reliable method of determining whether an intervention is efficacious. None of the studies identified in MMWR were randomized, and none cited randomized data. Due to a high likelihood of confounding variables or spurious findings,[26] observational studies of masking are unlikely to provide reliable information about the ability of masks to prevent infection or transmission of SARS-CoV-2 or other respiratory viruses and are, with few exceptions, inappropriate for causal inference.

Only one study mentioned conflicting data on masking efficacy, despite the existing overall negative randomized data.[1,22] Interestingly, the focus of this study was influenza and it was an international study.[11]

Taken together, the absence of randomized data, the lack of acknowledgment of conflicting or randomized data on mask efficacy, and the tendency to conclude that masks are efficacious either without any or without sufficient data to make causal claims, is suggestive of bias within the journal. Our findings may also help explain why the CDC remains an international outlier in continuing to recommend masks for COVID-19 under certain circumstances, including for children as young as 2 years of age.[27]

Concerns about publication bias within MMWR have been raised previously, when follow-up data to a 2-week study with a limited sample were submitted, which failed to identify evidence of school mask mandate effectiveness, was rejected from the MMWR.[26,28] In another school masking study, errors in data analysis and methodology, which normally would warrant retraction, were not addressed by the journal.[29]

One *Journal of the American Medical Association* (JAMA) Viewpoint[30] described how, starting September 11, 2020, political appointees may have "demanded the ability to review and revise scientific reports" in MMWR, and concern was raised about "political appointees trying to influence the scientific process." The extent to which this happened or is still happening is unclear. However, even prior to this, unlike other peer-reviewed scientific journals, MMWR publications have not and do not undergo any external peer review. Rather, they undergo a "clearance process,"[10,31] which is sometimes referred to as "internal peer review."[30] Both political involvement and lack of input from external domain experts could influence the journal's ability to objectively evaluate scientific data. But the extent to which either of these explain our findings is beyond the scope of this paper.

However, the process by which scientific data are interpreted and published in MMWR and then promoted by the CDC is not transparently communicated to the public. Because the CDC uses data published in the MMWR journal to develop its guidelines, the quality of scientific data and data interpretation within the journal have major implications for public health and well-being in the United States, extending far beyond masks.

Our search did not identify any mask articles published prior to 2020, although our search was not restricted by date. Ninety percent of mask studies published in the MMWR had one or more authors with CDC affiliations. There was a median of 13 authors per paper and, although there were some authors who co-authored multiple papers, there was a total of 1544 paper authors, which speaks to the large amount of effort that went into studying and publishing about this topic in the journal. It is, thus, disappointing that, due to the intrinsic limitation of the study designs, the sum of the work was inconclusive, yet strong conclusions were drawn and communicated to the public nonetheless.

LIMITATIONS

Our study has important limitations. Some of the study characteristics we graded were subjective. For those (tone of conclusion, use of causal language), we used a double-blinded system, and kappa statistics suggested there was substantial agreement about the categorization of studies. Second, our search criteria were broad and resulted in a number of studies that did not specifically study masks, thus, our overall findings are not representative of studies of masks alone. However, this strategy did allow us to identify numerous studies that drew conclusions about masks without having a study design that could evaluate their effectiveness.

CONCLUSION

We found that, while <20% of MMWR studies pertaining to masks generated any statistical evidence of mask effectiveness and no randomized investigations were published, more than 75% of the publications arrived at a favorable conclusion about using masks, and 70% of studies testing masks used causal language. Similarly, language about the studies' implications, including the importance of masking, was used in multiple publications despite lack of supporting evidence.

None of the MMWR studies were randomized and none mentioned higher-quality randomized studies, which fail to find evidence of mask effectiveness. The extent to which our findings apply to scientific topics beyond masks is outside of the scope of our investigation. However, with regards to the topic of mask effectiveness, our findings highlight the journal's lack of reliance on high-quality data and a tendency to make strong but unsupported causal conclusions about mask effectiveness.

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SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjmed.2023.08.026.

SUPPLEMENTARY MATERIAL

Study Characteristics Stratified by Testing or Not Testing Mask Effectiveness

The study characteristics, overall and stratified by mask testing or not, are presented in Table 1. For studies not testing masks (n = 54), the age groups with the highest percentage of studies were all age groups (31.5%; n = 17) and adults (31.5%; n = 17). Many studies included participants from multiple regions (44.4%; n = 24), but the single region with the most studies was the Great Lakes region (16.7%; n = 9), followed by the Far West (9.3%; n = 5). The most common setting was in the community (42.6%; n = 23), followed by the kindergarten through high school setting (15.1%; n = 8). The most common study design was an observational study with no comparator (including pre/post; 40.7%; n = 22), followed by outbreak investigation/contact tracing (29.6% n = 16). The median number of authors for these 54 studies was 13 (interquartile range [IQR] 9, 26).

For studies testing masks (n = 23), the age groups with the highest percentage of studies were all age groups (39.1%; n = 9) and adults (30.4%; n = 7). Many studies included participants from multiple regions of the United States (34.8%; n = 8), but the single region with the most studies was the Southeast region (17.4%; n = 4). The most common setting was in the community (52.2%; n = 12), followed by the kindergarten through high school setting (17.4%; n = 4). The most common study design was an observational study with a comparator (including pre/post; 39.1%; n=9), followed by case control (21.7% n = 5). Two (of 23; 8.7%) were mannequin studies, 1/23 (4.3%) was a modeling study, and none were randomized trials. The median number of authors on these 23 studies was 12 (IQR 9, 31).

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Physical interventions to interrupt or reduce the spread of respiratory viruses (Review)

Jefferson T, Dooley L, Ferroni E, Al-Ansary LA, van Driel ML, Bawazeer GA, Jones MA, Hoffmann TC, Clark J, Beller EM, Glasziou PP, Conly JM

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TABLE OF CONTENTS

ABSTRACT 1
PLAIN LANGUAGE SUMMARY 3
SUMMARY OF FINDINGS 5
BACKGROUND 9
OBJECTIVES 10
METHODS 10
RESULTS 12
Figure 1. 13
Figure 2. 15
Figure 3. 16
Figure 4. 25
DISCUSSION 30
AUTHORS' CONCLUSIONS 34
ACKNOWLEDGEMENTS 35
REFERENCES 37
CHARACTERISTICS OF STUDIES 57
DATA AND ANALYSES 173
Analysis 1.1. Comparison 1: Randomised trials: medical/surgical masks versus no masks, Outcome 1: Viral illness 174
Analysis 2.1. Comparison 2: Randomised trials: N95 respirators compared to medical/surgical masks, Outcome 1: Viral illness 175
Analysis 2.2. Comparison 2: Randomised trials: N95 respirators compared to medical/surgical masks, Outcome 2: Viral illness in healthcare workers 176
Analysis 3.1. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 1: Viral illness 178
Analysis 3.2. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 2: ARI or ILI or influenza (including outcome with most events from each study) 179
Analysis 3.3. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 3: Influenza or ILI: sensitivity analysis including outcomes with the most precise and unequivocal definitions 179
Analysis 3.4. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 4: ARI or ILI or influenza: subgroup analysis 180
Analysis 3.5. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 5: Absenteeism 180
Analysis 4.1. Comparison 4: Randomised trials: hand hygiene + medical/surgical masks compared to control, Outcome 1: Viral illness 181
Analysis 5.1. Comparison 5: Randomised trials: hand hygiene + medical/surgical masks compared to hand hygiene, Outcome 1: Viral illness 182
Analysis 6.1. Comparison 6: Randomised trials: gargling compared to control, Outcome 1: Viral illness 182
Analysis 6.2. Comparison 6: Randomised trials: gargling compared to control, Outcome 2: SARS-CoV-2 183
ADDITIONAL TABLES 184
APPENDICES 309
WHAT'S NEW 321
HISTORY 321
CONTRIBUTIONS OF AUTHORS 323
DECLARATIONS OF INTEREST 323
SOURCES OF SUPPORT 324
DIFFERENCES BETWEEN PROTOCOL AND REVIEW 324
NOTES 324
INDEX TERMS 324

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[Intervention Review]

Physical interventions to interrupt or reduce the spread of respiratory viruses

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ABSTRACT

Background

Viral epidemics or pandemics of acute respiratory infections (ARIs) pose a global threat. Examples are influenza (H1N1) caused by the H1N1pdm09 virus in 2009, severe acute respiratory syndrome (SARS) in 2003, and coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in 2019. Antiviral drugs and vaccines may be insufficient to prevent their spread. This is an update of a Cochrane Review last published in 2020. We include results from studies from the current COVID-19 pandemic.

Objectives

To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.

Search methods

We searched CENTRAL, PubMed, Embase, CINAHL, and two trials registers in October 2022, with backwards and forwards citation analysis on the new studies.

Selection criteria

We included randomised controlled trials (RCTs) and cluster-RCTs investigating physical interventions (screening at entry ports, isolation, quarantine, physical distancing, personal protection, hand hygiene, face masks, glasses, and gargling) to prevent respiratory virus transmission.

Data collection and analysis

We used standard Cochrane methodological procedures.

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Main results

We included 11 new RCTs and cluster-RCTs (610,872 participants) in this update, bringing the total number of RCTs to 78. Six of the new trials were conducted during the COVID-19 pandemic; two from Mexico, and one each from Denmark, Bangladesh, England, and Norway. We identified four ongoing studies, of which one is completed, but unreported, evaluating masks concurrent with the COVID-19 pandemic.

Many studies were conducted during non-epidemic influenza periods. Several were conducted during the 2009 H1N1 influenza pandemic, and others in epidemic influenza seasons up to 2016. Therefore, many studies were conducted in the context of lower respiratory viral circulation and transmission compared to COVID-19. The included studies were conducted in heterogeneous settings, ranging from suburban schools to hospital wards in high-income countries; crowded inner city settings in low-income countries; and an immigrant neighbourhood in a high-income country. Adherence with interventions was low in many studies.

The risk of bias for the RCTs and cluster-RCTs was mostly high or unclear.

Medical/surgical masks compared to no masks

We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).

N95/P2 respirators compared to medical/surgical masks

We pooled trials comparing N95/P2 respirators with medical/surgical masks (four in healthcare settings and one in a household setting). We are very uncertain on the effects of N95/P2 respirators compared with medical/surgical masks on the outcome of clinical respiratory illness (RR 0.70, 95% CI 0.45 to 1.10; 3 trials, 7779 participants; very low-certainty evidence). N95/P2 respirators compared with medical/surgical masks may be effective for ILI (RR 0.82, 95% CI 0.66 to 1.03; 5 trials, 8407 participants; low-certainty evidence). Evidence is limited by imprecision and heterogeneity for these subjective outcomes. The use of a N95/P2 respirators compared to medical/surgical masks probably makes little or no difference for the objective and more precise outcome of laboratory-confirmed influenza infection (RR 1.10, 95% CI 0.90 to 1.34; 5 trials, 8407 participants; moderate-certainty evidence). Restricting pooling to healthcare workers made no difference to the overall findings. Harms were poorly measured and reported, but discomfort wearing medical/surgical masks or N95/P2 respirators was mentioned in several studies (very low-certainty evidence).

One previously reported ongoing RCT has now been published and observed that medical/surgical masks were non-inferior to N95 respirators in a large study of 1009 healthcare workers in four countries providing direct care to COVID-19 patients.

Hand hygiene compared to control

Nineteen trials compared hand hygiene interventions with controls with sufficient data to include in meta-analyses. Settings included schools, childcare centres and homes. Comparing hand hygiene interventions with controls (i.e. no intervention), there was a 14% relative reduction in the number of people with ARIs in the hand hygiene group (RR 0.86, 95% CI 0.81 to 0.90; 9 trials, 52,105 participants; moderate-certainty evidence), suggesting a probable benefit. In absolute terms this benefit would result in a reduction from 380 events per 1000 people to 327 per 1000 people (95% CI 308 to 342). When considering the more strictly defined outcomes of ILI and laboratory-confirmed influenza, the estimates of effect for ILI (RR 0.94, 95% CI 0.81 to 1.09; 11 trials, 34,503 participants; low-certainty evidence), and laboratory-confirmed influenza (RR 0.91, 95% CI 0.63 to 1.30; 8 trials, 8332 participants; low-certainty evidence), suggest the intervention made little or no difference. We pooled 19 trials (71, 210 participants) for the composite outcome of ARI or ILI or influenza, with each study only contributing once and the most comprehensive outcome reported. Pooled data showed that hand hygiene may be beneficial with an 11% relative reduction of respiratory illness (RR 0.89, 95% CI 0.83 to 0.94; low-certainty evidence), but with high heterogeneity. In absolute terms this benefit would result in a reduction from 200 events per 1000 people to 178 per 1000 people (95% CI 166 to 188). Few trials measured and reported harms (very low-certainty evidence).

We found no RCTs on gowns and gloves, face shields, or screening at entry ports.

Authors' conclusions

The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions. There were additional RCTs during the pandemic related to physical interventions but a relative paucity given the importance of the question of masking and its relative effectiveness and the concomitant measures of mask adherence which would be highly relevant to the measurement of effectiveness, especially in the elderly and in young children.

There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use

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of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes. Harms associated with physical interventions were under-investigated.

There is a need for large, well-designed RCTs addressing the effectiveness of many of these interventions in multiple settings and populations, as well as the impact of adherence on effectiveness, especially in those most at risk of ARIs.

PLAIN LANGUAGE SUMMARY

Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?

Key messages
We are uncertain whether wearing masks or N95/P2 respirators helps to slow the spread of respiratory viruses based on the studies we assessed.

Hand hygiene programmes may help to slow the spread of respiratory viruses.

How do respiratory viruses spread?
Respiratory viruses are viruses that infect the cells in your airways: nose, throat, and lungs. These infections can cause serious problems and affect normal breathing. They can cause flu (influenza), severe acute respiratory syndrome (SARS), and COVID-19.

People infected with a respiratory virus spread virus particles into the air when they cough or sneeze. Other people become infected if they come into contact with these virus particles in the air or on surfaces on which they land. Respiratory viruses can spread quickly through a community, through populations and countries (causing epidemics), and around the world (causing pandemics).

Physical measures to try to prevent respiratory viruses spreading between people include:

· washing hands often;

· not touching your eyes, nose, or mouth;

· sneezing or coughing into your elbow;

· wiping surfaces with disinfectant;

· wearing masks, eye protection, gloves, and protective gowns;

· avoiding contact with other people (isolation or quarantine);

· keeping a certain distance away from other people (distancing); and

· examining people entering a country for signs of infection (screening).

What did we want to find out?
We wanted to find out whether physical measures stop or slow the spread of respiratory viruses from well-controlled studies in which one intervention is compared to another, known as randomised controlled trials.

What did we do?
We searched for randomised controlled studies that looked at physical measures to stop people acquiring a respiratory virus infection.

We were interested in how many people in the studies caught a respiratory virus infection, and whether the physical measures had any unwanted effects.

What did we find?
We identified 78 relevant studies. They took place in low-, middle-, and high-income countries worldwide: in hospitals, schools, homes, offices, childcare centres, and communities during non-epidemic influenza periods, the global H1N1 influenza pandemic in 2009, epidemic influenza seasons up to 2016, and during the COVID-19 pandemic. We identified five ongoing, unpublished studies; two of them evaluate masks in COVID-19. Five trials were funded by government and pharmaceutical companies, and nine trials were funded by pharmaceutical companies.

No studies looked at face shields, gowns and gloves, or screening people when they entered a country.

We assessed the effects of:

· medical or surgical masks;

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· N95/P2 respirators (close-fitting masks that filter the air breathed in, more commonly used by healthcare workers than the general public); and

· hand hygiene (hand-washing and using hand sanitiser).

We obtained the following results:

Medical or surgical masks

Ten studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask in the community studies only, wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (9 studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (6 studies; 13,919 people). Unwanted effects were rarely reported; discomfort was mentioned.

N95/P2 respirators

Four studies were in healthcare workers, and one small study was in the community. Compared with wearing medical or surgical masks, wearing N95/P2 respirators probably makes little to no difference in how many people have confirmed flu (5 studies; 8407 people); and may make little to no difference in how many people catch a flu-like illness (5 studies; 8407 people), or respiratory illness (3 studies; 7799 people). Unwanted effects were not well-reported; discomfort was mentioned.

Hand hygiene

Following a hand hygiene programme may reduce the number of people who catch a respiratory or flu-like illness, or have confirmed flu, compared with people not following such a programme (19 studies; 71,210 people), although this effect was not confirmed as statistically significant reduction when ILI and laboratory-confirmed ILI were analysed separately. Few studies measured unwanted effects; skin irritation in people using hand sanitiser was mentioned.

What are the limitations of the evidence?
Our confidence in these results is generally low to moderate for the subjective outcomes related to respiratory illness, but moderate for the more precisely defined laboratory-confirmed respiratory virus infection, related to masks and N95/P2 respirators. The results might change when further evidence becomes available. Relatively low numbers of people followed the guidance about wearing masks or about hand hygiene, which may have affected the results of the studies.

How up to date is this evidence?
We included evidence published up to October 2022.

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Summary of findings 1. Medical/surgical masks compared to no masks for preventing the spread of viral respiratory illness

Randomised studies: medical/surgical masks compared to no masks for preventing the spread of viral respiratory illness

Patient or population: general population
Setting: community and hospitals
Intervention: medical/surgical masks
Comparison: no masks

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no masks	Risk with randomised studies: masks				
Viral respiratory illness - influenza/COVID-like illness	Study population 160 per 1000	152 per 1000 (134 to 174)	RR 0.95 (0.84 to 1.09)	276,917 (9 RCTs)	⊕⊕⊕⊖ Moderate[a]	
Viral respiratory illness - laboratory-confirmed influenza/SARS-CoV-2	Study population 40 per 1000	40 per 1000 (29 to 57)	RR 1.01 (0.72 to 1.42)	13,919 (6 RCTs)	⊕⊕⊕⊖ Moderate[b]	
Adverse events	-		-	(3 RCTs)	⊕⊖⊖⊖ Very low[a,c]	Adverse events were not reported consistently and could not be meta-analysed. Adverse events reported for masks included warmth, discomfort, respiratory difficulties, humidity, pain, and shortness of breath, in up to 45% of participants.

***The risk in the intervention group** (and its 95% confidence interval) is based on the median observed risk in the comparison group of included studies and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

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Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for study limitations (lack of blinding).
[b]Downgraded one level for imprecision (wide confidence intervals).
[c]Downgraded two levels for imprecision (only three studies enumerated adverse events; another study mentioned no adverse events).

Summary of findings 2. N95 respirators compared to medical/surgical masks for preventing the spread of viral respiratory illness

Randomised studies: N95 respirators compared to medical/surgical masks for preventing the spread of viral respiratory illness

Patient or population: general population and healthcare workers
Setting: hospitals and households
Intervention: N95 masks
Comparison: medical/surgical masks

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with medical masks	Risk with randomised studies: N95				
Viral respiratory illness - clinical respiratory illness	Study population 120 per 1000	84 per 1000 (54 to 132)	RR 0.70 (0.45 to 1.10)	7799 (3 RCTs)	⊕⊝⊝⊝ Very Low[a,b,c]	All studies were conducted in hospital settings with healthcare workers.
Viral respiratory illness - influenza-like illness	Study population 50 per 1000	41 per 1000 (33 to 52)	RR 0.82 (0.66 to 1.03)	8407 (5 RCTs)	⊕⊕⊝⊝ Low[a,b]	1 study was conducted in households (MacIntyre 2009).
Viral respiratory illness - laboratory-confirmed influenza	Study population 70 per 1000	77 per 1000 (63 to 94)	RR 1.10 (0.90 to 1.34)	8407 (5 RCTs)	⊕⊕⊕⊝ Moderate[b]	1 study was conducted in households (MacIntyre 2009).
Adverse events	-		-	(5 RCTs)	⊕⊝⊝⊝ Very Low[a,b,c]	There was insufficient consistent reporting of adverse events to enable meta-analysis. Only 1 study reported detailed adverse events: discomfort was reported in 41.9% of N95 wearers versus 9.8% of medical mask wearers (P < 0.001); headaches

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were more common with N95 (13.4% versus 3.9%; P < 0.001); difficulty breathing was reported more often in the N95 group (19.4% versus 12.5%; P = 0.01); and N95 caused more problems with pressure on the nose (52.2% versus 11.0%; P < 0.001). 4 RCTs either reported no adverse events or only reported on comfort wearing masks.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the median risk in the comparison group and the observed __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for study limitations (lack of blinding).
[b]Downgraded one level for imprecision (wide confidence interval or no meta-analysis conducted).
[c]Downgraded one level for inconsistency of results (heterogeneity).

Summary of findings 3. Hand hygiene compared to control for preventing the spread of viral respiratory illness

Hand hygiene compared to control for preventing the spread of viral respiratory illness

Patient or population: general population and healthcare workers
Setting: schools, childcare centres, homes, offices, nursing homes
Intervention: hand hygiene
Comparison: control

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with control	Risk with hand hygiene				
Acute respiratory illness	Study population		RR 0.86 (0.81 to 0.90)	52,105 (9 RCTs)	⊕⊕⊕⊖ Moderate[a]	
	380 per 1000	327 per 1000 (308 to 342)				

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Influenza-like illness	Study population		RR 0.94 (0.81 to 1.09)	34,503 (11 RCTs)	⊕⊕⊖⊖ Low[a,b]	
	90 per 1000	85 per 1000 (73 to 98)				
Laboratory-confirmed influenza	Study population		RR 0.91 (0.63 to 1.30)	8332 (8 RCTs)	⊕⊕⊖⊖ Low[b,c]	
	80 per 1000	73 per 1000 (50 to 104)				
Composite of acute respiratory illness, influenza-like illness, laboratory-confirmed influenza	Study population		RR 0.89 (0.83 to 0.94)	71,210 (19 RCTs)	⊕⊕⊖⊖ Low[a,b]	
	200 per 1000	178 per 1000 (166 to 188)				
Adverse events	-		-	(2 RCTs)	⊕⊖⊖⊖ Very low[a,b,c]	Data were insufficient to conduct meta-analysis. 1 study reported that no adverse events were observed, and another study reported that skin reaction was recorded for 10.4% of participants in the hand sanitiser group versus 10.3% in the control group.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the median observed risk in the comparison groups of included studies and the __relative effect__ of the intervention (and its 95% CI).
CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded one level for study limitation (majority of studies were unblinded, with participant-assessed outcome).
[b]Downgraded one level for inconsistent results across studies.
[c]Downgraded one level for imprecision (wide confidence interval or no meta-analysis conducted).

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BACKGROUND

Description of the condition

Epidemic and pandemic viral infections pose a serious threat to people worldwide. Epidemics of note include severe acute respiratory syndrome (SARS) in 2003 and the Middle East respiratory syndrome (MERS), which began in 2012, and the current SARS-CoV-2 pandemic. Major pandemics include the H1N1 influenza caused by the H1N1pdm09 virus in 2009 and the coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

Even non-epidemic acute respiratory infections (ARIs) place a huge burden on healthcare systems around the world, and are a prominent cause of morbidity (WHO 2017). Furthermore, ARIs are often antecedents to lower respiratory tract infections (RTIs) caused by bacterial pathogens (i.e. pneumonia), which cause millions of deaths worldwide, mostly in low-income countries (Schwartz 2018).

High viral load, high levels of transmissibility, susceptible populations, and symptomatic patients are considered to be the drivers of such epidemics and pandemics (Jefferson 2006a). Preventing the spread of respiratory viruses from person to person may be effective at reducing the spread of outbreaks.

Physical interventions, such as the use of masks and physical distancing measures, might prevent the spread of respiratory viruses which are considered to be transmitted by multiple modes of transmission including by respiratory particles of varying sizes spreading from infected to susceptible people and through direct and indirect contact (Kutter 2018; Leung 2021). It is recognised that there is a continuum of respiratory particle sizes varying between large droplet to fine aerosols, which is an important concept. Particles of a variety of sizes may be expelled from the human airway during coughing, sneezing, singing, talking, and during certain medical procedures (WHO 2021). In addition, transmission of respiratory viruses is likely highly complex, dependent on multiple host, virus and environmental factors, plus the myriad of interactions between these factors, which may influence the predominant modes of transmission in any given setting (Broderick 2008; Hendley 1988; Kutter 2018; Leung 2021). Current evidence suggests that the virus responsible for the current COVID-19 pandemic spreads mainly between people who are in close contact with each other (Onakpoya 2022a).

It is also unknown if all respiratory viruses or different strains of a specific respiratory virus transmit in a similar manner, further adding to the complexity of respiratory virus transmission.

Description of the intervention

Single measures of intervention such as the use of vaccines or antivirals, may be insufficient to contain the spread of influenza, but combinations of interventions may reduce the reproduction number to below 1 (Demicheli 2018a; Demicheli 2018b; Jefferson 2014; Jefferson 2018; Thomas 2010). When the reproduction number (or R0) is below 1, each infection causes less than one new secondary infection and the disease will eventually die out. For some respiratory viruses there are no licensed interventions, and a combination of social and physical interventions may be the only option to reduce the spread of outbreaks, particularly those that may be capable of becoming epidemic or pandemic in nature (Luby 2005). Such interventions were emphasised in the World Health Organization's latest Global Influenza Strategy 2019 to 2030, and have several possible advantages over other methods of suppressing ARI outbreaks since they may be instituted rapidly and may be independent of any specific type of infective agent, including novel viruses. In addition, the possible effectiveness of public health measures during the Spanish flu pandemic of 1918 to 1919 in US cities supports the impetus to investigate the existing evidence on the effectiveness of such interventions (Bootsma 2007), including quarantine (such as isolation, physical distancing) and the use of disinfectants. We also considered the major societal implications for any community adopting these measures (CDC 2005a; CDC 2005b; WHO 2006b; WHO 2020a; WHO 2020b).

How the intervention might work

Epidemics and pandemics are more likely during antigenic change (changes in the viral composition) in the virus or transmission from animals (domestic or wild) when there is no natural human immunity (Bonn 1997). High viral load, high levels of transmissibility, and symptomatic patients are considered to be the drivers of such epidemics and pandemics (Jefferson 2006b).

Physical interventions, such as the use of masks (Greenhalgh 2020; Howard 2020), physical distancing measures, school closures, and limitations of mass gatherings, might prevent the spread of the virus transmitted by infectious respiratory particles from infected to susceptible individuals. The use of hand hygiene, gloves, and protective gowns can also prevent the spread by limiting the transfer of viral particles onto and from fomites (inanimate objects such as flat surfaces, tabletops, utensils, porous surfaces, or nowadays cell phones, which can transmit the agent if contaminated) (Onakpoya 2022b). Such public health measures were widely adopted during the Spanish flu pandemic and have been the source of considerable debate (Bootsma 2007).

Why it is important to do this review

Although the benefits of physical interventions seem self-evident, given the global importance of interrupting respiratory virus transmission, having up-to-date estimates of their effectiveness is necessary to inform planning, decision-making, and policy. The continuance of outbreaks of COVID-19 and the reporting of several new trials assessing different barrier interventions in preventing the spread of SARS-COV-2 virus, have prompted this update (WHO 2022). Physical methods have several possible advantages over other methods of suppressing ARI outbreaks, including their rapid deployment and ability to be independent of the infective agent, including novel viruses.

The hallmark of the 2020 update was shifting from including all types of studies to a focus on randomised controlled trials (RCTs) only, which had substantially increased in number. This change enabled more robust evidence summaries from high-quality studies, which are much less prone to the risk of the multiple biases associated with observational studies, to help policy and decision makers in making national and global recommendations. The 2020 update identified 67 relevant studies, but none were carried out during the COVID-19 pandemic (Jefferson 2020). The three key messages of that update were: (1) hand hygiene programmes may help to slow the spread of respiratory viruses; (2) uncertainty whether wearing masks or N95/P2 respirators would help in slowing the spread of respiratory viruses; and (3) few studies were identified for other interventions. One study looked

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at quarantine, and none looked at eye protection, gowns and gloves, or screening people when they entered a country. However, during the last search of the 2020 update, six ongoing, unpublished studies were identified; three of them evaluate masks in COVID-19. The review authors are aware that several trials have now been published since the publication of the 2020 update, warranting this new update.

This is the fifth update (Jefferson 2009; Jefferson 2010; Jefferson 2011; Jefferson 2020) of a Cochrane Review first published in 2007 (Jefferson 2007).

OBJECTIVES

To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.

METHODS

Criteria for considering studies for this review

Types of studies

For this 2022 update we only considered individual-level randomised controlled trials (RCTs), or cluster-RCTs, or quasi-RCTs for inclusion.

In versions of this review prior to 2020 we also included observational studies (cohorts, case-controls, before-after, and time series studies). However, for this update there were sufficient randomised studies to address our study aims, so we excluded observational studies because randomisation is the optimal method to prevent systematic differences between participants in different intervention groups and, further, deciding who receives an intervention and who does not is influenced by many factors, including prognostic factors (Higgins 2011). This point is particularly relevant here because individuals who chose to implement physical interventions are likely to use multiple interventions, thus making it difficult to separate out the effect of single interventions. Further, they are likely to be different from individuals who do not implement physical interventions in ways that are difficult to measure.

Types of participants

People of all ages.

Types of interventions

We included RCTs and cluster-RCTs of trials investigating physical interventions or combinations of interventions to prevent respiratory virus transmission compared with doing nothing or with other interventions. The interventions of interest included: screening at entry ports, isolation, quarantine, physical distancing, personal protection (clothing, gloves, devices), hand hygiene, face masks, gargling, nasal washes, eye protective devices, face shields, disinfecting, and school closure.

Types of outcome measures

For the outcomes listed below we had no predetermined key time points of interest or adverse events of special interest, however, methods of assessment of cases of viral respiratory illness based on laboratory-confirmation needed to be based on an accurate test in combination with critical additional information. For example, a polymerase chain reaction (PCR) test in combination with symptoms of disease, or a serological test at baseline as well as at the end of follow-up were acceptable methods. Further, we stratified analyses by study-specific definitions for cases of viral respiratory illness which included a broad definition of acute respiratory infection (ARI), a more specific definition of influenza-like-illness (ILI), and the most precise definition of a laboratory-confirmed respiratory infection that identified the actual viral pathogen. For the studies conducted during the COVID-19 pandemic, we assumed that COVID-like illness was interchangeable with ILI. In the case of laboratory-confirmed respiratory infection we separated out SARS-CoV-2/influenza and other viral pathogens. We did not pool these outcomes as it cannot be assumed that the effects of physical interventions will be the same for the different viral pathogens. The one exception was for the comparison of hand-hygiene versus control where the estimated effects for ARI, ILI and laboratory-confirmed infection were highly consistent.

Primary outcomes

1. Numbers of cases of viral respiratory illness (including acute respiratory infections (ARI), influenza-like illness (ILI), COVID-like illness and laboratory-confirmed influenza, SARS-CoV-2 or other viral pathogens).
2. Adverse events related to the intervention.

Secondary outcomes

1. Deaths.
2. Severity of viral respiratory illness as reported in the studies.
3. Absenteeism.
4. Hospital admissions.
5. Complications related to the illness, e.g. pneumonia.

Search methods for identification of studies

Electronic searches

For this 2022 update, we refined the original search strategy using a combination of previously included studies and automation tools (Clark 2020). We converted this search using the Polyglot Search Translator (Clark 2020), and ran the searches in the following databases:

1. the Cochrane Central Register of Controlled Trials (CENTRAL) (2022, Issue 09), which includes the Acute Respiratory Infections Group's Specialised Register (searched 04 October 2022) (Appendix 1);
2. PubMed (01 January 2020 to 04 October 2022) (Appendix 2);
3. Embase (01 January 2020 to 04 October 2022) (Appendix 3);
4. CINAHL (Cumulative Index to Nursing and Allied Health Literature) (01 January 2020 to 04 October) (Appendix 4);
5. US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (January 2010 to 04 October 2022); and
6. World Health Organization International Clinical Trials Registry Platform (January 2010 to 04 October 2022).

We combined the database searches with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2011). Details of previous searches are available in Appendix 5.

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Searching other resources

We conducted a backwards-and-forwards citation analysis in Scopus on all newly included studies to identify other potentially relevant studies.

Data collection and analysis

Selection of studies

The search and citation analysis results were initially screened via the RobotSearch tool (Marshall 2018) to exclude all studies that were obviously not RCTs. We scanned the titles and abstracts of studies identified by the searches. We obtained the full-text articles of studies that either appeared to meet our eligibility criteria or for which there was insufficient information to exclude it. We then used a standardised form to assess the eligibility of each study based on the full article.

Data extraction and management

Five review authors (LA/GB/EF/EB/TOJ) independently applied the inclusion criteria to all identified and retrieved articles, and extracted data using a standard template that had been developed for and applied to previous versions of the review, but was revised to reflect our focus on RCTs and cluster-RCTs for this update. We resolved any disagreements through discussion with either PG or JMC acting as arbiter. We extracted and reported descriptions of interventions using the Template for Intervention Description and Replication (TIDieR) template (Table 1).

Assessment of risk of bias in included studies

Four review authors (EF/EB/GB/MJ) independently assessed risk of bias for the method of random sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), outcome reporting (attrition bias), and selective reporting (reporting bias). In addition, for the cluster trials, we assessed selection bias due to how recruitment of participants was conducted. Participants should be identified before the cluster is randomised or, if not, recruitment should be by someone masked to the cluster allocation. Further, we considered whether there were sufficient numbers of clusters in each treatment group to ensure comparable groups, and excluded one study from the analysis due to insufficient number of clusters. We used the Cochrane risk of bias tool to assess risk of bias, classifying each risk of bias domain as 'low', 'high', or 'unclear'. The following were indications for low risk of bias:

1. method of random sequence generation: the method was well-described and is likely to produce balanced and truly random groups;
2. allocation concealment: the next treatment allocation was not known to participant/cluster or treating staff until after consent to join the study;
3. blinding of participants and personnel: the method is likely to maintain blinding throughout the study;
4. blinding of outcome assessors: all outcome assessors were unaware of treatment allocation;
5. outcome reporting: participant attrition throughout the study is reported, and reasons for loss are appropriately described; and
6. selective reporting: all likely planned and collected outcomes have been reported.

Measures of treatment effect

When possible, we performed meta-analysis and summarised effectiveness as risk ratio (RR) using 95% confidence intervals (CIs). For studies that could not be pooled, we used the effect measures reported by the trial authors (such as RR or incidence rate ratio (IRR) with 95% CI or, when these were not available, relevant P values). Where multiple analyses were reported on the same outcome we chose the analysis based on preferences for: (1) an adjusted analysis (over an unadjusted analysis), and (2) an analysis based on a longer follow-up period, or a greater number of outcomes events.

Unit of analysis issues

Many of the included studies were cluster-RCTs. To avoid any unit of analysis issues, we only included treatment effect estimates that were based on methods that were appropriate for the analysis of cluster trials, such as mixed models and generalised estimating equations. Given this restriction, we used the generalised inverse-variance method of meta-analysis. Some cluster-RCTs that did not report cluster-adjusted treatment effects provided sufficient data (number of events and participants by treatment group and intraclass correlations) for us to calculate appropriate treatment effect estimates and standard errors using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021a). For studies with multiple treatment groups but only one control group, where appropriate, we adjusted standard errors upwards to avoid unit of analysis errors in the meta-analyses. We did this by splitting the control group into equal sized groups and adjusting standard errors upwards to account for the reduced sample size of the control subgroups (Higgins 2021b).

Dealing with missing data

Previously, whenever details of studies were unclear, or studies were only known to us by abstracts or communications at meetings, we corresponded with first or corresponding authors. For this 2022 review, we did not contact authors of studies.

Assessment of heterogeneity

Aggregation of data was dependent on types of comparisons, sensitivity and homogeneity of definitions of exposure, populations and outcomes used. We calculated the I^2statistic and Chi^2 test for each pooled estimate to assess the presence of statistical heterogeneity (Higgins 2002; Higgins 2003).

Assessment of reporting biases

Given the widely disparate nature of our evidence base, we limited our assessment of possible reporting biases to funnel plot visual inspection if we had > 10 included studies for any single meta-analysis.

Data synthesis

If possible and appropriate, we combined studies in a meta-analysis. We used the generalised inverse-variance random-effects model where cluster-RCTs were included in the analysis. We chose the random-effects model because we expected clinical heterogeneity due to differences in pooled interventions and outcome definitions, and methodological heterogeneity due to pooling of RCTs and cluster-RCTs.

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Subgroup analysis and investigation of heterogeneity

We conducted one post hoc subgroup analyses of adults (18 years +) versus children (0 to 18 years) for the comparison of hand hygiene versus control.

We did not conduct further investigation of heterogeneity due to insufficient numbers of studies included in the comparisons.

Sensitivity analysis

We conducted a sensitivity analysis for hand hygiene versus control where we included the most precise and unequivocal measure of viral respiratory illness reported for each included study.

Summary of findings and assessment of the certainty of the evidence

We created three summary of findings tables using the following outcomes: numbers of cases of viral respiratory illness (including ARIs, ILI, COVID-like illness and laboratory-confirmed influenza/SARS-CoV-2 or other respiratory viruses), and adverse events related to the intervention (Summary of findings 1; Summary of findings 2; Summary of findings 3). We planned to include the secondary outcomes of deaths; severity of viral respiratory illness as reported in the studies; absenteeism; hospital admissions; and complications related to the illness (e.g. pneumonia). However, these data were poorly reported in the included studies. We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of evidence as it related to the studies which contributed data to the meta-analyses for the prespecified outcomes (Atkins 2004). We used the methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), employing GRADEpro GDT software (GRADEpro GDT). We justified all decisions to down- or upgrade the certainty of the evidence in footnotes, and made comments to aid the reader's understanding of the review where necessary.

RESULTS

Description of studies

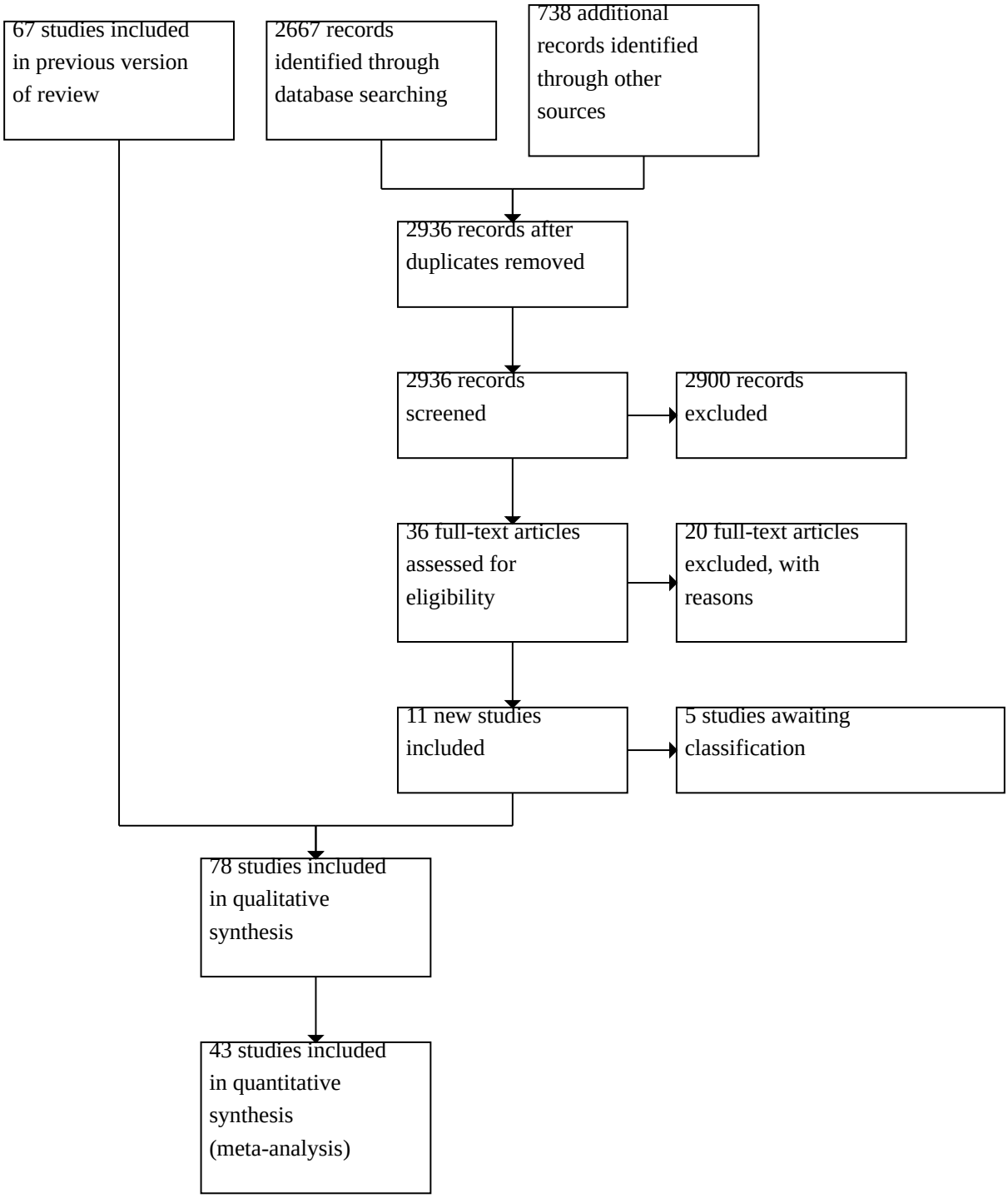
See Characteristics of included studies and Characteristics of excluded studies tables. Five trials were funded by government and pharmaceutical companies (Aiello 2010; Aiello 2012; Chard 2019; Yeung 2011; Zomer 2015), and nine trials were funded by pharmaceutical companies (Arbogast 2016; Carabin 1999; Luby 2005; Nicholson 2014; Sandora 2005; Sandora 2008; Turner 2004a; Turner 2004b; Turner 2012).

Results of the search

For this 2022 update we found 2667 records through database and trial registry searching, as well as 738 record through citation searching. After removing duplicates we had 2936 records that underwent title and abstract screening.
We identified a total of 202 titles in this 2022 update. We excluded 180 titles and retrieved the full papers of 35 studies, to include 11 new studies. See Figure 1.

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Figure 1. Study flow diagram.



Included studies

In this 2022 update we included 11 new studies (610,872 participants); randomised controlled trials (RCTs) (n = 5) or cluster-RCTs (n = 6) published between 2020 and 2022. In total 78 studies are included in this review update. For detailed descriptions of the interventions of the included studies, see Table 1.

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Eighteen trials focused on using masks (Abaluck 2022; Aiello 2010; Aiello 2012; Alfelali 2020; Barasheed 2014; Bundgaard 2021; Canini 2010; Cowling 2008; Ide 2016; Jacobs 2009; Loeb 2009; MacIntyre 2009; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; MacIntyre 2016; Radonovich 2019; Suess 2012). Thirteen of the 18 trials compared medical/surgical masks to no mask (control) (Abaluck 2022; Aiello 2010; Aiello 2012; Alfelali 2020; Barasheed 2014; Bundgaard 2021; Canini 2010; Cowling 2008; Jacobs 2009; MacIntyre 2009; MacIntyre 2015; MacIntyre 2016; Suess 2012). One study compared catechin-treated masks to no mask (Ide 2016), and one study included cloth masks versus control (third arm in MacIntyre 2015). Three of the 18 trials were in healthcare workers (Ide 2016; Jacobs 2009; MacIntyre 2015), whilst the remaining trials were in non-healthcare workers (students, households, families, or pilgrims). Only one trial was conducted during the H1N1 pandemic season (Suess 2012), and two trials were conducted during the SARS-CoV-2 pandemic (Abaluck 2022; Bundgaard 2021).

Five of the 18 trials compared N95 masks or P2 masks to medical/surgical masks (Loeb 2009; MacIntyre 2009; MacIntyre 2011; MacIntyre 2013; Radonovich 2019). All of these trials, except for one study that was conducted on household individuals (MacIntyre 2009), included healthcare workers either in a hospital setting, Loeb 2009; MacIntyre 2011; MacIntyre 2013, or an outpatient setting (MacIntyre 2009; Radonovich 2019).

One trial evaluated the effectiveness of quarantining workers of one of two sibling companies in Japan whose family members had developed an influenza-like illness (ILI) during the 2009 to 2010 H1N1 influenza pandemic (Miyaki 2011). Another trial conducted during the SARS-CoV-2 pandemic in Norway investigated fitness centre access with physical distancing compared to no access (Helsingen 2021); and one cluster trial compared daily testing for contacts of individuals with SARS-CoV-2 compared to self-isolation at home in English secondary schools (Young 2021).

Nineteen trials compared hand hygiene interventions with no hand hygiene (control) and provided data suitable for meta-analysis. The populations in these trials included adults, children, and families, in settings such as schools (Biswas 2019; Stebbins 2011), childcare centres (Azor-Martinez 2018; Correa 2012; Roberts 2000; Zomer 2015), homes/households (Cowling 2008; Cowling 2009; Larson 2010; Little 2015; Nicholson 2014; Ram 2015; Sandora 2005; Simmerman 2011), offices (Hubner 2010), military trainees (Millar 2016), villages (Ashraf 2020; Swarthout 2020), and nursing homes (Teesing 2021). None of the trials were conducted during a pandemic, although some of the studies were conducted during peak influenza seasons.

A further 10 trials that compared a variety of hand hygiene modalities to control provided insufficient information to include in meta-analyses. Three trials were in children: one was conducted in daycare centres in Denmark examining a multimodal hygiene programme (Ladegaard 1999), and two trials compared a hand hygiene campaign or workshop in an elementary school environment in Saudi Arabia, Alzaher 2018, and Egypt, Talaat 2011. Three trials tested virucidal hand treatment in an experimental setting, Gwaltney 1980; Turner 2004a, and in a community, Turner 2012, in the USA. Feldman 2016 compared hand-washing with chlorhexidine gluconate amongst Israeli sailors. One trial compared hand sanitiser packaged in a multimodal hygiene programme amongst office employees in the USA (Arbogast 2016). Two trials were conducted in a long-term facility setting: one trial examined the effect of a bundled hand hygiene programme on infectious risk in nursing home residents in France (Temime 2018), and the other trial compared the effect of using hand sanitisers in healthcare workers on the rate of infections (including respiratory infections) in nursing home residents in Hong Kong (Yeung 2011).

Five trials compared different hand hygiene interventions in a variety of settings such as schools (Morton 2004, in kindergartens and elementary schools in the USA; Priest 2014, in primary schools in New Zealand; and Pandejpong 2012 in kindergartens in Thailand). One study was conducted in low-income neighbourhoods in Karachi, Pakistan (Luby 2005), and one was conducted in a workplace environment in Finland (Savolainen-Kopra 2012). A variety of interventions were used across these trials such as soap and water (Luby 2005; Savolainen-Kopra 2012), hand sanitiser (Morton 2004; Pandejpong 2012; Priest 2014; Savolainen-Kopra 2012), body wash (Luby 2005), and alcohol-based hand wipes (Morton 2004), with or without additional hygiene education. There was considerable variation in interventions, and the information in the trial reports was insufficient to permit meta-analysis.

Seven trials compared a combined intervention of hand hygiene and face masks with control. Four of these trials were carried out in households in Germany (Suess 2012), Thailand (Simmerman 2011), Hispanic immigrant communities in the USA (Larson 2010), and households in Hong Kong (Cowling 2009). Two trials were conducted amongst university student residences (Aiello 2010; Aiello 2012), and two trials in groups of pilgrims at the annual Hajj (Aelami 2015; Alfelali 2020). Moreover, six trials evaluated the incremental benefit of combining surgical masks in addition to hand hygiene with soap (Simmerman 2011), hand sanitiser (Aiello 2010; Aiello 2012; Larson 2010; Suess 2012), or both (Cowling 2009), versus mask or hand hygiene alone on the outcomes of ILI and influenza. Aelami 2015 investigated a hygienic package (alcohol-based hand rub (gel or spray), surgical masks, soap, and paper handkerchiefs) with a control group.

Seven trials compared a multimodal combination of hand hygiene and disinfection of surfaces, toys, linen, or other components of the environment with a control (Ban 2015; Carabin 1999; Ibfelt 2015; Kotch 1994; McConeghy 2017; Sandora 2008; White 2001). Variation in scope and type of interventions and insufficient data in trial reports precluded meta-analysis. All studies except for one were in children (McConeghy 2017), which was in a nursing home population).

Three trials included in two papers investigated the role of virucidal tissues in interrupting transmission of naturally occurring respiratory infections in households (Farr 1988a; Farr 1988b; Longini 1988). Four cluster-RCTs implemented complex, multimodal sanitation, education, cooking, and hygiene interventions (Chard 2019; Hartinger 2016; Huda 2012; Najnin 2019). All four of these trials were conducted in low-income countries in settings with minimal to no access to basic sanitation.

Three trials assessed the effect of gargling on the incidence of upper respiratory tract infections (URTIs) or influenza: gargling with povidone-iodine (Satomura 2005), green tea (Ide 2014), and tap water (Goodall 2014). Two trials investigated the use of mouth/nasal washes on the incidence of SARS-CoV-2 infection in healthcare workers during the COVID-19 pandemic (Almanza-Reyes 2021; Gutiérrez-García 2022). One trial investigated the use of glasses against the transmission of SARS-CoV-2 (Fretheim 2022a).

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Ongoing studies

We identified four ongoing studies during the course of the COVID-19 pandemic, of which one is completed, but unreported (NCT04471766). The trials evaluated masks concurrent with the COVID-19 pandemic. Three trials on other interventions are ongoing (Brass 2021; NCT03454009; NCT04267952).

Studies awaiting classification

We identified five studies awaiting classification (Contreras 2022; Croke 2022; Delaguerre 2022; Loeb 2022; Varela 2022).

A previous RCT (NCT04296643) reported as ongoing in the last version has now been recently published but was not able to be included in the summary of findings pooled results (Loeb 2022). In a multicentre, randomised non-inferiority trial of 1009 healthcare workers (HCWs) across four countries randomised to medical mask versus fit-tested N95 respirators for direct care of COVID-19 patients or long-term care residents, laboratory-confirmed SARS-CoV-2 was found in 10.46% (52/497) versus 9.27% (47/507) in the medical/surgical mask group and fit-tested N95 respirator group (hazard ratio 1.14 (95% CI 0.77 to 1.69), respectively. There was a 1.19% absolute increase in risk of COVID-19 with medical masks versus N95 respirator 95% CI (-2.5% to 4.9%). There were 47 (10.8%) adverse events related to the intervention reported in the medical mask group and 59 (13.6%) in the N95 respirator group. The use of medical masks was found to be non-inferior to N95 respirators in the direct care of COVID-19 patients and the study crossed over into the more transmissible Omicron variant period of the COVID-19 pandemic.

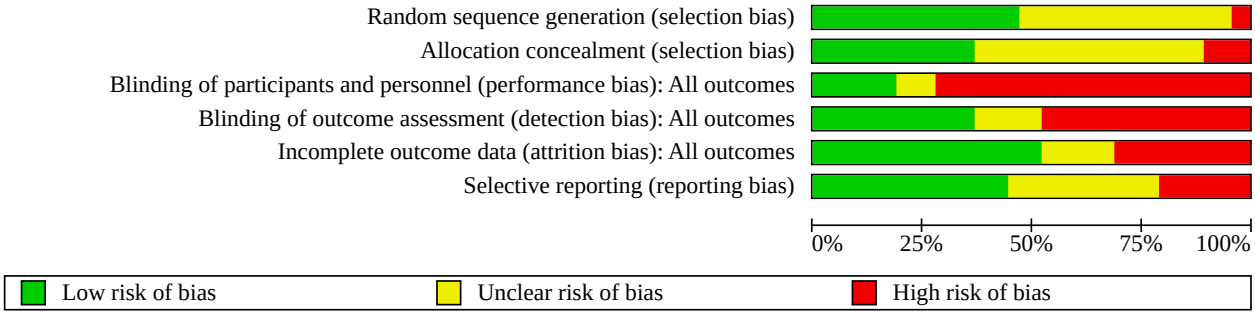
Excluded studies

We excluded a total of 180 studies. We identified 20 new studies for exclusion at the data extraction stage of this 2022 update, all of which appeared to be eligible at screening. Five of the 20 studies were ineligible due to evaluating treatments for patients with disease (Cyril Vitug 2021; Ferrer 2021; Meister 2022; Sanchez Barrueco 2022; Sevinc Gul 2022), two were excluded because they did not assess clinical outcomes (Costa 2021; Seneviratne 2021), four were excluded due to not assessing viral outcomes (Gharebaghi 2020; Giuliano 2021; Karakaya 2021; Kawyannejad 2020), five were excluded as they were experiments that did not measure any of our outcomes of interest (Ahmadian 2022; Dalakoti 2022; Egger 2022; Malaczek 2022; Montero-Vilchez 2022); three were excluded because they were not RCTs (Chen 2022; Lim 2022; Mo 2022), and one was excluded as it was a report of another study (Munoz-Basagoiti 2022).

Risk of bias in included studies

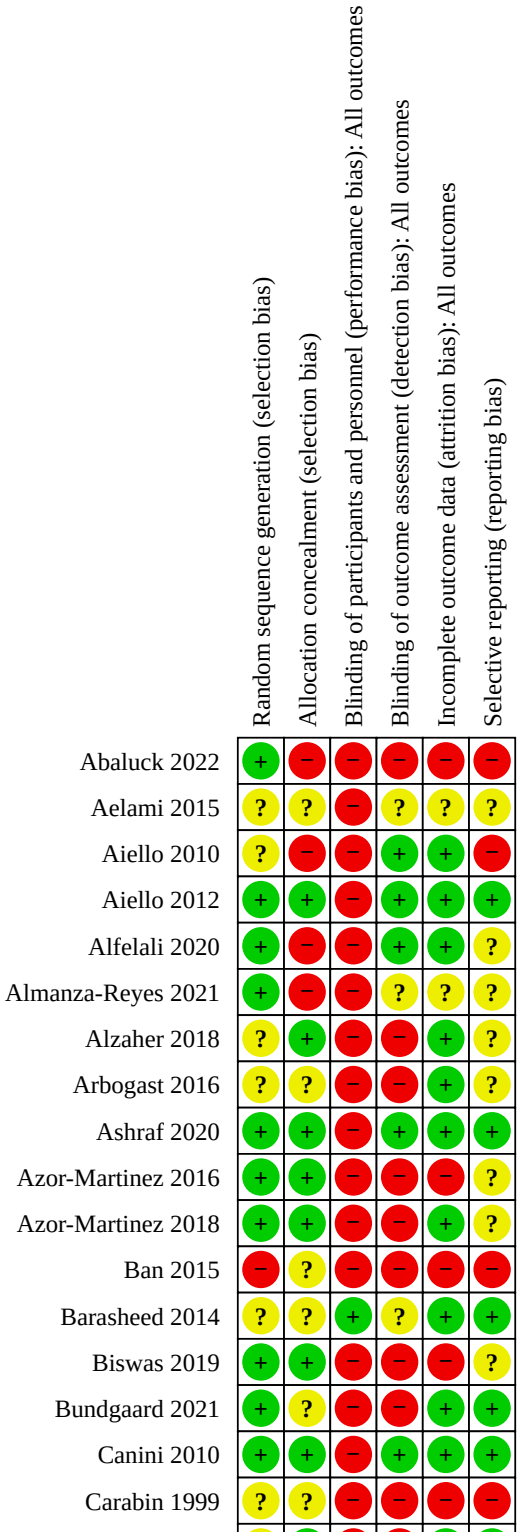
The overall risk of bias is presented graphically in Figure 2 and summarised by included study in Figure 3. Details on the judgements can be found in the descriptions of individual included studies (Characteristics of included studies table). Out of 78 included studies, only two were rated as low risk of bias for all domains. One of those studies compared two different types of masks (Radonovich 2019), and the other compared hand sanitiser to no treatment (Turner 2012). Notably, neither of these two studies was blinded, however, trial procedures were sufficiently robust that the risk of performance bias was low. Overall,approximately only 20% of the studies were rated as low risk of performance bias. This risk of bias domain was particularly problematic because most interventions studied could not be blinded from participants and/or investigators. The two risks of bias domains that were rated the least problematic were attrition bias and random sequence generation where around 50% of studies were rated as low risk of bias. Allocation concealment, blinded outcome assessment and selective reporting were rated as low risk of bias for around 40% of the included studies. Many of the included studies were cluster-RCTs where the randomisation process was not well reported leading to ratings of unclear risk of bias.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included trials.



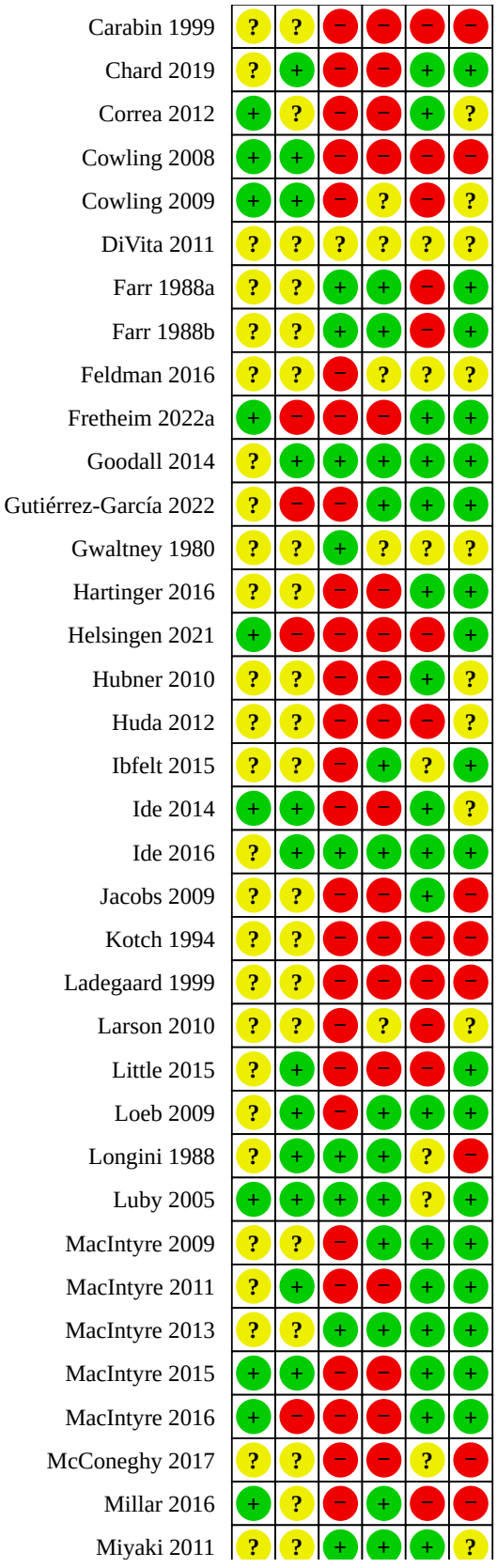
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Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included trial.



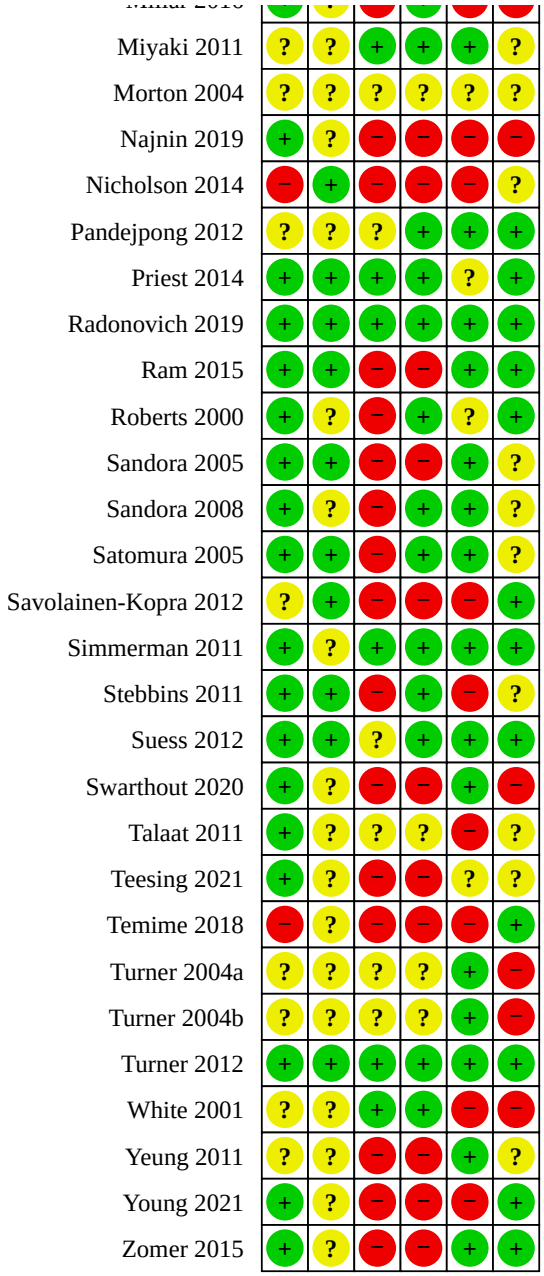
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Figure 3. (Continued)



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Figure 3. (Continued)



Allocation

For this 2022 review, 10 of the 11 newly included studies provided adequate information on randomisation and were judged to have low risk of bias (Abaluck 2022; Alfelali 2020; Almanza-Reyes 2021; Ashraf 2020; Bundgaard 2021; Fretheim 2022a; Helsingen 2021; Swarthout 2020; Teesing 2021; Young 2021). Six of these studies described the use of a computerised random number generator (Almanza-Reyes 2021; Bundgaard 2021; Helsingen 2021; Swarthout 2020; Teesing 2021; Young 2021). Almanza-Reyes 2021 described the use of computer-generated stratified block scheme, while Bundgaard 2021 reported the use of a computer algorithm stratified by the five regions of Denmark. In Fretheim 2022a, the investigators used a digital platform (Nettskjema) for recruitment, randomisation and allocation. Three studies mentioned the use of a random number generator, with no additional specifics (Helsingen 2021; Swarthout 2020; Teesing 2021), while Young 2021 mentioned that randomisation was performed in blocks of two and stratified using nine strata to ensure a sample representative of schools and colleges in England. Abaluck 2022 reported pairwise cross randomisation, whilst Ashraf 2020 reported using a block random number generator. Alfelali 2020 described using coin-tossing by an individual who was not a member of the research team (i.e. a fellow pilgrim who was not a participant in the trial, a tour operator, or a medical volunteer). One study provided insufficient information to judge the sequence generation bias (Gutiérrez-García 2022).

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The success of randomisation was judged as low risk of bias in one study only that used an off-site investigator to allocate groups (Ashraf 2020). Four new studies provided insufficient information to make a judgment on the adequacy of the process (Bundgaard 2021; Swarthout 2020; Teesing 2021; Young 2021). The remaining six newly included studies were judged as high risk of allocation bias (Abaluck 2022; Alfelali 2020; Almanza-Reyes 2021; Fretheim 2022a; Gutiérrez-García 2022; Helsingen 2021). In Abaluck 2022, there was a significant difference in the numbers of households included in each treatment group, suggestive of a lack of allocation concealment. Alfelali 2020 used coin tossing, which can lead to a large imbalance. In Almanza-Reyes 2021 baseline prognostic factors (vaccination and frequency of handwashing) were unbalanced between the two arms. In Fretheim 2022a, a higher number of participants used face masks in the intervention group. In Gutiérrez-García 2022 there as a significant age difference between the two groups. Helsingen 2021 described assigning the randomised sequence by a member of the research team, with no further description.

For the review published in 2020, information on sequence generation was overall poorly reported in most of the included studies. Nineteen of the included studies provided adequate information on the randomisation scheme and were judged as at low risk of bias (Aiello 2012; Azor-Martinez 2016; Azor-Martinez 2018; Biswas 2019; Canini 2010; Correa 2012; Ide 2014; MacIntyre 2015; MacIntyre 2016; Millar 2016; Najnin 2019; Radonovich 2019; Ram 2015; Simmerman 2011; Stebbins 2011; Suess 2012; Talaat 2011; Turner 2012; Zomer 2015). Nine studies described the use of computerised sequence generation program/software (Aiello 2012; Azor-Martinez 2018; Biswas 2019; Canini 2010; Millar 2016; Najnin 2019; Radonovich 2019; Talaat 2011; Turner 2012). One study used random number tables for sequence generation (Azor-Martinez 2016). Three studies described using the random function in Microsoft Excel (Microsoft Excel 2018) (Correa 2012; MacIntyre 2016; Suess 2012). Two studies used statistical software to generate a randomisation allocation (MacIntyre 2015; Priest 2014). Two studies reported using block randomisation: Ram 2015 used block randomisation, and an independent investigator-generated the list of random assignments, whilst Simmerman 2011 performed block randomisation. Stebbins 2011 used constrained randomisation, and Zomer 2015 reported using stratified randomisation by means of computer generation with a 1:1 ratio in each of the strata.

Fourteen studies reported insufficient information to permit a judgement on the adequacy of the process to minimise selection bias (Aelami 2015; Alzaher 2018; Arbogast 2016; Barasheed 2014; Chard 2019; DiVita 2011; Feldman 2016; Hubner 2010; Ibfelt 2015; McConeghy 2017; Miyaki 2011; Pandejpong 2012; Savolainen-Kopra 2012; Yeung 2011). Six studies provided some description about sequence generation, but it was still unclear (Hartinger 2016; Huda 2012; Ide 2016; Little 2015; MacIntyre 2011; MacIntyre 2013). Huda 2012 mentioned random number tables, but it was unclear if this was for random selection or randomisation. Ide 2016 used computer-generated randomisation, but the method was not stated. Hartinger 2016 used covariate-constrained randomisation, but the method was not described. In Little 2015, participants were automatically randomly assigned by the intervention software, but the sequence generation was not described. Two studies used a secure computerised randomisation program (MacIntyre 2011; MacIntyre 2013), but the sequence generation was not described.

Three of the studies included in the 2020 review, were poorly randomised (Ban 2015; Nicholson 2014; Temime 2018). Ban 2015 included only two clusters, and the randomisation scheme was not reported. Nicholson 2014 used coin tossing, which can lead to a large imbalance. Temime 2018 used “simple randomisation” with no further description.

For the RCTs included in previous versions of the review, three were poorly reported with no description of randomisation sequence or concealment of allocation (Gwaltney 1980; Turner 2004a; Turner 2004b). The quality of the cluster-RCTs varied, with four studies not providing a description of the randomisation procedure (Carabin 1999; Kotch 1994; Morton 2004; White 2001). We rated seven studies as at low risk of bias for sequence generation (Cowling 2008; Cowling 2009; Luby 2005; Roberts 2000; Sandora 2005; Sandora 2008; Satomura 2005), and a further six studies as at unclear risk of bias (Farr 1988a; Farr 1988b; Ladegaard 1999; Loeb 2009; Longini 1988; MacIntyre 2009).

Many of the newly included cluster-RCTs did not report adequately on allocation concealment. Twenty-one of these studies reported adequate allocation and were judged as at low risk of bias (Aiello 2012; Alzaher 2018; Azor-Martinez 2016; Azor-Martinez 2018; Biswas 2019; Canini 2010; Chard 2019; Goodall 2014; Ide 2014; Ide 2016; Little 2015; MacIntyre 2011; MacIntyre 2015; Nicholson 2014; Priest 2014; Radonovich 2019; Ram 2015; Savolainen-Kopra 2012; Stebbins 2011; Suess 2012; Turner 2012). Aiello 2012 randomised all residence houses in each of the residence halls prior to the intervention implementation. Alzaher 2018 allocated schools prior to all schoolgirls attending selected schools being invited to participate. Azor-Martinez 2016 allocated schools/classes prior to children's recruitment. Azor-Martinez 2018 assigned clusters prior to recruitment. Biswas 2019 completed the allocation prior to individuals being recruited. Chard 2019 allocated schools prior to individuals being recruited. Goodall 2014 used opaque, sealed, serially numbered envelopes that were only accessed when two study personnel were present. Ide 2014 also reported using individual drawing of sealed, opaque envelopes to randomly assign participants to the study groups. MacIntyre 2011 randomised hospitals prior to inclusion of participants. In MacIntyre 2015, hospital wards were randomised prior to recruitment of individuals. Nicholson 2014 used coin tossing to assign communities to intervention or control arms. Radonovich 2019 used constrained randomisation to resolve any potential imbalance between covariates between the trial arms. Four studies reported the use of central randomisation: Canini 2010 used central randomisation by employing an interactive voice response system; Ide 2016 used central randomisation services; Little 2015 participants were automatically randomly assigned by the intervention software; and Ram 2015 described a central allocation through data collectors notifying the field research officer, who consulted the block randomisation list to make the assignment of the household compound to intervention or control. Savolainen-Kopra 2012 randomised clusters by matching prior to the onset of the interventions. Four studies reported that allocation was assigned by personnel (investigator, physician, or statistician) unaware of the randomisation sequence (Priest 2014; Stebbins 2011; Suess 2012; Turner 2012). Twenty-two studies reported insufficient information to permit a judgement on the adequacy of the process to minimise selection bias (Aelami 2015; Arbogast 2016; Ban 2015; Barasheed 2014; Correa 2012; DiVita 2011; Feldman 2016; Hartinger 2016; Hubner 2010; Huda 2012; Ibfelt 2015; MacIntyre

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2013; McConeghy 2017; Millar 2016; Miyaki 2011; Najnin 2019; Pandejpong 2012; Simmerman 2011; Talaat 2011; Temime 2018; Yeung 2011; Zomer 2015). Two studies provided some information about allocation, but it was not enough to permit a judgement on the risk of bias (Barasheed 2014; Simmerman 2011). Barasheed 2014 randomised pilgrim tents using an independent study co-ordinator who was not an investigator, but did not describe how this was done. Simmerman 2011 described using a study co-ordinator to assign households to the study arm (after consent was obtained). Only one of the newly added studies was judged as at high risk of bias, where the random assignment was allocated by doctors enrolling the participants (MacIntyre 2016). Of the previously included RCTs, 14 provided no or an insufficient description of concealment of allocation (Carabin 1999; Farr 1988a; Farr 1988b; Gwaltney 1980; Kotch 1994; Ladegaard 1999; Larson 2010; MacIntyre 2009; Morton 2004; Roberts 2000; Sandora 2008; Turner 2004a; Turner 2004b; White 2001). We assessed all of the remaining studies as at low risk of bias (Canini 2010; Cowling 2008; Cowling 2009; Loeb 2009; Longini 1988; LLuby 2005; Sandora 2005;Satomura 2005). Aiello 2010 used the drawing of a uniform ticket with the name of each hall out of a container and was rated as at high risk of bias.

Blinding

Although blinding is less of a concern in cluster-RCTs, the risk of bias is substantial when the outcomes are subjective and the outcome assessor is not blinded.

In this 2022 review, five RCTs (Almanza-Reyes 2021; Bundgaard 2021; Fretheim 2022a; Gutiérrez-García 2022; Helsingen 2021), and six cluster-RCTs were all judged to have a high risk of detection bias (Abaluck 2022; Alfelali 2020; Ashraf 2020; Swarthout 2020; Teesing 2021; Young 2021).

We judged two of the newly included studies to have a low risk of detection bias as the outcome is laboratory-confirmed (Alfelali 2020; Gutiérrez-García 2022). One study provided insufficient information to enable judgment (Almanza-Reyes 2021). The remaining eight of the 11 new studies have a high risk of detection bias (Abaluck 2022; Ashraf 2020; Bundgaard 2021; Fretheim 2022a; Helsingen 2021; Swarthout 2020; Teesing 2021; Young 2021). In Abaluck 2022, investigators dropped individuals for whom symptom data were missing. In addition, other outcomes were subjective and can be influenced by the unblinded mask promoters, and mask surveillance staff. Moreover, blood testing in the protocol specified baseline testing which was not done, and no further explanation was provided. In Ashraf 2020, although the data collection team was separate from the intervention team, they were not blinded, and the outcome was respiratory illness measured through caregiver-reported symptoms. In Bundgaard 2021, case detection was based on patient-reported symptoms on home tests. In Fretheim 2022a, the outcome was self-reported positive COVID-19 test result, notified to the Norwegian Surveillance System for Communicable Diseases (MSIS). However, the public policy requiring confirmatory PCR-test had changed during the study, which may have affected reporting. In Helsingen 2021, although the outcome was a positive test for COVID-19 based on SARS-CoV-2 ribonucleic acid, the samples were collected and sent by participants, and there was a difference in adherence in testing between the two groups. Swarthout 2020, Teesing 2021, and Young 2021 all had subjective outcomes and assessors were not blinded. As for the detection bias, six of the newly included studies were considered to have a high risk of detection bias (Bundgaard 2021; Gutiérrez-García 2022; Helsingen 2021; Swarthout 2020; Teesing 2021; Young 2021. In Bundgaard 2021, case detection was based on patient-reported symptoms and results from home point-of-care (POCT) testing. The primary outcome of Gutiérrez-García 2022 was participants' self-reported symptoms. Case detection in Helsingen 2021 was based on a home-test kit. Swarthout 2020, Teesing 2021, and Young 2021 had subjective outcomes.

In the 2020 review, we judged 36 studies to have a high risk of bias (Aiello 2012; Abaluck 2022; Alfelali 2020; Almanza-Reyes 2021; Alzaher 2018; Arbogast 2016; Ashraf 2020; Azor-Martinez 2016; Azor-Martinez 2018; Ban 2015; Biswas 2019; Bundgaard 2021; Carabin 1999; Chard 2019; Correa 2012; Cowling 2008; Gutiérrez-García 2022; Helsingen 2021; Ide 2014; Kotch 1994; Ladegaard 1999; Little 2015; MacIntyre 2011; MacIntyre 2015; MacIntyre 2016; McConeghy 2017; Najnin 2019; Nicholson 2014; Ram 2015; Sandora 2008; Savolainen-Kopra 2012; Swarthout 2020; Teesing 2021; Temime 2018; Young 2021; Zomer 2015). We assessed five cluster-RCTs as at low risk of bias. Farr 1988a and Farr 1988b were double-blinded studies and were judged as at low risk of bias. MacIntyre 2013 and Simmerman 2011 reported laboratory-confirmed influenza, and blinding would not have affected the result. In Miyaki 2011 the self-reported respiratory symptoms were confirmed by a physician.

We judged four cluster-RCTs to have a low risk of detection bias because the outcome was laboratory-confirmed influenza (Alfelali 2020; Barasheed 2014; Suess 2012), or physician-confirmed ILI, Pandejpong 2012. Another two cluster-RCTs were judged to have a low risk of bias because outcome assessors were blinded (Abaluck 2022; Ashraf 2020). One RCT (Almanza-Reyes 2021) and two cluster-RCTs (Talaat 2011; Yeung 2011) provided insufficient data to judge the effect of non-blinding. Talaat 2011 included outcomes that were both self-reported ILI and laboratory-confirmed influenza. In Yeung 2011 the detection of cases was based on records for hospitalisation related to infection (including pneumonia). Eleven cluster-RCTs were not blinded, but we judged the primary outcome to be unaffected by non-blinding. Seven trials reported laboratory-confirmed influenza (Aiello 2012; Cowling 2009; Larson 2010; Loeb 2009; MacIntyre 2009; Millar 2016; Stebbins 2011). Four studies reported self-reported outcomes (Canini 2010; Priest 2014; Roberts 2000; Sandora 2008), but outcome assessors were not aware of the intervention assignment. Five RCTs were double-blinded and were judged as at low risk of bias (Goodall 2014; Ide 2016; Longini 1988; Luby 2005; White 2001), whilst two studies were single-blinded where investigators, Radonovich 2019, or laboratory personnel, Turner 2012, were blinded. Four RCTs were not blinded and were judged as at high risk of bias given the subjective nature of the outcome assessed (Hubner 2010; Ibfelt 2015; Jacobs 2009; Satomura 2005). Turner 2004a and Turner 2004b were double-blind studies, but insufficient information was provided to assess the risk of bias.

Incomplete outcome data

In this 2022 review, six of the 11 newly included studies had reasonable attrition and provided sufficient evidence about participant flow throughout the study and reasons of loss to follow-up, and hence were assessed as having a low risk of attrition bias (Alfelali 2020; Ashraf 2020; Bundgaard 2021; Fretheim 2022a; Gutiérrez-García 2022; Swarthout 2020). Two studies provided insufficient information to assess the attrition risk (Almanza-

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Reyes 2021; Teesing 2021). The remaining three studies were judged at high risk of attrition bias. In Abaluck 2022, laboratory testing results were only available for 40% of the symptomatic participants. In Helsingen 2021, more people in the control group withdrew from the study and reasons for withdrawal were not provided. In the Young 2021 study there was high attrition at different rates between the two groups.

In the 2020 review, we assessed 26 newly included trials as having a low risk of attrition bias, with sufficient evidence from the participant flow chart, and explanation of loss to follow-up (which was minimal) similar between groups (Aiello 2012; Alzaher 2018; Arbogast 2016; Azor-Martinez 2018; Barasheed 2014; Canini 2010; Chard 2019; Correa 2012; Goodall 2014; Hartinger 2016; Hubner 2010; Ide 2014; Ide 2016; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; MacIntyre 2016; Miyaki 2011; Pandejpong 2012; Radonovich 2019; Ram 2015; Simmerman 2011; Suess 2012; Turner 2012; Yeung 2011; Zomer 2015). Seven studies did not report sufficient information on incomplete data (attrition bias) (Aelami 2015; DiVita 2011; Feldman 2016; Hartinger 2016; Ibfelt 2015; McConeghy 2017; Priest 2014). Twelve studies had a high risk of attrition bias (Azor-Martinez 2016; Ban 2015; Biswas 2019; Huda 2012; Little 2015; Millar 2016; Najnin 2019; Nicholson 2014; Savolainen-Kopra 2012; Stebbins 2011; Talaat 2011; Temime 2018). In Azor-Martinez 2016, attrition levels were high and differed between the two groups. Ban 2015 did not report on reasons for loss to follow-up. Biswas 2019 did not provide information on missing participants (28 children in the control schools and two children in the intervention schools). Huda 2012 did not provide a flow diagram of study participants. Little 2015 had high attrition that differed between the two groups. Attrition in Millar 2016 differed amongst the three groups. In addition, ARI cases were captured utilising clinic-based medical records for those participants who sought hospital care only. In Najnin 2019, there was high migration movement during the study, which could have distorted the baseline characteristics even more. There was no description of how such migration and changes in the intervention group were dealt with. In Nicholson 2014, households were removed from the study if they provided no data for five consecutive weeks. Although attrition was reported in Savolainen-Kopra 2012, and 76% of volunteers who were recruited at the beginning of the reporting period completed the study, new recruits were added during the study to replace volunteers lost in most clusters. The total number of reporting participants at the end of the trial was 626 (91.7%) compared to the beginning, meaning that 15.7% of participants were replaced during the study. In Stebbins 2011,reasons for episodes of absence in 66% of the study participants were not reported. Talaat 2011 did not provide a flow chart of clusters flow during the study period and provided no information on withdrawal. Temime 2018 was greatly biased due to underreporting of outcomes in the control groups. Furthermore, no study flow chart was provided, and there was no reporting on any exclusions.

Selective reporting

For this 2022 review update, six of the 11 newly included studies reported all specified outcomes and were judged to have a low risk of selective reporting (Ashraf 2020; Bundgaard 2021; Fretheim 2022a; Gutiérrez-García 2022; Helsingen 2021; Young 2021). Three studies had no published protocol and were considered to have an unclear risk of selective reporting (Alfelali 2020; Almanza-Reyes 2021; Teesing 2021). The remaining two new included studies are considered to have a high risk of bias in this domain. Abaluck 2022 did not report on prespecified seroconversion, while in Swarthout 2020, none of the outcomes reported were prespecified in the trial registry.

In the 2020 review, 22 included studies reported all specified outcomes and were judged as at low risk of reporting bias (Aiello 2012; Barasheed 2014; Canini 2010; Chard 2019; Goodall 2014; Hartinger 2016; Ibfelt 2015; Ide 2016; Little 2015; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; MacIntyre 2016; Pandejpong 2012; Priest 2014; Radonovich 2019; Savolainen-Kopra 2012; Simmerman 2011; Suess 2012; Temime 2018; Turner 2012; Zomer 2015). For 18 studies, it is unlikely that other outcomes were measured and not reported, although no protocol was available to assess reporting bias (Aelami 2015; Alzaher 2018; Arbogast 2016; Azor-Martinez 2016; Azor-Martinez 2018; Ban 2015; Biswas 2019; Correa 2012; DiVita 2011; Feldman 2016; Hubner 2010; Huda 2012; Ide 2014; Miyaki 2011; Nicholson 2014; Stebbins 2011; Talaat 2011; Yeung 2011). Three studies were at high risk of reporting bias (McConeghy 2017; Millar 2016; Najnin 2019). In McConeghy 2017, URTI was mentioned in the methods (the intervention presumably would have targeted these), but only lower respiratory tract infection (LRTI) and overall infection were reported. Millar 2016 was originally conducted for another purpose; we could not find the respiratory outcomes reported in the study as part of the original study protocol. In Najnin 2019, the published study protocol did not include respiratory illness as an outcome.

Other potential sources of bias

An additional consideration for cluster-RCTs is identification/recruitment bias, where individuals are recruited in the trial after clusters are randomised. Such bias can introduce an imbalance amongst groups.

In this 2022 review, of the six cluster-RCTs included, we judged four to have a low risk of identification/recruitment bias (Abaluck 2022; Ashraf 2020; Swarthout 2020; Teesing 2021). In Abaluck 2022, all of people in the village were assigned to one study arm (control, cloth mask or surgical mask villages). In Ashraf 2020, participants were unaware of their intervention group assignment until after the baseline survey and randomisation. In Swarthout 2020, village clusters comprised of 12 enrolled households, while in Teesing 2021 randomisation was done per nursing home. Alfelali 2020 recruited individuals after cluster-randomisation and is judged to have a high risk of recruitment bias, while in Young 2021, participation of students and staff contacts were made after random assignment of the school through written consent or electronic completion of a consent form.

Of the cluster-RCTs included in our 2020 review, we judged 13 to have a low risk of identification/recruitment bias (Arbogast 2016; Biswas 2019; Canini 2010; Cowling 2008; Longini 1988; Luby 2005; MacIntyre 2015; MacIntyre 2016; Roberts 2000; Sandora 2005; Suess 2012; Temime 2018; White 2001). In Arbogast 2016, all identified individuals (office workers) were included in the assigned cluster. Schools were identified and then randomised to the clusters; students were then randomly selected from each classroom and school. Nine studies described the identification of participants, consenting/enrolling, and then randomising to the clusters (Canini 2010; Cowling 2008; Longini 1988; Luby 2005; MacIntyre 2015; MacIntyre 2016; Roberts 2000; Sandora 2005; White 2001). Suess 2012 identified and consented patients, then recruitment was performed by physicians unaware of cluster assignment. In Temime

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2018, directors of the included nursing homes agreed to participate in the study before randomisation, and written consent was not required from the residents.

Amongst the newly included studies, we judged four cluster-RCTs as at low risk of identification/recruitment bias (Abaluck 2022; Swarthout 2020; Teesing 2021; Young 2021). In Abaluck 2022, the village was the unit of randomisation and all households received one arm of the study (control, surgical mask or cloth mask). In Swarthout 2020, village clusters were each randomised by blocks (group of nine adjacent clusters) into eight groups. In Teesing 2021 nursing homes were computer randomised after baseline hand hygiene measurements to either the intervention arm or the control arm. In Young 2021, schools were randomly assigned (1:1) to either a policy of offering contacts daily testing over seven days to allow continued school attendance (intervention group) or to follow the usual policy of isolation of contacts for 10 days (control group). In two studies there were insufficient details to permit a judgement of the risk of bias (Alfelali 2020; Ashraf 2020).

In the 2020 review, we judged 11 cluster-RCTs as at high risk of identification/recruitment bias (Aiello 2010; Aiello 2012; Azor-Martinez 2018; Chard 2019; Correa 2012; Cowling 2009; Larson 2010; McConeghy 2017; Nicholson 2014; Priest 2014; Savolainen-Kopra 2012). In Aiello 2010 and Aiello 2012, recruitment continued for two weeks after the start of the study, which could have introduced bias. Six trials identified and recruited participants after cluster randomisation (Azor-Martinez 2018; Chard 2019; Cowling 2009; Larson 2010; McConeghy 2017; Nicholson 2014). Three trials recruited new participants after the start of the study to replace those lost to follow-up (Correa 2012; Priest 2014; Savolainen-Kopra 2012). We judged five cluster-RCTs to have probable identification/recruitment bias (Alzaher 2018; Barasheed 2014; MacIntyre 2011; Najnin 2019; Radonovich 2019), whereas in 19 studies there were insufficient details to permit a judgement of risk of bias (Carabin 1999; DiVita 2011; Feldman 2016; Hartinger 2016; Huda 2012; Ibfelt 2015; Kotch 1994; Ladegaard 1999; MacIntyre 2009; MacIntyre 2013; Millar 2016; Miyaki 2011; Pandejpong 2012; Radonovich 2019; Sandora 2008; Stebbins 2011; Talaat 2011; Yeung 2011; Zomer 2015).

Two of the newly included cluster-RCTs reported intracluster correlation coefficient (ICC) to adjust sample size, taking into consideration clustering effects, and described adjusting outcomes for clustering effect using different statistical methods, or provided justification for not performing adjusted analysis for clustering (Alfelali 2020; Swarthout 2020). For four studies there were insufficient details to permit a judgement of risk of bias (Abaluck 2022; Ashraf 2020; Teesing 2021; Young 2021) since they provided insufficient details on ICC and/or did not perform adjusted analysis or justified the absence of it.

Twenty-six cluster-RCTs identified in the 2020 review reported intracluster correlation coefficient (ICC) to adjust sample size, taking into consideration clustering effects, and described adjusting outcomes for clustering effect using different statistical methods, or provided justification for not performing adjusted analysis for clustering (Aiello 2010; Aiello 2012; Arbogast 2016; Canini 2010; Carabin 1999; Correa 2012; Cowling 2008; Cowling 2009; Hartinger 2016; Huda 2012; Little 2015; Luby 2005; MacIntyre 2009; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; MacIntyre 2016; McConeghy 2017; Priest 2014; Radonovich 2019; Ram 2015; Roberts 2000; Stebbins 2011; Suess 2012; Talaat 2011; Temime 2018). Five cluster-RCTs did not report the ICC but described adjusting outcomes for clustering effect using different statistical methods, or explained why adjusted analysis for clustering was not performed (Biswas 2019; Chard 2019; McConeghy 2017; Simmerman 2011; Zomer 2015). Thirteen cluster-RCTs provided insufficient details on ICC and/or did not perform adjusted analysis or justified the absence of it (Alzaher 2018; Azor-Martinez 2016; Azor-Martinez 2018; Barasheed 2014; Feldman 2016; Larson 2010; Millar 2016; Miyaki 2011; Najnin 2019; Nicholson 2014; Pandejpong 2012; Savolainen-Kopra 2012; Yeung 2011). Two cluster-RCTs reported the ICC but did not perform adjusted analysis or justified the absence of it (Sandora 2005; Sandora 2008).

Effects of interventions

See: **Summary of findings 1** Medical/surgical masks compared to no masks for preventing the spread of viral respiratory illness; **Summary of findings 2** N95 respirators compared to medical/surgical masks for preventing the spread of viral respiratory illness; **Summary of findings 3** Hand hygiene compared to control for preventing the spread of viral respiratory illness

Comparison 1: Medical/surgical masks compared to no masks

We included 12 trials (10 of which were cluster-RCTs) comparing medical/surgical masks versus no masks (Abaluck 2022; Alfelali 2020; Aiello 2012; Barasheed 2014; Bundgaard 2021; Canini 2010; Cowling 2008; Jacobs 2009; MacIntyre 2009; MacIntyre 2015; MacIntyre 2016; Suess 2012). Two trials were conducted with healthcare workers (HCWs) (Jacobs 2009; MacIntyre 2015), whilst the other 10 studies included people living in the community. In the acute care hospital setting, as opposed to the community setting, variable mask use occurred, according to usual practices in the settings where the studies were undertaken, varying from just under 16% most of the time to 23.6% wearing for > 70% of all working hours (Jacobs 2009; MacIntyre 2015). We therefore excluded the two studies in the acute care hospital setting from the meta-analysis, and report results from these studies narratively. Ten trials were conducted in non-pandemic settings, and two were conducted during the SARS-CoV-2 pandemic (Abaluck 2022; Bundgaard 2021).

Primary outcomes

1. Numbers of cases of viral respiratory illness

Influenza/COVID-like illness

Pooling of nine trials conducted in the community found an estimate of effect for the outcomes of influenza/COVID-like illness cases (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials; 276,917 participants; moderate-certainty evidence; Analysis 1.1) suggesting that wearing a medical/surgical mask will probably make little or no difference for this outcome. Two studies in healthcare workers provided inconclusive results with very wide confidence intervals: RR 0.88, 95% CI 0.02 to 32; and RR 0.26, 95% CI 0.03 to 2.51, respectively (Jacobs 2009; MacIntyre 2015).

Laboratory-confirmed influenza/SARS-CoV-2 cases

Similarly, the estimate of effect for laboratory-confirmed influenza/SARS-CoV-2 cases (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence; Analysis 1.1) suggests that wearing a medical/surgical mask probably makes little or no difference compared to not wearing a mask for this outcome.

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Laboratory-confirmed other respiratory viruses

One community study reported on laboratory-confirmed other respiratory viruses, showing RR 0.58, 95% CI 0.25 to 1.31; Analysis 1.1, and another study in healthcare workers reported RR 0.79, 95% CI 0.42 to 1.52 (MacIntyre 2015).

Assessing both source control and personal protection

The design of most trials assessed whether masks protected the wearer. Six trials were cluster-RCTs, with all participants in the intervention clusters required to wear masks, thus assessing both source control and personal protection. In two trials the clusters were households with a member with new influenza; neither of these studies found any protective effect (RR 1.03 in 105 households (Canini 2010); RR 1.21 in 145 households (MacIntyre 2009)). In two trials the clusters were college dormitories during the influenza season; neither study found any reduction (RR 1.10 in 37 dormitories (Aiello 2012); RR 0.90 in three dormitories (Aiello 2010)).

Studies conducted during the SARS-CoV-2 pandemic

Two studies were conducted during the SARS-CoV-2 pandemic (Abaluck 2022; Bundgaard 2021), with the former being a very large cluster-RCT of villages in Bangledesh and the latter a large RCT conducted in Denmark.

Exclusion of study due to insufficient number of clusters

We excluded Aiello 2010 from the meta-analysis since we did not consider 'randomisation' of three clusters to three arms to be a proper randomised trial.

2. Adverse events related to the intervention

Canini 2010 reported that 38 (75%) of participants in the intervention arm experienced discomfort with the mask use due to warmth (45%), respiratory difficulties (33%), and humidity (33%). Children reported feeling pain more frequently (3/12) than other participants wearing adult face masks (1/39; P = 0.04). In MacIntyre 2015, adverse events associated with face mask use were reported in 40.4% (227/562) of HCWs in the medical-mask arm. General discomfort (35.1%; 397/1130) and breathing problems (18.3%; 207/1130) were the most frequently reported adverse events. Suess 2012 reported that the majority of participants (107/172; 62%) did not report any problems with mask-wearing. More adults reported no problems (71%) compared to children (36/72; 50%; P = 0.005). The main issues when wearing a face mask for adults as well as for children were "heat/humidity" (18/34; 53% of children; 10/29; 35% of adults; P = 0.1), followed by "pain" and "shortness of breath". Alfelali 2020 reported the most common side effects of wearing a mask in Hajj pilgrims were difficulty in breathing (26%) and discomfort (22%). Although no details were provided, Bundgaard 2021 mentioned that 14% of participants had adverse reactions. Cowling 2008 and Abaluck 2022 mentioned that no adverse events were reported. The other trials did not report measuring adverse outcomes.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Jacobs 2009 reported that participants in the mask group were significantly more likely to experience more days with headache and feeling bad. They found no significant differences between the two groups for symptom severity scores. None of the other trials reported this outcome.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 2: N95/P2 respirators compared to medical/surgical masks

We included five trials comparing medical/surgical masks with N95/P2 respirators (Loeb 2009; MacIntyre 2009; MacIntyre 2011; MacIntyre 2013; Radonovich 2019). All of these trials except MacIntyre 2009 included HCWs. MacIntyre 2009 included carers and household members of children with a respiratory illness recruited from a paediatric outpatient department and a paediatric primary care practice in Sydney, Australia. None of the trials were conducted during the SARS-CoV-2 pandemic.

Primary outcomes

1. Numbers of cases of viral respiratory illness

Clinical respiratory illness

Pooling of three trials found an estimate of effect suggesting considerable uncertainty as to whether an N95/P2 respirator provides any benefit compared to medical/surgical masks for the outcome of clinical respiratory illness (RR 0.70, 95% CI 0.45 to 1.10; 7799 participants, very low-certainty evidence; Analysis 2.1) (MacIntyre 2011; MacIntyre 2013 (two arms); Radonovich 2019).

Influenza-like-illness

Based on five trials conducted in four healthcare settings and one household, the estimates of effect for the outcome of ILI (RR 0.82, 95% CI 0.66 to 1.03; 8407 participants, low-certainty evidence; Analysis 2.1) suggest that N95/P2 respirators may make little or no difference for this outcome (Loeb 2009; MacIntyre 2009; MacIntyre 2011; MacIntyre 2013; Radonovich 2019).

Laboratory-confirmed influenza

The estimate of the effect for the outcome of laboratory-confirmed influenza infection (RR 1.10, 95% CI 0.90 to 1.34; 8407 participants, moderate-certainty evidence; Analysis 2.1) suggests that the use of a N95/P2 respirator compared to a medical/surgical mask probably makes little or no difference for this more precise and objective outcome.

The outcomes clinical respiratory illness and ILI were reported separately. Considering how these outcomes were defined, it is highly likely that there was considerable overlap between the two, therefore these outcomes were not combined into a single clinical outcome (Analysis 2.1). The laboratory-confirmed viral respiratory infection outcome included influenza primarily but multiple other

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common viral respiratory pathogens were also included in several studies. The laboratory-confirmed viral infection outcome was considered more precise and objective in comparison to the clinical outcomes, which were more subjective and considered to be less precise. The findings did not change when we restricted the evidence to HCWs (Analysis 2.2).

2. Adverse events related to the intervention

Harms were poorly reported, but generally discomfort wearing medical/surgical masks and N95/P32 respirators was mentioned in several studies. Radonovich 2019 mentioned that participants wearing the N95 respirator reported skin irritation and worsening of acne. MacIntyre 2011 reported that adverse events were more common with N95 respirators; in particular, discomfort was reported in 41.9% of N95 wearers versus 9.8% of medical-mask wearers (P < 0.01); headaches were more common with N95 (13.4% versus 3.9%; P < 0.01); difficulty breathing was reported more often in the N95 group (19.4% versus 12.5%; P = 0.01); and N95 caused more problems with pressure on the nose (52.2% versus 11.0%; P < 0.01). In MacIntyre 2013, fewer participants using the N95 respirator reported problems (38% (195/512) versus 48% (274/571) of participants in the medical-mask arm; P = 0.001). Loeb 2009 mentioned that no adverse events were reported.

The one trial conducted in the community mentioned that more than 50% of participants reported concerns with both types of masks, mainly that wearing them was uncomfortable, but there were no significant differences between the P2 (N95) and surgical-mask groups (MacIntyre 2009).

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Loeb 2009 reported that 42 participants (19.8%) in the surgical-mask group reported an episode of work-related absenteeism compared with 39 (18.6%) of participants in the N95 respiratory group (absolute risk difference −1.24%, 95% CI −8.75% to 6.27%; P = 0.75).

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Loeb 2009 reported that there were no episodes of LRTIs.

Comparison 3: Hand hygiene compared to control

Nineteen trials compared hand hygiene interventions with control and provided sufficient data to include in meta-analyses (Ashraf 2020; Azor-Martinez 2018; Biswas 2019; Correa 2012; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Little 2015; Millar 2016; Nicholson 2014; Ram 2015; Roberts 2000; Sandora 2005; Simmerman 2011; Stebbins 2011; Swarthout 2020; Teesing 2021; Zomer 2015). The populations of these studies included adults, children, and families, in settings such as schools, childcare centres, homes, and offices. None of the studies was conducted during a pandemic, although a few studies were conducted during peak influenza seasons. A further 16 trials comparing hand hygiene to a control had other outcomes or insufficient information to include in meta-analyses (Alzaher 2018; Arbogast 2016; Azor-Martinez 2016; DiVita 2011; Feldman 2016; Gwaltney 1980; Ladegaard 1999; Luby 2005; Morton 2004; Priest 2014; Savolainen-Kopra 2012; Talaat 2011; Temime 2018; Turner 2012; White 2001; Yeung 2011). The results of these trials were consistent with the findings of our meta-analyses. The results for all outcomes from the 19 trials that were meta-analysed and the 16 trials that were not meta-analysed are shown in Table 2.

Primary outcomes

1. Numbers of cases of viral respiratory illness

Acute respiratory infection (ARI)

Pooling of nine trials for the broad outcome of ARI showed a 14% relative reduction in the numbers of participants with ARI (RR 0.86, 95% CI 0.81 to 0.90; 52,105 participants, moderate-certainty evidence; Analysis 3.1.1) in the hand hygiene group (Analysis 3.1), suggesting a probable benefit (Ashraf 2020; Azor-Martinez 2018; Correa 2012; Larson 2010; Little 2015; Millar 2016; Nicholson 2014; Sandora 2005; Swarthout 2020).

Influenza-like-illness (ILI) and laboratory-confirmed influenza

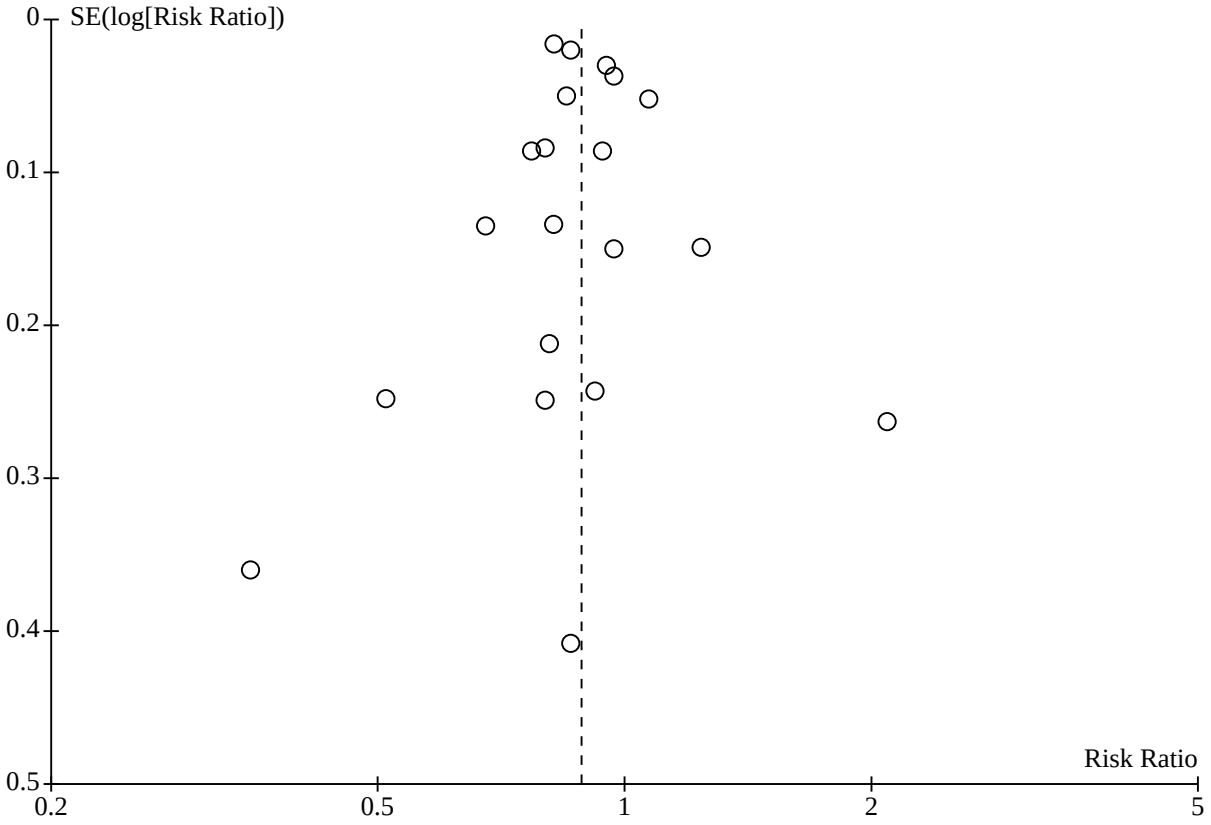
When considering the more strictly defined outcomes of ILI (Biswas 2019; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Little 2015; Ram 2015; Roberts 2000; Simmerman 2011; Teesing 2021; Zomer 2015), and laboratory-confirmed influenza (Biswas 2019; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Ram 2015; Simmerman 2011; Stebbins 2011) the estimates of the effect were heterogeneous, suggesting that hand hygiene may make little or no difference (RR 0.94, 95% CI 0.81 to 1.09 for ILI; 34,503 participants, low-certainty evidence; Analysis 3.1.2); (RR 0.91, 95% CI 0.63 to 1.30 for laboratory-confirmed influenza; 8332 participants; low-certainty evidence; Analysis 3.1.3).

Composite outcome ‘ARI or ILI or influenza'

All 19 trials could be pooled for analysis of the composite outcome ‘ARI or ILI or influenza’, with each study only contributing once with the most comprehensive outcome (in terms of number of events) reported showing an 11% relative reduction in participants with a respiratory illness, suggesting that hand hygiene may offer a benefit (RR 0.89, 95% CI 0.83 to 0.94; low-certainty evidence; Analysis 3.2), but with high heterogeneity. A funnel plot of the 19 trial results did not appear to suggest any small study effects for this outcome (Figure 4).

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Figure 4.



Sensitivity analysis

In a sensitivity analysis we used only the most precise and unequivocal (with laboratory confirmed considered the most precise and an undefined ARI considered the least precise) outcome reported in each of 12 studies identified by JMC, an infectious disease physician, and found an estimate of effect in favour of hand hygiene, but with wider CIs (RR 0.88, 95% CI 0.77 to 1.02; Analysis 3.3).

Subgroup analysis by age group

We considered that studies in children might have a different effect than studies in adults, so we conducted subgroup analysis by age group. We found no evidence of a difference in treatment effect by age group (P = 0.18; Analysis 3.4).

2. Adverse events related to the intervention

Correa 2012 reported that no adverse events were observed; in the study by Priest 2014, skin reaction was recorded for 10.4% of participants in the hand sanitiser group versus 10.3% in the control group (RR 1.01, 95% CI 0.78 to 1.30).

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Three trials measured absenteeism from school or work and demonstrated a 36% relative reduction in the numbers of participants with absence in the hand hygiene group (RR 0.64, 95% CI 0.58 to 0.71; Analysis 3.5) (Azor-Martinez 2016; Hubner 2010; Nicholson 2014).

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 4: Hand hygiene + medical/surgical masks compared to control

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

Six trials (Aelami 2015; Aiello 2012; Cowling 2009; Larson 2010; Simmerman 2011; Suess 2012) were able to be pooled to compare the use of the combination of hand hygiene and medical/surgical masks with control. Four of these trials were in households, two in university student residences, and one at the annual Hajj pilgrimage. For the outcomes ILI and laboratory-confirmed influenza, pooling demonstrated an estimate of effect suggesting little or no difference between the hand hygiene and medical/surgical mask combination and control. The number of trials and

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events was lower than for comparisons of hand hygiene alone, or medical/surgical masks alone, and the confidence interval was wide. For ILI, the RR for intervention compared to control was 1.03 (95% CI 0.77 to 1.37; 4504 participants; Analysis 4.1.1), and for influenza it was 0.97 (95% CI 0.69 to 1.36; 3121 participants; Analysis 4.1.2). Full results of these trials are shown in Table 3

2. Adverse events related to the intervention

Adverse events related to mask wearing in the study by Suess 2012 are reported under Comparison 1 (medical/surgical masks). There was no mention of adverse events related to hand hygiene.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness, e.g. pneumonia

Not reported.

Comparison 5: Hand hygiene + medical/surgical masks compared to hand hygiene

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI and laboratory-confirmed influenza)

Three trials studied the addition of medical/surgical masks to hand hygiene (Cowling 2009; Larson 2010; Simmerman 2011). All three trials had three arms, and are also included in the comparison of hand hygiene plus medical/surgical mask versus control (Comparison 4). All three studies showed no difference between hand hygiene plus medical/surgical mask groups and hand hygiene alone, for all outcomes. The estimates of effect suggested little or no difference when adding masks to hand hygiene compared to hand hygiene alone: for the outcome ILI (RR 1.03, 95% CI 0.69 to 1.53; 3 trials) and the outcome laboratory-confirmed influenza (RR 0.99, 95% CI 0.69 to 1.44), the estimates of effect were not different and the CIs were relatively wide, suggesting little or no difference (Analysis 5.1). However, the CIs around the estimates were wide and do not rule out an important benefit.

2. Adverse events related to the intervention

Not reported.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 6: Medical/surgical masks compared to other (non-N95) masks

One trial compared medical/surgical masks with cloth masks in hospital healthcare workers (MacIntyre 2015), and another trial compared catechin-treated masks versus control masks in healthcare workers and staff of hospitals, rehabilitation centres, and nursing homes in Japan (Ide 2016).

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

MacIntyre 2015 found that the rate of ILI was higher in the cloth mask arm compared to the medical/surgical masks arm (RR 13.25, 95% CI 1.74 to 100.97).

Ide 2016 did not find a benefit from the catechin-treated masks over untreated masks on influenza infection rates (adjusted odds ratio (OR) 2.35, 95% CI 0.40 to 13.72; P = 0.34).

2. Adverse events related to the intervention

In MacIntyre 2015 adverse events associated with face mask use were reported in 40.4% (227/562) of HCWs in the medical/surgical mask arm and 42.6% (242/568) in the cloth mask arm (P = 0.45). The most frequently reported adverse events were general discomfort (35.1%; 397/1130) and breathing problems (18.3%; 207/1130). Laboratory tests showed the penetration of particles through the cloth masks to be very high (97%) compared with medical/surgical masks (44%). Ide 2016 reported that there were no serious adverse events associated with the intervention.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

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Comparison 7: Soap + water compared to sanitiser, and comparisons of different types of sanitiser

Two trials compared soap and water with sanitiser (Azor-Martinez 2018; Savolainen-Kopra 2012). Another trial compared different types of hand sanitiser in a virus challenge study (Turner 2004a; Turner 2004b), and one trial studied the frequency of use of hand sanitiser (Pandejpong 2012). The full results of these four trials are shown in Table 4.

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

In the trial by Azor-Martinez 2018, ARI incidence was significantly higher in the soap-and-water group compared with the hand sanitiser group (rate ratio 1.21, 95% CI 1.06 to 1.39). In contrast, there was no significant difference between interventions in Savolainen-Kopra 2012. In the rhinovirus challenge study (Turner 2004a; Turner 2004b), all hand sanitisers tested led to a significant lowering of infection rates, but no differences between sanitisers were observed. The study sample size was small.

2. Adverse events related to the intervention

Two trials stated that no adverse events were observed (Pandejpong 2012; Savolainen-Kopra 2012).

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

The authors of Azor-Martinez 2018 also observed a significant benefit for hand sanitiser in reduction in days absent, whereas there was no difference between intervention groups in the Savolainen-Kopra 2012 trial. The study on frequency of use of sanitiser found that use of sanitiser every hour significantly reduced days absent compared with use every two hours or with use only before the lunch break (Pandejpong 2012).

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 8: Surface/object disinfection (with or without hand hygiene) compared to control

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

Six trials contributed data to this comparison (Ban 2015; Carabin 1999; Ibfelt 2015; Kotch 1994; McConeghy 2017; Sandora 2008). Full results of these trials are shown in Table 5. Five of the six trials combined disinfection with other interventions such as hand hygiene education, provision of hand hygiene products, and audits. Ban 2015 utilised a combination of provision of hand hygiene products, and cleaning and disinfection of surfaces, and demonstrated a significant reduction in ARI in the intervention group (OR 0.47, 95% CI 0.48 to 0.65). A similar result was seen in Carabin 1999, with a significant reduction in episodes of ARI. Two studies tested multi component interventions and observed no significant difference in ARI outcomes (Kotch 1994; McConeghy 2017).

One trial compared disinfection alone to usual care (Ibfelt 2015). This study demonstrated a significant reduction in some viruses detected on surfaces in the childcare centres (adenovirus, rhinovirus, respiratory syncytial virus (RSV), and metapneumovirus), but not in other viruses, including coronavirus.

2. Adverse events related to the intervention

Not reported.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Only one study measured this outcome (Sandora 2008), observing no significant difference between groups for the outcome of absence due to respiratory illness (rate ratio for intervention to control 1.10, 95% CI 0.97 to 1.24).

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 9: Complex interventions compared to control

Complex interventions are either multifaceted environmental programmes (such as those in low-income countries) or combined interventions including hygiene measures and gloves, gowns, and masks.

Four trials studied complex hygiene and sanitation interventions in low-income country settings (Chard 2019; Hartinger 2016; Huda 2012; Najnin 2019). Full results from these studies are given in Table 6.

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

All four trials of complex interventions observed no significant differences between groups in rates of viral respiratory illness.

2. Adverse events related to the intervention

Not reported.

Secondary outcomes

1. Deaths

Not reported.

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2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 10: Physical distancing/quarantine

We found three RCTs that assessed physical distancing/quarantine interventions. A quasi-cluster-RCT assessed the effectiveness of quarantining workers of one of two sibling companies in Japan whose family members developed an ILI during the 2009 to 2010 H1N1 influenza pandemic (Miyaki 2011). Workers in the intervention group were asked to stay home on full pay until five days after the household member(s) showed resolution of symptoms or two days after alleviation of fever. A second RCT conducted during the SARS-CoV-2 pandemic investigated whether attending fitness centres with physical distancing was non-inferior compared to no access in terms of COVID-19 transmission (Helsingen 2021). The third study was a cluster-RCT conducted during the SARS-CoV-2 pandemic that compared voluntary daily lateral flow device testing for seven days with negative contacts remaining at school to self-isolation of school-based COVID-19 contacts for 10 days in a non-inferiority design (Young 2021).

Primary outcomes

1. Numbers of cases of viral respiratory illness (including laboratory-confirmed influenza and SARS-CoV-2)

Miyaki 2011 reported adherence with the intervention was 100%. In the intervention group 2.75% of workers contracted influenza, compared with 3.18% in the control group (Cox hazard ratio 0.799, 95% CI 0.66 to 0.97; P = 0.02), indicating that the rate of infection was reduced by 20% in the intervention group. However, the risk of a worker being infected was 2.17-fold higher in the intervention group where workers stayed at home with their infected family members. The authors concluded that quarantining workers who have infected household members could be a useful additional measure to control the spread of respiratory viruses in an epidemic setting.

Helsingen 2021 reported 3016 participants were tested for SARS-CoV-2 resulting in one positive case in the fitness centre access arm versus zero in the no access arm at 14 days (risk difference (RD) 0.053%, 95% CI − 0.050 to 0.156%; P = 0.32). In addition, 11 in the fitness centre access arm versus 27 in the no access arm tested positive for SARS-CoV-2 antibodies at one month (RD − 0.87%, 95% CI − 1.52% to − 0.23%; P = 0.001). The authors concluded that access to fitness centres with physical distancing and low population prevalence of SARS-CoV-2 infection did not increase risk of SARS-CoV-2 infection.

Results from Young 2021 suggested no difference between the two treatment arms for SARS-CoV-2 infection (RR 0.96, 95% CI 0.75 to 1.22) leading the study authors to conclude non-inferiority of daily contact testing of school-based contacts (intervention) compared to self-isolation (control).

2. Adverse events related to the intervention

Not reported.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Young 2021 reported COVID-19 related absences from school were similar in the two treatment groups (RR 0.80, 95% CI 0.54 to 1.19).

4. Hospital admissions

Helsingen 2021 reported no hospital admissions in either treatment arm.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 11: Eye protection compared to control

Primary outcomes

1. Numbers of cases of viral respiratory illness (including laboratory-confirmed influenza and SARS-CoV-2)

We only identified one trial of eye protection which was a preprint only (Fretheim 2022a). This was a pragmatic RCT conducted in Norway from 2 February to 24 April 2022, where 3717 participants were randomised to an intervention group asked to wear glasses (e.g. sunglasses) for two weeks when close to others in public spaces. COVID-19 cases in the national registry were 3.7% in the intervention group (68/1852) and 3.5% (65/1865) in the control group (RR 1.10, 95% CI 0.75 to 1.50). Positive COVID-19 tests based on self-reporting were 9.6% and 11.5% (RR 0.83, 95% CI 0.69 to 1.00). Given the high risk of bias and wide CIs, no policy conclusions can be drawn, but replication studies are clearly warranted. Almost a third of the participants reported respiratory infections. However, a lower proportion of those (215 participants) were in the intervention group compared to the control group (RR 0.90; 95% CI 0.82 to 0.99).

2. Adverse events related to the intervention

A total of 76 participants reported a negative experience from participating in the trial (53 in the intervention group and 23 in the control group). The most common complaint related to the combination of wearing glasses and face masks, and 21 participants in the intervention group cited fogging as an issue. Some participants reported feeling tired or uncomfortable wearing glasses, and a few participants complained of reduced vision when wearing sunglasses or reading glasses. In the control group some participants reported headaches from not being able to wear glasses, and one participant in the intervention group reported a fall due to reduced vision.

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Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness, e.g. pneumonia

Not reported.

Comparison 12: Gargling/nose rinsing compared to control

Five trials investigated the effect of gargling/nose rinsing. Satomura 2005 compared throat gargling with povidone-iodine versus tap water in healthy adults. Ide 2014 compared gargling with green tea versus tap water in high school students, and Goodall 2014 compared gargling with tap water with no gargling in university students. Two additional trials were conducted during the SARS-CoV-2 pandemic: Almanza-Reyes 2021 compared silver mouth wash/nose rinse versus conventional mouthwashes and nose rinse in health workers; and Gutiérrez-García 2022 compared neutral electrolysed water mouth and nose rinses versus no rinses in health workers.

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza and SARS-CoV-2)

Satomura 2005 reported that gargling with tap water reduced the incidence of URTIs compared to the control group (usual care) (hazard ratio (HR) 0.60, 95% CI 0.39 to 0.95). Gargling with povidone-iodine did not reduce the incidence of URTIs compared to the control group (HR 0.88, 95% CI 0.58 to 1.34).

Goodall 2014 found no difference in laboratory-confirmed URTIs between the gargling (tap water) and no-gargling groups (RR for gargling versus no gargling 0.82, 95% CI 0.53 to 1.26; P = 0.36).

In a meta-analysis of gargling versus control based on two trials the pooled estimate of effect suggested little or no difference for the outcome of clinical URTI due to gargling (RR 0.91, 95% CI 0.63 to 1.31; 830 participants; Analysis 6.1) (Goodall 2014; Satomura 2005).

There was no difference in the incidence of laboratory-confirmed influenza between high school students gargling with green tea compared with those using tap water (adjusted OR 0.69, 95% CI 0.37 to 1.28; P = 0.24) (Ide 2014). There was also no difference in the incidence of clinically defined influenza (adjusted OR 0.75, 95% CI 0.50 to 1.13; P = 0.17). However, the authors reported that adherence to the interventions amongst students was low.

Almanza-Reyes 2021 reported the incidence of SARS-CoV-2 infection was statistically significantly lower in the silver mouth wash/nose rinse group (two out of 114, 1.8%) compared to the conventional mouthwash group (33 out of 117, 28.2%), and Gutiérrez-García 2022 reported the incidence of COVID-19-positive cases in the nasal and oral rinses group was 1% compared to 13% in the control group (RR 0.09, 95% CI of 0.01 to 0.72). A meta-analysis of these two studies showed a 93% reduction in risk of SARS-CoV-2 (RR 0.07, 95% CI 0.02 to 0.23; 394 participants; Analysis 6.2).

2. Adverse events related to the intervention

Satomura 2005 reported no adverse events during the 60-day intervention period. Ide 2014 also did not observe any adverse events during the study. Goodall 2014 did not report on adverse effects. There were no adverse reactions in the study by Almanza-Reyes 2021 or side effects in the study by Gutiérrez-García 2022.

Secondary outcomes

1. Deaths

Not reported.

2. Severity of viral respiratory illness as reported in the studies

Satomura 2005 reported that the mean peak score in bronchial symptoms was lower in the water gargling group (0.97) than in the povidone-iodine gargling group (1.41) and the control group (1.40), P = 0.055. Other symptoms were not significantly different between groups. Goodall 2014 reported that symptom severity was greater in the gargling group for clinical and laboratory-confirmed URTI, but this was not statistically significant (225.3 versus 191.8, and 210.5 versus 191.8, respectively). Ide 2014 did not report symptom or illness severity.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

Comparison 13: Virucidal tissues compared to control

Two reports (three trials) conducted in the USA studied the effect of virucidal tissues (Farr 1988a; Farr 1988b; Longini 1988). Full results from these studies are given in Table 7.

Primary outcomes

1. Numbers of cases of viral respiratory illness (including ARIs, ILI, and laboratory-confirmed influenza)

The three trials of virucidal tissues reported no differences in infection rates between tissues and placebo, and between tissues and no tissues (Farr 1988a; Farr 1988b; Longini 1988).

2. Adverse events related to the intervention

Farr 1988b reported cough in 4% of participants using virucidal tissues versus 57% in the placebo group, but 24% reported nasal burning in the virucidal tissue group versus 8% in the placebo group. Longini 1988 did not report on adverse effects.

Secondary outcomes

1. Deaths

Not reported.

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2. Severity of viral respiratory illness as reported in the studies

Not reported.

3. Absenteeism

Not reported.

4. Hospital admissions

Not reported.

5. Complications related to the illness (e.g. pneumonia)

Not reported.

DISCUSSION

Summary of main results

See Table 8.

1. Medical/surgical masks compared to no masks

The pooled estimates of effect from randomised controlled trials (RCTs) and cluster-RCTs for wearing medical/surgical masks compared to no masks in the community suggests probably little or no difference in interrupting the spread of influenza-like illness (ILI)/COVID-19 like illness (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; moderate-certainty evidence), or laboratory-confirmed influenza/SARS-CoV-2 (RR 1.01, 95% CI 0.72 to 1.42; moderate-certainty evidence). Six trials were cluster-RCTs, with all participants in the intervention clusters required to wear masks, thus assessing both source control and personal protection. In two trials the clusters were households with a member with new influenza; neither trial found any protective effect (RR 1.03 in 105 households (Canini 2010); RR 1.21 in 145 households (MacIntyre 2009). In two trials the clusters were college dormitories during the influenza season; neither trial found any reduction (RR 1.10 in 37 dormitories (Aiello 2012); RR 0.90 in three dormitories (Aiello 2010)). Two studies were conducted during the COVID-19 pandemic and their addition had minimal impact on the pooled estimate of effect previously reported from the earlier studies focused on influenza (Abaluck 2022; Bundgaard 2021). We excluded Aiello 2010 from meta-analysis since we did not consider 'randomisation' of three clusters to three arms was a proper randomised trial.

Less than half of the trials comparing masks with no masks addressed harms of mask wearing (Canini 2010; Cowling 2008; MacIntyre 2015; Suess 2012). Warmth, respiratory difficulties, humidity, and general discomfort were the most frequently reported adverse events. Neither of the RCTs conducted during the COVID-19 pandemic directly assessed harms of mask wearing. More adults reported no harms compared to children.

In one trial cloth masks were associated with a significantly higher risk of both ILI and laboratory-confirmed respiratory virus infection in healthcare workers (HCWs) (MacIntyre 2015). In addition, filtration capacity of the two-ply cotton cloth masks was found to be only 3% and markedly less than with medical/surgical masks based on standardised particle testing. The authors suggested moisture retention, poor filtration, and penetration of the virus through the mask as plausible explanations for the increased risk of infection.

We did not find any randomised trials assessing the effectiveness of barrier interventions using a combination of masks, gloves, and gowns.

2. N95 respirators compared to medical/surgical masks

Comparisons between N95 respirators and medical/surgical masks, used as needed for exposure to at-risk patients, for the outcomes of clinical respiratory illness and the outcome of laboratory-confirmed influenza showed estimates of effect suggesting considerable uncertainty for any benefit of N95 respirators for the former outcome and probably little or no difference for the latter outcome. Five trials (four in healthcare settings and one in a household setting) compared N95/P2 respirators with medical/surgical masks. Pooling of three of these trials showed an estimate of effect suggesting considerable uncertainty as to whether there was any benefit comparing N95 respirators and medical/surgical face masks for the outcome of clinical respiratory illness (RR 0.70, 95% CI 0.45 to 1.10; very low-certainty evidence), and that N95 respirators may make little or no difference for the outcome of ILI (RR 0.82, 95% CI 0.66 to 1.03; low-certainty evidence), and probably little or no difference for the outcome of laboratory-confirmed influenza (RR 1.10, 95% CI 0.90 to 1.34; moderate-certainty evidence). The presence of imprecision (wide CIs) and heterogeneity, particularly for the more subjective and less precise outcomes of clinical respiratory illness and ILI compared to laboratory-confirmed influenza infection, makes it difficult to assess whether there may be a benefit of either medical/surgical masks or N95/P2 respirators. Restricting the pooling to HCWs made no difference to the overall findings. The two trials with the largest event rates were quite consistent in their findings of no significant differences between N95 and medical/surgical masks for the outcomes of laboratory-confirmed influenza and all laboratory-confirmed viral infections (Loeb 2009; Radonovich 2019). Three of the trials contributing to this analysis were carried out by members of the same group (MacIntyre 2009; MacIntyre 2011; MacIntyre 2013).

In general, harms were poorly reported or not reported at all in trials comparing N95 respirators with surgical masks. General discomfort resulting in reduced wear adherence was the most frequently reported harm.

3. Hand hygiene compared to control

We found that the estimate of effect may offer a benefit for hand hygiene for the composite outcome 'acute respiratory infections (ARI) or ILI or influenza' (RR 0.89, 95% CI 0.83 to 0.94; low-certainty evidence), and probably offers a benefit for the outcomes ARI alone (RR 0.86, 95% CI 0.81 to 0.90; moderate-certainty evidence), and absenteeism (RR 0.64, 95% CI 0.58 to 0.71). An observed estimate of effect in favour of hand hygiene for laboratory-confirmed influenza, but with wider CIs may be a consequence of smaller sample sizes in conjunction with a more rigorous outcome measure.

4. Hand hygiene + medical/surgical masks compared to control

The estimate of effect of combined hand hygiene and medical/surgical mask interventions compared to control in six (mostly small) trials suggested that the intervention may make little or no difference for the outcomes ILI (RR 1.03, 95% CI 0.77 to 1.37), and laboratory-confirmed influenza (four trials) (RR 0.97, 95% CI 0.69 to 1.36).

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5. Hand hygiene + medical/surgical masks compared to hand hygiene

We also found an estimate of effect suggesting that adding medical/surgical masks to hand hygiene compared to hand hygiene alone may make little or no difference for the outcomes ILI (RR 1.03, 95% CI 0.69 to 1.53; 3 trials), and laboratory-confirmed influenza (RR 0.99, 95% CI 0.69 to 1.44).

6. Medical/surgical masks compared to other (non-N95) masks

One trial found that medical/surgical masks were more effective than cloth masks at reducing the rate of ILI (RR 13.25, 95% CI 1.74 to 100.97) (MacIntyre 2015), but the extremely wide CIs make this finding difficult to interpret. One trial did not find a benefit from catechin-treated masks over untreated masks on influenza infection rates (adjusted odds ratio (OR) 2.35, 95% CI 0.40 to 13.72; P = 0.34) (Ide 2016).

Harms of wearing masks were reported in 40.4% of HCWs using medical/surgical masks, and in 42.6% of those wearing cloth masks (P = 0.45) (MacIntyre 2015). The penetration of particles was higher in cloth masks (97%) compared to medical/surgical masks (44%).

7. Soap + water compared to sanitiser, and comparisons of different types of sanitiser

There were too few trials comparing different types of hand hygiene interventions to be certain of any true differences between soap and water, alcohol-based hand sanitisers, or other types of interventions. Also, it is uncertain whether the incremental effect of adding virucidals or antiseptics to hand-washing actually decreased the respiratory disease burden outside the confines of the rather atypical studies. The extra benefit may have been, at least in part, accrued by confounding additional routines.

8. Surface/object disinfection (with or without hand hygiene) compared to control

We identified six trials on surface/object disinfection (with or without hand hygiene), and although they were heterogeneous (and therefore could not be pooled), three of them showed a clear benefit compared to controls (Ban 2015; Carabin 1999; Ibfelt 2015).

We found no RCTs of nose disinfection, or disinfection of living quarters, as described in observational studies reported in Jefferson 2011.

9. Complex interventions compared to control

Four trials studied complex hygiene and sanitation interventions, all in low-income country settings (Chard 2019; Hartinger 2016; Huda 2012; Najnin 2019). These trials could not be pooled due to the heterogeneity of the interventions and settings. All four trials found no significant differences between groups in the rates of viral respiratory illness.

10. Physical distancing/quarantine compared to control

We identified one trial that evaluated the effect of quarantine and found a reduction in influenza transmission to co-workers when those with infected household members stayed home from work (Miyaki 2011). However, staying home increased their risk of being infected two-fold. Two studies conducted during the COVID-19 pandemic on SARS-cov-2 transmission showed (1) non-inferiority of daily contact testing of school-based contacts (intervention) compared to self-isolation (control) (Young 2021); and (2) access to fitness centres with physical distancing and low population prevalence of SARS-CoV-2 infection did not increase risk of SARS-cov-2 infection (Helsingen 2021).

11. Eye protection compared to control

We only identified one trial of eye protection which was a preprint only (Fretheim 2022a).

12. Gargling compared to control

Three trials addressed the use of gargling in preventing respiratory infections (Goodall 2014; Ide 2014; Satomura 2005). Although the trials used a variety of liquids and different outcomes, pooling the results of the two trials that compared gargling with tap water versus control did not show a favourable effect in reducing URTIs (RR 0.91, 95% CI 0.63 to 1.31) (Goodall 2014; Satomura 2005). Two trials of mouthwash/nose rinse were conducted during the SARS-cov-2 pandemic in HCWs: Almanza-Reyes 2021 compared silver mouth wash/nose rinse versus conventional mouthwashes and nose rinse; and Gutiérrez-García 2022 compared neutral electrolysed water mouth and nose rinses versus no rinses. Both studies reported large protective effects of the intervention on SARS-CoV-2 infection with reported outcomes of SARS-C0V-2 infection in 28.2% and 12.7% in the HCWs not using the interventions versus 1.8% and 1.2% in those using the intervention, despite the use of full personal protective equipment (PPE) and the high outcome rates raise questions about risk of bias, and no data were provided about baseline rates in other settings with full use of PPE.

13. Virucidal tissues compared to control

Two reports (three trials) identified in Jefferson 2011 studied the effect of virucidal tissues compared to placebo or no tissues (Farr 1988a; Farr 1988b; Longini 1988). These trials found no differences in infection rates and could not be pooled.

Overall completeness and applicability of evidence

Several features need consideration before making generalisations based on the included studies.

The settings of the included studies, which were conducted over five decades, were heterogeneous and ranged from suburban schools, Carabin 1999, to emergency departments, intensive care units, and paediatric wards, Loeb 2009, in high-income countries; slums in low-income countries (Luby 2005); and an upper Manhattan immigrant Latino neighbourhood (Larson 2010). Few attempts were made to obtain socio-economic diversity by (for example) involving more schools in the evaluations of the same programme. We identified only a few studies from low-income countries, where the vast majority of the burden of ARIs lies and where inexpensive interventions are so critical. Additionally, limited availability of over-the-counter medications and national universal comprehensive health insurance provided with consequent physician prescription of symptomatic treatment may further limit the generalisability of findings.

The included trials generally reported few events and were conducted mostly during non-epidemic periods with the exception of the trials carried out during the influenza H1N1 and SARS-CoV-2 pandemics. The large study by Radonovich 2019 is an exception as it crossed over two of the highest reporting years for influenza in

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the USA between 2010 and 2017 (Elflein 2019). None of the trials were conducted during pandemics of SARS-CoV-1or in outbreaks of Middle East respiratory syndrome (MERS).

Of the trials assessing the effect of masks, six were carried out in those at greater exposure (i.e. HCWs) (Jacobs 2009; Loeb 2009; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; Radonovich 2019). None of these studies included HCWs undertaking aerosol-generating procedures, for which the World Health Organization (WHO) currently recommends the N95 or equivalent mask. Three trials on hand hygiene interventions were carried out in nursing homes, and included HCWs (McConeghy 2017; Temime 2018; Yeung 2011). The scarcity of RCTs on HCWs limits the generalisability of such results.

The variable quality of the methods of some studies is striking. Incomplete or no reporting of randomisation (Turner 2004a), blinding (Farr 1988a; Farr 1988b), numerators and denominators (Carabin 1999; Kotch 1994), interventions, and cluster coefficients in the relevant trials (Carabin 1999), led to a considerable loss of information. Potential biases were often not discussed.

Inappropriate placebos caused design problems. In some studies the placebo probably carried sufficient effect to dilute the intervention effects (Longini 1988). Two valiant attempts with virucidal tissues probably failed because placebo handkerchiefs were impregnated with a dummy compound that stung the users' nostrils (Farr 1988a; Farr 1988b).

Some studies used impractical interventions. Volunteers subjected to the intervention hand cleaner (organic acids) were not allowed to use their hands between cleaning and virus challenge, so the effect of normal use of the hands on the intervention remains unknown (Turner 2004a; Turner 2004b). Two per cent aqueous iodine painted on the hands, although a successful antiviral intervention, causes unacceptable cosmetic staining, which is impractical for all but those at the highest risk of epidemic contagion (Gwaltney 1980).

Adherence with interventions, especially educational programmes, was a problem for many studies despite the importance of many such low-cost interventions. Adherence with mask wearing varied; it was generally around 60% to 80%, but was reported to be as low as 40% (see Table 1). Overall, the logistics of carrying out trials that involve sustained behaviour change are demanding, particularly in challenging settings such as immigrant neighbourhoods or students' halls of residence.

The identified trials provided sparse and unsystematic data on adverse effects of the intervention, and few of the RCTs measured or reported adherence with the intervention, which is especially important for the use of medical/surgical masks or N95 respirators. No studies investigated how the level of adherence may have influenced the effect size.

We identified one study assessing the effects of eye protection (Fretheim 2022a), and we identified three studies on physical distancing/quarantine (Helsingen 2021; Miyaki 2011; Young 2021). The dearth of evidence and predominant setting of seasonal viral circulation limits generalisability of our findings to other contexts and any future epidemics due to other respiratory viruses such as the COVID-19 pandemic although there have been increasing numbers of RCTs and cluster-RCTs in the latter setting which are adding to the evidence base.

The two recent small trials from Mexico assessing local mouth/nose rinses airways prophylactic as interventions treatments report large but uncertain reductions in transmission to healthcare workers which warrant further study and replication by other investigator (Almanza-Reyes 2021; Gutiérrez-García 2022).

Certainty of the evidence

We found the available evidence base identified through our search processes to be of variable quality. Reporting of sequence generation and allocation concealment were poor in 30% to 50% of studies across the categories of intervention comparisons. Given the nature of the intervention comparison, blinding of treatment allocation after randomisation was rarely achieved. Although blinding of outcome assessment is highly feasible and desirable, most outcomes were assessed by self-reports. Outcomes in some studies were poorly defined, with a lack of clarity as to the possible aetiological agents (bacterial versus viral). Some studies used laboratory-confirmed outcomes, both adding precision and avoiding indirectness by having an accurate outcome measure and lowering the risk of bias (see Table 9 for heterogeneity of trial outcome definitions). We found no evidence of selective reporting of outcomes within the included studies. We believe publication bias is unlikely, as the included studies demonstrated a range of effects, both positive and negative, over all study sizes. The variable quality of the studies hampers drawing any firm conclusions.

Potential biases in the review process

The non-drug (and often locally manufactured) nature of most of the interventions in this review, the lack of effective regulation in some settings, and the possible endless number of manufacturers make it difficult to gauge the existence of unpublished data. Non-drug interventions typically have no or very loose regulation.

In this 2022 update, we again focused on RCTs and cluster-RCTs, providing a higher level of evidence compared with the previous version of the review, which also meta-analysed observational studies when appropriate (Jefferson 2011). However, many of the trials were small and hence underpowered, and at high or unclear risk of bias due to poor reporting of methods and lack of blinding. The populations, outcomes, comparators, and interventions tested were heterogeneous.

Due to the urgency of this update in the context of the COVID-19 pandemic, we did not contact trial authors to request missing data. This means that we have not considered studies that included other non-respiratory infections, and did not provide stratified data by type of infection.

Agreements and disagreements with other studies or reviews

Several reviews of RCTs have found broadly similar results to this review for face masks. In a meta-analysis comparing surgical masks with N95 respirators, Smith 2016 pooled three trials and found an estimate of effect suggesting no difference for laboratory-confirmed respiratory infections (OR 0.89, 95% CI 0.64 to 1.24) or ILI (OR 0.51, 95% CI 0.19 to 1.41) (Loeb 2009; MacIntyre 2011; MacIntyre 2013). A similar meta-analysis, Offeddu 2017, based on two trials concluded that masks (either N95/P2 respirators or medical/surgical masks) were effective against clinical respiratory infections (RR 0.59, 95% CI 0.46 to 0.77) and ILI (RR 0.34, 95% CI 0.14

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to 0.82) (MacIntyre 2011; MacIntyre 2015). Pooling of two studies (MacIntyre 2011; MacIntyre 2013) also found an estimate of effect that favoured N95 respirators to medical/surgical masks for clinical respiratory infections (RR 0.47, 95% CI 0.36 to 0.62), but not for ILI, (RR 0.59, 95% CI 0.27 to 1.28) based on three studies (Loeb 2009: MacIntyre 2011; MacIntyre 2013). The outcome of clinical respiratory infection is considered to be the most subjective and least precise outcome.

A recent meta-analysis included five trials comparing N95/P2 respirators with medical/surgical masks and found no difference between groups for either influenza (RR 1.09, 95% CI 0.92 to 1.28), or respiratory viral infections (RR 0.89, 95% CI 0.70 to 1.11) (Long 2020). By excluding Loeb 2009 (an open, non-inferiority RCT that compared medical/surgical masks with N95 respirators in protecting HCWs against influenza), the authors reported a significant protective effect against viral infections (RR 0.61, 95% CI 0.39 to 0.98). The authors do not report a rationale for the exclusion in the sensitivity analysis, and do not report on exclusion of the studies with low weighting, which arguably would be more relevant in a sensitivity analysis. The two trials that make up 96% of the weighting demonstrated no significant differences in the outcome events (Loeb 2009; Radonovich 2019). A recent meta-analysis of four RCTs adjusting for clustering, which compared N95 respirators with the use of medical/surgical masks, found pooled estimates of effect that did not demonstrate any difference in any laboratory-confirmed viral respiratory infection (OR 1.06, 95% CI 0.90 to 1.25), laboratory-confirmed influenza (OR 0.94, 95% CI 0.73 to 1.20), or clinical respiratory illness (OR 1.49, 95% CI 0.98 to 2.28), with the evidence profile suggesting that there was greater imprecision and inconsistency in the outcome of clinical respiratory illness (Bartoszko 2020). Moreover, in another recent systematic review that assessed the effectiveness of personal protective and environmental measures in non-healthcare settings (funded by the WHO), 10 RCTs reporting estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community were identified (Xiao 2020). The evidence from these RCTs suggested that the use of face masks either by infected persons or by uninfected persons does not have a substantial effect on influenza transmission.

The findings from several systematic reviews and meta-analyses over the last decade have not demonstrated any difference in the clinical effectiveness of N95 respirators or equivalent compared to the use of surgical masks when used by HCWs in multiple healthcare settings for the prevention of respiratory virus infections, including influenza.

Reviews based on observational studies have usually found a stronger protective effect for face masks, but have important biases. The review by Chu 2020 did not consider RCTs of influenza transmission, but only the observational studies examining impact on SARS, MERS, or SARS-CoV-2. For N95 masks versus no mask in HCWs, there was a large protective effective with an OR of 0.04 (95% CI 0.004 to 0.30); for surgical masks versus no masks, there was an OR of 0.33 (0.17 to 0.61) overall, but four of these studies were in healthcare settings. Chu 2020 has been criticised for several reasons: use of an outdated 'Risk of bias' tool; inaccuracy of distance measures; and not adequately addressing multiple sources of bias, including recall and classification bias and in particular confounding. Confounding is very likely, as preventive behaviours such as mask use, social distancing, and hand hygiene are correlated behaviours, and hence any effect estimates are likely to be overly optimistic.

The two RCTs of medical/surgical masks during the SARS-CoV-2 pandemic found uncertain evidence of a small or no effect (Abaluck 2022; Bundgaard 2021). The study by Abaluck 2022 found a statistically significant benefit of masks versus no masks for COVID-like-illness, however, this study was rated at high risk of bias for five of the six domains due to issues including baseline imbalance, subjective outcome assessment and incomplete follow-up across the groups. Despite this study contributing 45% of the weight towards the meta-analysis of influenza/COVID-like-illness for masks versus no masks, the updated conclusions from the analysis strengthened around little or no effect of mask use.

Also based on observational studies, Jefferson 2011 found a protective effect of wearing surgical masks with hygienic measures compared to not wearing masks in the SARS 2003 outbreak (OR 0.32, 95% CI 0.26 to 0.39). However, the evidence was based on case-control studies carried out during the outbreak. There was some additional but very limited supportive evidence from the cohort studies in Jefferson 2011.

Although the use of eye protection and physical distancing measures are widely believed to be effective in reducing transmission of respiratory viruses and mitigating the impact of an influenza pandemic, we found only one trial investigating the role of self-quarantine in reducing the incidence of H1N1 influenza events in the workplace, and no trials examining the effect of eye protection. The evidence for these measures was derived largely from observational studies and simulation studies, and the overall certainty of supporting evidence is relatively low. The finding of limited evidence evaluating these interventions was also consistent with a recent review funded by the WHO for the preparation of its guidelines on the use of non-pharmaceutical interventions for pandemic influenza in non-medical settings (Fong 2020).

There are several previous systematic reviews on hand hygiene and respiratory infections. Five of them reviewed the evidence in a community setting (Moncion 2019; Rabie 2006; Saunders-Hastings 2017; Warren-Gash 2013: Wong 2014), and three focused on children (Mbakaya 2017; Willmott 2016; Zivich 2018). The earliest review in 2006 included eight studies, three of which were RCTs (Rabie 2006). The pooled estimate of seven studies was described as “indicative” of the effect of hand hygiene, but the studies were of poor quality. The Warren-Gash 2013 review included 16 studies (10 of which were RCTs) and reported mixed and inconclusive results. A 2014 review identified 10 RCTs and reported that the combination of hand hygiene with face masks in high-income countries (five trials) significantly reduced the incidence of laboratory-confirmed influenza and ILI, whilst hand hygiene alone did not (Wong 2014). This significant reduction in laboratory-confirmed influenza and ILI for hand hygiene and face masks may have been based on the raw numbers without adjusting for any clustering effects in the included cluster trials, which produced inappropriately narrow CIs, and possibly biased treatment effect estimates. Moreover, trials from the low-income countries were not included in the review, and this significant effect was not demonstrated when all the trials identified in the review were combined. The Saunders-Hastings 2017 review of studies evaluating the effectiveness of personal protective measures in interrupting pandemic influenza transmission only

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identified two RCTs (Azor-Martinez 2014; Suess 2012), which reported a significant effect of hand hygiene. The Moncion 2019 review identified seven RCTs of hand hygiene compared to control, with mixed results for preventing the transmission of laboratory-confirmed or possible influenza. Systematic reviews of RCTs of hand hygiene interventions amongst children, Mbakaya 2017 and Willmott 2016, or at a non-clinical workplace, Zivich 2018, identified heterogeneous trials with quality problems including small numbers of clusters and participants, inadequate randomisation, and self-reported outcomes. Evidence of impact on respiratory infections was equivocal.

A rapid search for other systematic reviews of RCTs was conducted in September 2022, and none of high quality were found.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence summarised in this review on the use of masks is largely based on studies conducted during traditional peak respiratory virus infection seasons up until 2016. Two relevant randomised trials conducted during the COVID-19 pandemic have been published, but their addition had minimal impact on the overall pooled estimate of effect. The observed lack of effect of mask wearing in interrupting the spread of influenza-like illness (ILI) or influenza/COVID-19 in our review has many potential reasons, including: poor study design; insufficiently powered studies arising from low viral circulation in some studies; lower adherence with mask wearing, especially amongst children; quality of the masks used; self-contamination of the mask by hands; lack of protection from eye exposure from respiratory droplets (allowing a route of entry of respiratory viruses into the nose via the lacrimal duct); saturation of masks with saliva from extended use (promoting virus survival in proteinaceous material); and possible risk compensation behaviour leading to an exaggerated sense of security (Ammann 2022; Brosseau 2020; Byambasuren 2021; Canini 2010; Cassell 2006; Coroiu 2021; MacIntyre 2015; Rengasamy 2010; Zamora 2006).

Our findings show that hand hygiene has a modest effect as a physical intervention to interrupt the spread of respiratory viruses, but several questions remain. First, the high heterogeneity between studies may suggest that there are differences in the effect of different interventions. The poor reporting limited our ability to extract the information needed to assess any 'dose response' relationship, and there are few head-to-head trials comparing hand hygiene materials (such as alcohol-based sanitiser or soap and water). Second, the sustainability of hand hygiene is unclear where participants in some studies achieved 5 to 10 hand-washings per day, but adherence may have diminished with time as motivation decreased, or due to adverse effects from frequent hand-washing. Third, there is little evidence about the effectiveness of combinations of hand hygiene with other interventions, and how those are best introduced and sustained. Finally, some interventions were intensively implemented within small organisations, and involved education or training as a component, and the ability to scale these up to broader interventions is unclear.

Our findings with respect to hand hygiene should be considered generally relevant to all viral respiratory infections, given the diverse populations where transmission of viral respiratory infections occurs. The participants were adults, children and families, and multiple congregation settings including schools, childcare centres, homes, and offices. Most respiratory viruses, including the pandemic SARS-CoV-2, are considered to be predominantly spread via respiratory particles of varying size or contact routes, or both (WHO 2020c). Data from studies of SARS-CoV-2 contamination of the environment based on the presence of viral ribonucleic acid and infectious virus suggest significant fomite contamination (Lin 2022; Onakpoya 2022b; Ong 2020; Wu 2020). Hand hygiene would be expected to be beneficial in reducing the spread of SARS-CoV-2 similar to other beta coronaviruses (SARS-CoV-1, Middle East respiratory syndrome (MERS), and human coronaviruses), which are very susceptible to the concentrations of alcohol commonly found in most hand-sanitiser preparations (Rabenau 2005; WHO 2020c). Support for this effect is the finding that poor hand hygiene, despite the use of full personal protective equipment (PPE), was independently associated with an increased risk of SARS-CoV-2 transmission to healthcare workers in a retrospective cohort study in Wuhan, China in both a high-risk and low-risk clinical unit for patients infected with COVID-19 (Ran 2020). The practice of hand hygiene appears to have a consistent effect in all settings, and should be an essential component of other interventions.

The highest-quality cluster-RCTs indicate that the most effect on preventing respiratory virus spread from hygienic measures occurs in younger children. This may be because younger children are least capable of hygienic behaviour themselves (Roberts 2000), and have longer-lived infections and greater social contact, thereby acting as portals of infection into the household (Monto 1969). Additional benefit from reduced transmission from them to other members of the household is broadly supported by the results of other study designs where the potential for confounding is greater.

Routine long-term implementation of some of the interventions covered in this review may be problematic, particularly maintaining strict hygiene and barrier routines for long periods of time. This would probably only be feasible in highly motivated environments, such as hospitals. Many of the trial authors commented on the major logistical burdens that barrier routines imposed at the community level. However, the threat of a looming epidemic may provide stimulus for their inception.

Implications for research

Public health measures and physical interventions can be highly effective to interrupt the spread of respiratory viral infections, especially when they are part of a structured and co-ordinated programme that includes instruction and education, and when they are delivered together and with high adherence. Our review has provided important insights into research gaps that need to be addressed with respect to these physical interventions and their implementation and have been brought into a sharper focus as a result of the COVID-19 pandemic. The 2014 WHO document 'Infection prevention and control of epidemic - and pandemic-prone acute respiratory infections in health care' identified several research gaps as part of their GRADE assessment of their infection prevention and control recommendations, which remain very relevant (WHO 2014). Research gaps identified during the course of our review and the WHO 2014 document may be considered from the perspective of both general and specific themes.

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A general theme identified was the need to provide outcomes with explicitly defined clinical criteria for acute respiratory infections (ARIs) and discrete laboratory-confirmed outcomes of viral ARIs using molecular diagnostic tools which are now widely available. Our review found large disparities between studies with respect to the clinical outcome events, which were imprecisely defined in several studies, and there were differences in the extent to which laboratory-confirmed viruses were included in the studies that assessed them. Another general theme identified was the lack of consideration of sociocultural factors that might affect adherence with the interventions, especially those employed in the community setting. A prime example of this latter point was illustrated by the observations of the use of masks versus mask mandates during the COVID-19 pandemic. In addition, the cost and resource implications of the physical interventions employed in different settings would have important relevance for low- to middle-income countries. Resources have been a major issue with the COVID-19 pandemic, with global shortages of several components of PPE. Several specific research gaps related to physical interventions were identified within the WHO 2014 document and are congruent with many of the findings of this 2022 update, including the following: transmission dynamics of respiratory viruses from patients to healthcare workers during aerosol-generating procedures; a continued lack of precision with regards to defining aerosol-generating procedures; the safety of cohorting of patients with the same suspected but unconfirmed diagnosis in a common unit or ward with patients infected with the same known pathogen in healthcare settings; the optimal duration of the use of physical interruptions to prevent spread of ARI viruses; use of spatial separation or physical distancing (in healthcare and community settings, respectively) alone versus spatial separation or physical distancing with the use of other added physical interventions coupled with examining discrete distance parameters (e.g. one metre, two metres, or > two metres); the effectiveness of respiratory etiquette (i.e. coughing/sneezing into tissues or a sleeved bent elbow); the effectiveness of triage and early identification of infected individuals with an ARI in both hospital and community settings; the utility of entrance screening to healthcare facilities; use of frequent disinfection techniques appropriate to the setting (high-touch surfaces in the environment, gargling with oral disinfectants, and virucidal tissues or clothing) alone or in combination with facial masks and hand hygiene; the use of visors, goggles or other eyewear; the use of ultraviolet light germicidal irradiation for disinfection of air in healthcare and selected community settings; the use of air scrubbers and /or high-efficiency particulate absorbing filters and the use of widespread adherence with effective vaccination strategies.

There is a clear requirement to conduct large, pragmatic trials to evaluate the best combinations in the community and in healthcare settings with multiple respiratory viruses and in different sociocultural settings. Randomised controlled trials (RCTs) with a pragmatic design, similar to the Luby 2005 trial or the Bundgaard 2020 trial, should be conducted whenever possible. Similar to what has been observed in pharmaceutical interventions where multiple RCTs were rapidly and successfully completed during the COVID-19 pandemic, proving they can be accomplished, there should be a deliberate emphasis and directed funding opportunities provided to conduct well-designed RCTs to address the effectiveness of many of the physical interventions in multiple settings and populations, especially in those most at risk, and in very specific well-defined populations with monitoring of the adherence to the interventions.

Several specific research gaps deserve expedited attention and may be highlighted within the context of the COVID-19 pandemic. The use of face masks in the community setting represents one of the most pressing needs to address, given the polarised opinions around the world, and the increasing concerns over widespread microplastic pollution from the discarding of masks (Shen 2021). Both broad-based ecological studies, adjusting for confounding and high quality RCTs, may be necessary to determine if there is an independent contribution to their use as a physical intervention, and how they may best be deployed to optimise their contribution. The type of fabric and weave used in the face mask is an equally pressing concern, given that surgical masks with their cotton-polypropylene fabric appear to be effective in the healthcare setting, but there are questions about the effectiveness of simple cotton masks. In addition, any masking intervention studies should focus on measuring not only benefits but also adherence, harms, and risk compensation if the latter may lead to a lower protective effect. In addition, although the use of medical/surgical masks versus N95 respirators demonstrates no differences in clinical effectiveness to date, their use needs to be further studied within the context of a well-designed RCT in the setting of COVID-19, and with concomitant measurement of harms, which to date have been poorly studied. The recently published Loeb RCT conducted over a prolonged course in the current pandemic has provided the only evidence to date in this area (Loeb 2022).

Physical distancing represents another major research gap which needs to be addressed expediently, especially within the context of the COVID-19 pandemic setting as well as in future epidemic settings. The use of quarantine and screening at entry ports needs to be investigated in well-designed, high-quality RCTs given the controversies related to airports and travel restrictions which emerged during the COVID-19 pandemic. We found only one RCT investigating quarantine, and no trials of screening at entry ports or physical distancing. Given that these and other physical interventions are some of the primary strategies applied globally in the face of the COVID-19 pandemic, future trials of high quality should be a major global priority to be conducted within the context of this pandemic, as well as in future epidemics with other respiratory viruses of less virulence.

The variable quality and small scale of some studies is known from descriptive studies (Aiello 2002; Fung 2006; WHO 2006b), and systematic reviews of selected interventions (Meadows 2004). In summary, more high-quality RCTs are needed to evaluate the most effective strategies to implement successful physical interventions in practice, both on a small scale and at a population level. It is very unfortunate that more rigorous planning, effort and funding was not provided during the current COVID-19 pandemic towards high-quality RCTs of the basic public health measures. Finally, we emphasise that more attention should be paid to describing and quantifying the harms of the interventions assessed in this review, and their relationship with adherence.

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The following people conducted the editorial process for this 2022 update:

- Sign-off Editor (final editorial decision): Michael Brown (Michigan State University College of Human Medicine, USA).
- Managing Editor (selected peer reviewers, collated peer reviewer comments, provided editorial guidance to authors): Fiona Russell (Bond University, Australia).
- Contact Editor (assessed peer review comments and recommended an editorial decision): Allen Cheng (Monash University, Australia).
- Statistical Editor (provided comments): Teresa Neeman (Biological Data Science Institute, Australian National University, Australia).
- Copy Editor (copy-editing and production): Heather Maxwell.

Peer reviewers (provided comments and recommended an editorial decision):

- Clinical/content review: Roderick P. Venekamp.
- Consumer review: Janet Wale (Independent consumer representative).
- Methods review: Leslie Choi (Evidence Synthesis Development Editor, Cochrane Central Executive Team).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Abaluck 2022

Study characteristics	
Methods	Cluster-RCT Randomisation unit: villages (N = 600) Intervention duration: 8 weeks “Our intervention was designed to last 8 weeks in each village”
Participants	Inclusion criteria: community level participants Intervention = 178,322 individuals, control = 163,861 individuals (Total N = 342,183 adults)
Interventions	2 types of mask used: surgical and cloth masks PLUS a brief video of notable public figures discussing why, how, and when to wear a mask, PLUS a brochure based on WHO materials depicting proper mask-wearing. Control villages: the control group did not receive any interventions See Table 1 for details.
Outcomes	Effectiveness: primary outcome: symptomatic seroprevalence (symptomatic and seropositive) Laboratory: seropositivity was defined by having detectable IgG antibodies against SARS-CoV-2 Symptoms defined as per WHO-defined COVID-19 symptoms: (a) fever and cough; (b) 3 or more of the following symptoms (fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status); or (c) loss of taste or smell. Secondary outcomes: prevalence of proper mask-wearing as wearing either a project mask or an alternative face-covering over the mouth and nose and improper mask-wearing as wearing a mask in any way that did not fully cover the mouth and nose; prevalence of physical distancing per WHO guideline that defines physical distancing as one meter of separation; prevalence of symptoms consistent with COVID-19: definition (see above) Safety not assessed. However, study mentioned that there was no adverse events reported during the study period

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Abaluck 2022 *(Continued)*

Notes	The authors conclude that: a randomised trial of community-level mask promotion in rural Bangladesh during the COVID-19 pandemic shows that the intervention increased mask usage and reduced symptomatic SARS-CoV-2 infections, demonstrating that promoting community mask-wearing can improve public health (a scalable and effective method to promote mask adoption and reduce symptomatic SARS-CoV-2 infections.) Funding: this trial was financially supported by a grant from GiveWell.org to Innovations for Poverty Action. The trial authors declare no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number generator used
Allocation concealment (selection bias)	High risk	Significant differences in the numbers of households included in each treatment group suggestive of a lack of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants, mask promoters, and mask surveillance staff were not blinded as intervention materials were clearly visible
Blinding of outcome assessment (detection bias) All outcomes	High risk	Although the pre-specified analyses and sample exclusions were made by analysts blinded to the treatment assignment, investigators dropped individuals who were missing symptom data or who did not consent to blood spot collection from the primary outcome. One of the outcomes is COVID-19 symptoms reported by participants. Mask promoters, and mask surveillance staff were not blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Laboratory testing results were only available for around 40% of the symptomatic participants
Selective reporting (reporting bias)	High risk	Primary outcome of seroconversion was not reported

Aelami 2015

Study characteristics

Methods	A prospective cross-sectional study conducted during the Hajj season 2012. Pilgrims were randomised into 2 groups. The intervention group received education on personal hygiene including a hygienic package containing alcohol-based hand rub (gel or spray), surgical masks, soap, paper handkerchiefs, and user instructions; the control group did not receive any intervention. ILI was defined as the presence of at least 2 of the following during their stay: fever, cough, and sore throat. Questionnaires including demographic and clinical information were distributed amongst trained physicians before departure from Iran.
Participants	Total enrolled: 664 Iranian pilgrims (306 in the intervention group and 358 in the control group) Inclusion criteria: not reported Exclusion criteria: not reported

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Aelami 2015 *(Continued)*

Interventions	Hygiene education and package. See Table 1 for details.
Outcomes	ILI defined as the presence of at least 2 of the following during their stay: fever, cough, and sore throat. No safety outcomes were reported.
Notes	This is an abstract, therefore few details were reported. Funding not mentioned. Disclosure of interest: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient details provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient details provided
Selective reporting (reporting bias)	Unclear risk	Insufficient details provided

Aiello 2010

Study characteristics

Methods	Cluster-RCT assessing the effects of hand sanitiser and masks versus masks or no intervention on ILI symptoms. The trial was conducted in university halls of residence with more than 100 student residents in a US university during the 2006 to 2007 influenza "season". The study lasted 6 weeks. The units of randomisation were 7 of the 15 halls. 1 hall was very large (1240 residents), and the 6 remaining ones, which had between 110 and 830 residents, were combined into 2 clusters roughly equivalent in size. The 3 clusters were then randomised by random extraction of the clustered halls' names out of a container. The largest hall (single-cluster) was randomised to the mask and hand sanitiser arm; the 4-halls cluster received masks; and the remaining 2 halls were assigned as controls.
Participants	A total of 1297 with completed baseline survey and at least 1 weekly survey result were analysed (face mask and hand hygiene group = 367; face mask–only group = 378; control group = 552). Inclusion criteria: aged 18 or more, willing to wear mask and use alcohol-based hand sanitiser, have a throat swab specimen collected when ill, and complete the baseline and weekly surveys over the 6-week study period

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Aiello 2010 *(Continued)*

	Exclusion criteria: individuals reporting a skin allergy to alcohol were excluded Recruitment of students began in 26 November, but the trial did not go "live" with distribution of intervention materials until 22 January 2007 when the first case of influenza was confirmed on campus by laboratory tests. Enrolment continued until 16 February 2007, and the study was completed on 16 March 2007. During the study period there was a 1-week break when the majority of residents left campus. There were 1327 eligible participants, 1297 of which had a complete baseline survey and at least 1-weekly survey result. It is unclear what the ineligibility criteria were for the 30 missing (1327 minus 1297), but the explanation may be in the appendix.
Interventions	Alcohol-based hand sanitiser (62% ethyl alcohol in a gel base) in a squeeze bottle and TECNOL procedure masks with ear loops (KC Ltd) and educational material or masks and educational material or no intervention. Compliance was encouraged within halls and outside. Sleep wearing was optional. All participants received basic video-linked instruction on cough etiquette and hand sanitation. At baseline and weekly during the study, participants were asked to fill in a web-based survey collecting demographic and ILI symptom data. This was supplemented by direct observation of compliance by staff. Compliance with "optimal handwashing" (at least 20 seconds 5 or more times a day) was significantly higher in the sanitiser-and-mask arm. See Table 1 for details.
Outcomes	Laboratory details are described in appendix. Effectiveness: ILI, defined as cough and at least 1 constitutional symptom (fever/feverishness, chills, headache, myalgia). ILI cases were given contact nurses' phone numbers to record the illness and paid USD 25 to provide a throat swab. 368 participants had ILI, and 94 of these had a throat swab analysed by PCR. 10 of these were positive for influenza (7 for A and 3 for B). Safety: N/A
Notes	The authors conclude that "These findings suggest that face masks and hand hygiene may reduce respiratory illnesses in shared living settings and mitigate the impact of the influenza A (H1N1) pandemic". This conclusion is based on a significantly lower level of ILI incidence in the mask and hand sanitiser arm compared to the other 2 arms after adjustment for covariates (30% to 50% less in arm 1 compared to controls in the last 2 weeks of the study). Comparison with the ILI rate of the control arm may not be a reflection of the underlying rate of ILI because the intervention arm received instruction on hand sanitation and hand etiquette. The play of adjustments is unclear. The intracluster correlation coefficient is reported in the footer of Table 4. Its very small size suggests lack of clustering within halls. The role of spring break is mentioned in the Discussion, as are the results of this study compared to other studies included in our review (Cowling 2008 and MacIntyre 2009). The authors report that 147 of 1297 participants (11.3%) had ILI symptoms "at baseline" and were excluded from analysis. During the 6 weeks of the study, 368 of 1150 participants (32%) had ILI. This averages out at about 5% per week. It is unclear what the term "at baseline" means; presumably this means during the 2 to 3 weeks of participant enrolment. If this is so, the reason for the triggering of the interventions (tied to influenza isolation) are obscure, as the trial is supposedly about ILI, and an ILI outbreak was already under way "at baseline". This study has the same trial registration number as the Aiello 2012 study; the study was funded by government and pharmaceutical industry, i.e. this work was supported by funding from the Centers for Disease Control (CDC) and Prevention Grant U01 C1000441 (www.cdc.gov). Disclosure of interest: none declared.

Risk of bias

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Aiello 2010 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as randomised, but sequence generation not reported
Allocation concealment (selection bias)	High risk	The residence hall units were randomised by blindly selecting a uniform ticket with the name of each hall out of a container (A.S.M. and A.A.) for randomisation assignment to each study arm.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition is reported as follows: 9, 11, and 19 ineligible and 26, 52, and 21 lost to follow-up (respectively by arm), for a total of 39 and 99 for each reason for attrition. In total, 1297 (97%) of 1331 participants completed a baseline and at least 1-weekly survey. The text reports an ITT analysis with only 1 ILI episode included by participant. No reasons for the attrition of participants and swab volunteers are reported (were the swabs taken from a random sample or not?).
Selective reporting (reporting bias)	High risk	There is no information on the causes of ILI other than the reporting on the 10 influenza PCR-positive swabs of 94 out of 368 students with ILI. This is a very low rate (and the Discussion confirms that the influenza season was mild), but investigation of the other known causes of ILI is not even mentioned in the text. This is especially important because stress, alcohol intake levels, and influenza vaccination were a significant predictor of ILI symptoms (Table 1). The reason for selective testing and/or reporting of influenza viruses tests over the other causes of ILI are unclear, especially as the study objective was focused on ILI. The text is also difficult to follow, weaving the reporting of ILI and influenza without a clear rationale.

Aiello 2012

Study characteristics	
Methods	During the 2007 to 2008 influenza season, 1111 students residing in university residence halls were cluster-randomised by residence house (N = 37) to either face mask and hand hygiene, face mask only, or control arms. Discrete time survival analysis using generalised models estimated rate ratios according to study arm, each week and cumulatively over the 6-week intervention period, for clinically verified ILI and laboratory-confirmed influenza A or B.
Participants	A total of 1187 young adults living in 37 residence halls, randomly assigned to 1 of 3 groups for 6 weeks: face mask use (n = 392), face masks with hand hygiene (n = 349), control (n = 370) Inclusion criteria: aged 18 or more, willing to wear mask and use alcohol-based hand sanitiser, have a throat swab specimen collected when ill, and complete the baseline and weekly surveys over the 6-week study period Exclusion criteria: individuals reporting a skin allergy to alcohol were excluded

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Aiello 2012 *(Continued)*

Interventions	Participants were assigned to face mask and hand hygiene, face mask only, or control group during the study. See Table 1 for details.
Outcomes	Clinically verified ILI: case definition (presence of cough and at least 1 or more of fever/feverishness, chills, or body aches) Laboratory-confirmed influenza A or B. Throat swab specimens were tested for influenza A or B using RT-PCR. No safety outcomes reported.
Notes	This study has the same trial registration number as the Aiello 2010 study; the study was funded by government and pharmaceutical industry, i.e. this work was supported by funding from the Centers for Disease Control (CDC) and Prevention Grant U01 C1000441 (www.cdc.gov). Disclosure of interest: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generation of sequence described.
Allocation concealment (selection bias)	Low risk	All residence houses in each of the residence halls were randomised prior to the intervention implementation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding for study participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition low and similar in each group
Selective reporting (reporting bias)	Low risk	2 outcomes specified and reported.

Alfelali 2020

Study characteristics

Methods	Cluster open-label RCT Location: Mina, Greater Makkah, Saudi Arabia Follow up for 4 days
Participants	Arabic or English speaking Hajj pilgrims aged > 18 years from participating countries (Australia, Qatar and KSA) staying in allocated tents and able to provide signed informed consent were included.

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Alfelali 2020 *(Continued)*

Interventions	Mask wearing. See Table 1 for details.
Outcomes	Effectiveness: Laboratory: laboratory-confirmed viral respiratory infections (nasal swab on 650 participants only) Secondary outcomes: clinical respiratory infections in participants Safety reported on side effects of mask wearing The most common side effects: difficulty in breathing (26.2%); discomfort (22%); a small minority (3%) reported feeling hot, sweating, a bad smell or blurred vision with eyeglasses
Notes	The authors conclude that this trial was unable to provide conclusive evidence on facemask efficacy against viral respiratory infections most likely due to poor adherence to protocol. Funding: this report was made possible by a National Priorities Research Program grant (NPRP 6-1505-3-358) from the Qatar National Research Fund, a member of Qatar Foundation. Disclosure of interests: the other authors have no competing interests to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Coin-tossing by an individual who was not a member of the research team
Allocation concealment (selection bias)	High risk	Used coin tossing which can introduce imbalance
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Laboratory staff were blinded to the assigned intervention group
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported both intention-to-treat and per-protocol analysis and participant flow chart
Selective reporting (reporting bias)	Unclear risk	Insufficient information available.

Almanza-Reyes 2021

Study characteristics

Methods	RCT randomised using a computer-generated block scheme and stratified according to duty position, work shifts and the area/department of the service FU duration: 9 weeks
Participants	Workers (doctors, nurses, administrators) in a hospital for the exclusive recruitment of patients diagnosed with COVID-19 “General Tijuana Hospital”

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Almanza-Reyes 2021 *(Continued)*

Interventions	Experimental group: mouthwash and nose rinse Silver mouth wash: 50 mL spray bottle containing AgNPs solution with 1 wt% concentration (0.6 mg/mLmetallic silver). Mix 4 to 6 spray shots (corresponding to volume ~ 0.5 mL) of this solution with 20 mL of water and to gargle with obtained solution for 15 to 30 seconds at least 3 times a day. Or use as nasal lavages on the inner part of the nasal alae and nasal passage with the same solution using a cotton swab twice a day. Mouth spray: cover evenly the oral cavity with the direct 1 to 2 spray shots of solution without its previous dilution in water. Control group: instructed to do mouth wash and nose rinse with a conventional mouthwash the way they normally did before the study See Table 1 for details.
Outcomes	Effectiveness: Laboratory: Lab-confirmed infection using RT-PCR; symptoms of respiratory tract infection (RTI) no definition given; clinical Evacuation: CT (Toshiba Aquilion 16, Japan) chest scan (random selection) Safety: done using self-reported by participants using a questionnaire. “The present study also showed that no harmful side effects were observed in the 114 participants who used AgNPs as a mouthwash and nose rinse solution for 9 weeks”
Notes	Authors conclude that the mouth and nasal rinse with AgNPs helps in the prevention of SARS-CoV-2 infection in health personnel who are exposed to patients diagnosed with COVID-19. Funding: Funded studies A. Pestryakov Development Program "Priority 2030" Tomsk Polytechnic University https://tpu.ru/en. Conflict of interest statement: the authors have declared that no competing interests exist.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated stratified block scheme
Allocation concealment (selection bias)	High risk	Unbalanced baseline prognostic factors (vaccination and frequency of handwashing)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No participant flow chart reported.
Selective reporting (reporting bias)	Unclear risk	No protocol available

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Alzaher 2018

Study characteristics	
Methods	A cluster-RCT conducted amongst girls attending 4 primary schools between January and March 2018. The participants attended a hand-hygiene workshop. The schoolgirls' absences were followed up for 5 weeks. Incidence rate, percentage of absence days, and absence rate were calculated for total and upper respiratory infections absences.
Participants	A total of 496 schoolgirls aged of 6 to 12 years, attending 4 public primary girls' schools in the city of Riyadh, Saudi Arabia between January and March 2018. Students were randomised to education group (n = 234) or control group (n = 262). Exclusion criteria: not reported
Interventions	Hand hygiene workshop. See Table 1 for details.
Outcomes	Incidence rate, percentage of absence days, and absence rate were calculated for total and upper respiratory infections absences. The episode of URIs was defined as having 2 of the following symptoms for a day or 1 of the symptoms for 2 or more consecutive days: 1) a runny nose, 2) a stuffy or blocked nose or noisy breathing, 3) sneezing, 4) a cough, 5) a sore throat, and 6) feeling hot, having a fever or a chill. No safety outcomes reported.
Notes	Source of funding is unclear. Disclosure of interest: none mentioned.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient detail provided.
Allocation concealment (selection bias)	Low risk	Schools allocated prior to all schoolgirls attending selected schools were invited to participate.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Unclear risk	No protocol available

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Arbogast 2016

Study characteristics	
Methods	A 13.5-month prospective cluster-RCT executed with alcohol-based hand sanitiser in strategic workplace locations and personal use (intervention group) and brief hand hygiene education (both groups). Four years of retrospective data were collected for all participants.
Participants	Data for a total of 1183 participants were analysed (intervention group = 525, control group = 607). Inclusion criteria: all employees at 3 facilities who were 18 years of age or older, were enrolled in the company health insurance coverage, did not transfer between sites, and worked onsite full time (≥ 32 hours) were eligible for the study Exclusion criteria: not reported
Interventions	Alcohol-based hand sanitiser in strategic workplace locations and personal use (intervention group) and brief hand hygiene education (both groups). See Table 1 for details.
Outcomes	1. The number of healthcare insurance claims, for a defined set of preventable illnesses, per participant per year 2. Absenteeism, defined as the number of sick episodes per participant per year Claims based on ICD-9 codes No safety outcomes reported.
Notes	Only 2 clusters (1 per group) included, hence study data not included in meta-analysis. Industry funded. Disclosure of interest: none mentioned.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition minimal and similar in 2 groups
Selective reporting (reporting bias)	Unclear risk	No protocol available

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Ashraf 2020

Study characteristics	
Methods	Geographically pair-matched community-based cluster-randomised trial Used a random number generator to block Open-label Block randomised: unit of randomisation was a group of compounds visited by a single local promoter
Participants	1. Infants (target child) will be eligible to participate in the study if: a. they are in utero at the baseline survey. b. their parents/guardians are planning to stay in the study village for the next 12 months (if a mother is planning to give birth at her natal home and then return, she will still be a candidate for enrolment) 2. Children < 36 months old at baseline that are living in the compound of a target child will be eligible to participate in diarrhoea measurement if: a. they are < 36 months old at the baseline survey; b. their parents/guardians are planning to stay in the study village for the next 12 months. 3. Children 18 to 27 months old at baseline that are living in the compound of a target child will be eligible to participate in intestinal parasite specimen collection if: a. they are 18 to 27 months old at the baseline survey; b. their parents/guardians are planning to stay in the study village for the next 12 months.
Interventions	6 intervention arms: water quality, sanitation, hand washing, combined WSH, nutrition, nutrition + WSH Intervention was delivered at the household or the compound level See Table 1 for details.
Outcomes	Effectiveness: Primary outcome: 7-day prevalence of acute respiratory illness (ARI). Defined as: caregiver-reported symptoms of persistent cough or panting, wheezing, or difficulty breathing (1 or 2) in the 7 days before the interview. No clinical data were collected Secondary analyses: alternate combinations of the measured symptoms: 7-day prevalence of only panting, wheezing, or difficulty breathing (2) and ARI plus fever ([1 or 2] and 3) Outcomes were measured approximately 12 and 24 months following intervention roll out. Safety not assessed
Notes	The authors conclude that: single targeted water, sanitation, and hygiene interventions reduced reported respiratory illness in young children. There was no apparent respiratory health benefit from combining WASH interventions. Financial support: this research was funded by Global Development grant OPPGD759 from the Bill & Melinda Gates Foundation to the University of California, Berkeley, CA. S. P. L., S. A., M. I., B. F. A., and J. M. C. report grants from the Bill & Melinda Gates Foundation during the conduct of the study. P. K. R. reports grants from Leland Stanford University during the conduct of the study for support to the WASH Benefits project. M. R. reports grants and non financial support from the Bill & Melinda Gates Foundation (through a subcontract from UC Berkeley) during the conduct of the study. Disclosure of interest: none mentioned.

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Ashraf 2020 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number generator
Allocation concealment (selection bias)	Low risk	Random allocation by an offsite investigator
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The research team who implemented the intervention was separate from the data collection team. The analysis was carried out masked to the allocated group.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Provided participants flow diagram showing minimal attrition.
Selective reporting (reporting bias)	Low risk	Reported the pre-specified outcomes.

Azor-Martinez 2016

Study characteristics	
Methods	Randomised, controlled, and open study with an 8-month follow-up. The experimental group washed their hands with soap and water, together with using hand sanitiser, and the control group followed their usual handwashing procedures. Absenteeism rates due to URIs were compared between the 2 groups through a multivariate Poisson regression analysis. The per cent of days missed in both groups were compared with a z test.
Participants	A sample of 1341 (intervention group = 621, control group = 720) Inclusion criteria: children 4 to 12 years old, attending 5 state schools in Almeria (Spain) whose parents/guardians had signed an informed consent document Exclusion criteria: children who had any of the following chronic illnesses that predisposed them to infection: neoplasia, primary and secondary immunodeficiencies, cystic fibrosis, chronic treatment with high doses of steroids or immunosuppressants
Interventions	Hand-washing workshops of 2-hour duration. The experimental group washed their hands with soap and water together with using hand sanitiser, whilst the control group followed usual hand-washing procedures. See Table 1 for details.
Outcomes	Absenteeism rates due to URIs Per cent of days missed Respiratory illness was defined by 2 of the following symptoms during 1 day, or 1 of the symptoms for 2 consecutive days: (1) runny nose; (2) stuffy or blocked nose or noisy breathing; (3) cough; (4) feeling hot or feverish or having chills; (5) sore throat; or (6) sneezing.

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Azor-Martinez 2016 *(Continued)*

	A school absenteeism case (episode) was defined as when a child failed to attend school due to an URI. Common infectious illnesses, such as conjunctivitis, and skin infections were not included. Other causes for absenteeism, such as doctors' appointments, family vacations, and accident injuries, were also excluded. No safety outcomes reported.
Notes	Government funded Disclosure of interest: none mentioned.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A random number table was used.
Allocation concealment (selection bias)	Low risk	Schools/classes allocated prior to children recruited.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	High risk	Attrition levels high and different in the 2 groups
Selective reporting (reporting bias)	Unclear risk	No protocol available

Azor-Martinez 2018

Study characteristics

Methods	A cluster-RCT, controlled, and open study of 911 children aged 0 to 3 years attending 24 DCCs in Almería, Spain, with an 8-month follow-up. 2 intervention groups of DCC families performed educational and hand hygiene measures, 1 with soap and water (n = 274), another with hand sanitiser (n = 339), and the control group followed usual hand-washing procedures (n = 298). Respiratory infection (RI) episode rates were compared through multilevel Poisson regression models. The percentage of days missed were compared with Poisson exact tests.
Participants	A total of 911 children attending 24 DCCs in Almería (Spain). Inclusion criteria: children between 0 and 3 years old enrolled in DCCs and attending for at least 15 hours per week whose parents or guardians had signed an informed consent Exclusion criteria: children with chronic illness or medication that could affect their likelihood of contracting an infection

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Azor-Martinez 2018 *(Continued)*

	Data were analysed for 911 participants: hand sanitiser group (n = 339), soap and water group (n = 274), and control group (n = 298).
Interventions	2 intervention groups. 1 group used soap and water, another used hand sanitiser, whilst the control group followed usual hand-washing procedures. Groups received 1-hour hand hygiene workshop. See Table 1 for details.
Outcomes	Primary: RI incidence rate Secondary: (1) the presence or absence of at least 1 antibiotic prescription for each new RI episode during the study period (topical antibiotics were excluded), and (2) the percentage of RI absenteeism days in the 3 groups calculated as the ratio of RI absenteeism days to all possible days of attendance DCC absenteeism episode was defined as when a child failed to attend a DCC because of an RI. Respiratory illness was defined as the presence of 2 of the following symptoms during 1 day or the presence of 1 of the symptoms for 2 consecutive days: (1) runny nose, (2) stuffy or blocked nose or noisy breathing, (3) cough, (4) feeling hot or feverish or having chills, (5) sore throat, or (6) sneezing. No safety outcomes reported.
Notes	Government funded. This work was supported by a grant from the Andalusia Department of Health. Competing interests: the authors have indicated they have no potential conflicts of interest to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer randomisation using statistical software for the sequence
Allocation concealment (selection bias)	Low risk	Clusters assigned prior to recruitment.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition minimal and similar in 3 groups
Selective reporting (reporting bias)	Unclear risk	No protocol available

Ban 2015

Study characteristics

Methods	Quote: "Group randomised" trial. Only 2 clusters, which were 2 kindergartens in Xiantao City, Hubei Province, China.

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Ban 2015 *(Continued)*

Participants	Data for a total of 393 participants were analysed (intervention group = 194, control group = 199). 5 classes (221 children) randomly selected from 1 kindergarten in the intervention group and 6 classes (244 children) randomly selected from another kindergarten in the control group. Children were aged 5 or under. There were 72 exclusions from the analysis.
Interventions	Intervention group: hand hygiene and surface-cleaning education and provision of products for kindergarten and home use. Control group: usual practice. See Table 1 for details.
Outcomes	Respiratory illness, defined as: 2 or more of the following: fever, cough and expectoration, runny nose and nasal congestion, collected by parental questionnaire. Axillary temperature higher than 37.3 °C or the range of temperature fluctuation is more than 1 °C. 'Cough and expectoration' were defined as 3 or more coughs in a single hour and lasting for 4 or more hours in a single day, with or without expectoration. 'Runny nose and nasal congestion' were defined as a runny nose lasting for 4 or more hours in 1 day, with or without nasal congestion.
Notes	Funding not mentioned. Disclosure of interest: none mentioned.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method not described, and only 2 clusters.
Allocation concealment (selection bias)	Unclear risk	Method not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	High risk	Parental report, and parents were aware of treatment allocation
Selective reporting (reporting bias)	High risk	Attrition reported and balanced between groups, but high rate of attrition in a trial with small numbers of participants.

Barasheed 2014

Study characteristics

Methods	Pilot, non-blinded, parallel, cluster-RCT
Participants	22 tents were randomly selected from the Australian pilgrims camped in Mina, during Hajj in 2011; 12 tents were allocated to the mask group and 10 tents to the control group. A total of 164 Australian pilgrims were recruited: 75 in the mask group (39 ‘cases’ and 36 ‘contacts’) and 89 in the control group (36 ‘cases’ and 53 ‘contacts’).

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Barasheed 2014 *(Continued)*

	Inclusion criteria for index case: 1) Australian pilgrims of any gender aged > 15 years who attend the Hajj 2011, and 2) have symptoms of respiratory infection for 3 days. For close tent contact: 1) Australian pilgrims of any gender aged 15 years or more who attend the Hajj 2011, and 2) pilgrims who share the same tent and sleep "immediately close" to the index case. Exclusion criteria: for index case: 1) pilgrims who do not suffer from symptoms of respiratory infection, 2) pilgrims who present with symptoms of respiratory infection for > 3 days, and 3) children aged less than 15 years. For close tent contact: 1) pilgrims who are symptomatic at presentation, 2) pilgrims who are not close tent contacts of an index case, and 3) children aged less than 15 years. Only 10% to 15% of potential participants took part in the study.
Interventions	"supervised mask use" versus "no supervised mask use". See Table 1 for details.
Outcomes	Laboratory: 2 nasal swabs from all ILI cases and contacts, 1 for influenza POCT using the QuickVue Influenza (A+B) assay (Quidel Corporation, San Diego, USA) and 1 for later nucleic acid testing for influenza and other respiratory viruses. However, there was a problem with getting POCT on time during Hajj. Effectiveness: to assess the effectiveness of face masks in the prevention of transmission of ILI. ILI was defined as subjective (or proven) fever plus 1 respiratory symptom (e.g. dry or productive cough, runny nose, sore throat, shortness of breath). Safety: none planned or reported
Notes	The study was conducted from 4 November 2011 to 10 November 2011. Compliance with face mask use by pilgrims was 56 of 75 (76%) in the mask group and 11 of 89 (12%) in the control group (P < 0.001). The proportion of face mask user in the 'mask' tents was 76% for both males (19/25) and females (38/50). The most often reported reason for not wearing face masks was discomfort (15%). Government funded: Qatar National Research Fund (QNRF). The other authors have declared no conflict of interest in relation to this work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information provided.
Allocation concealment (selection bias)	Unclear risk	Quote: "tents were randomised to either intervention group (supervised mask tent) or control group (no supervised mask tent) by an independent study coordinator who was not an investigator", but did not mention how
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Because advice from the Saudi Ministry of Hajj to all pilgrims included recommending the wearing of masks, all pilgrims, both cases and controls, were asked about mask-wearing"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Self-reported outcomes (nasal swab was performed for those who reported ILI symptoms and was not intended as systematic detection). ILI was defined as subjective (or proven) fever plus 1 respiratory symptom.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up, all numbers were reported from enrolment to analysis
Selective reporting (reporting bias)	Low risk	All planned outcomes were reported.

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Biswas 2019

Study characteristics	
Methods	Cluster-RCT in 24 primary schools in Dhaka to assess the effectiveness of hand sanitiser and a respiratory hygiene education intervention in reducing ILI and laboratory-confirmed influenza during June to September 2015. 12 schools were randomly selected to receive hand sanitiser and respiratory hygiene education, and 12 schools received no intervention. Field staff actively followed children daily to monitor for new ILI episodes (cough with fever) through school visits and by phone if a child was absent. When an illness episode was identified, medical technologists collected nasal swabs to test for influenza viruses.
Participants	A total of 10,855 students were enrolled in the study (intervention schools = 5077 children; control schools = 5778 children). Children aged 5 to 10 years educated in 24 randomly selected primary schools in Dhaka, Bangladesh Exclusion: schools that offered education above grade 5 because of differences in student populations, as well as schools that had previously received a hand or respiratory hygiene intervention
Interventions	Hand sanitiser and respiratory hygiene education versus no intervention. See Table 1 for details.
Outcomes	Incidence of ILI Incidence of laboratory-confirmed influenza (RT-PCR) An ILI episode was defined as measured fever ≥ 38 °C or subjective fever and cough. If a child was absent, the field staff followed up by phone to identify the reason for absenteeism and to determine if the child met the ILI case definition. If a child in a participating school had an ILI episode, a trained medical technologist visited the child's household to obtain consent from the child's parent/guardian and collect a nasal swab from the child within 48 hours of symptom onset. If it was outside the 48-hour window, the sample was not collected. No safety outcomes reported.
Notes	Government funded. Disclosure of interest: none mentioned.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Sequence generated using a computer-based random number generator.
Allocation concealment (selection bias)	Low risk	Allocation completed prior to individuals being recruited.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias)	High risk	Information missing for 30 children (28 children in the control schools and 2 children in the intervention schools)

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Biswas 2019 *(Continued)*
All outcomes

Selective reporting (reporting bias)	Unclear risk	No protocol available

Bundgaard 2021

Study characteristics

Methods	Investigator-initiated, nationwide, unblinded, randomised controlled trial stratified by the 5 regions of Denmark
Participants	Inclusion criteria: community-dwelling adults aged 18 years or older without current or prior symptoms or diagnosis of COVID-19 reported being outside the home amongst others for at least 3 hours per day, and who did not wear masks during their daily work. Exclusion criteria: previously tested positive for SARS-CoV-2 and wear face masks at work
Interventions	Exposure: mask (N = 2392) Control group: no mask (N = 2470) Both groups received materials and instructions for antibody testing on receipt and at 1 month; materials and instructions for collecting an oropharyngeal/nasal swab sample for polymerase chain reaction (PCR) testing at 1 month and whenever symptoms compatible with COVID-19 occurred during follow-up. They registered symptoms and results of the antibody test in the online REDCap system. Written instructions and instructional videos guided antibody testing, oropharyngeal/nasal swabbing, and proper use of masks, and a help line was available to participants. See Table 1 for details.
Outcomes	Study duration: 1 month Effectiveness: primary outcome (composite) SARS-CoV-2 infection, defined as a positive result on an oropharyngeal/nasal swab test for SARS-CoV-2, development of a positive SARS-CoV-2 antibody test result (IgM or IgG) during the study period, or a hospital-based diagnosis of SARS-CoV-2 infection or COVID-19. Secondary outcome: PCR evidence of infection with other respiratory viruses Safety: adverse reaction: 14% in mask group (no further descriptions)
Notes	The authors conclude that inconclusive results, missing data, variable adherence, patient-reported findings on home tests, no blinding, and no assessment of whether masks could decrease disease transmission from mask wearers to others. Funding: the primary funding source was The Salling Foundations. Disclsure can be viewed at www.acponline.org /authors/icmje/ConflictOfInterestForms.do?msNum=M20-6817.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer algorithm stratified by the 5 regions of Denmark
Allocation concealment (selection bias)	Unclear risk	Insufficient information reported

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Bundgaard 2021 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded. Patient reported symptoms, POCT testing, patient-reported findings on home tests.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participant flow chart showed acceptable attrition
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported.

Canini 2010

Study characteristics	
Methods	A cluster-RCT conducted in France during the 2008 to 2009 influenza season. Households were recruited during a medical visit of a household member with a positive rapid influenza A test and symptoms lasting less than 48 hours. Households were randomised either to the mask or control group for 7 days. In the intervention arm, the index case had to wear a surgical mask from the medical visit and for a period of 5 days. The trial was initially intended to include 372 households, but was prematurely interrupted after the inclusion of 105 households (306 contacts) following the advice of an independent steering committee. Generalised estimating equations were used to test the association between the intervention and the proportion of household contacts who developed an ILI during the 7 days following the inclusion.
Participants	A total of 105 households were randomised, which represented 148 contacts in the intervention arm and 158 in the control arm. The study was conducted in 3 French regions (Ile de France, Aquitaine, and Franche-Comté) and included households of size 3 to 8. Exclusion criteria: if index patient was treated for asthma or chronic obstructive pulmonary disease or was hospitalised
Interventions	Surgical mask versus no mask. See Table 1 for details.
Outcomes	The primary endpoint was the proportion of household contacts who developed an ILI during the 7 days following inclusion. Exploratory cluster-level efficacy outcome, the proportion of households with 1 or more secondary illness in household contacts. A temperature over 37.8 °C with cough or sore throat was used as primary clinical case definition. Adverse reactions due to mask-wearing
Notes	Government funded. Competing interests: the authors have declared that no competing interests exist.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

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Canini 2010 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomisation lists were generated by a computerised program.
Allocation concealment (selection bias)	Low risk	Randomisation was performed centrally by the GP after written consent on an interactive voice response system dedicated to the study.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All households included in analysis.
Selective reporting (reporting bias)	Low risk	All specified outcomes reported.

Carabin 1999

Study characteristics	
Methods	Cluster-RCT carried out in DCCs in the Canadian province of Quebec between 1 September 1996 and 30 November 1997 (15 months). The aim was to test the effects of a hygiene programme on the incidence of diarrhoea and fecal contamination (data not extracted) and on colds and URTIs. The design included before and after periods analysed to assess the Hawthorne effect of study participation on control DCCs. The unit of randomisation was DCC, but analysis was also carried out at classroom and single-child level. This is a common mistake in cluster-RCT analysis. DCCs were stratified by URTI incidence preceding the trial and randomised by location. Cluster coefficients are not reported.
Participants	A total of 1729 children aged 18 to 36 months in 47 DCCs (83 toddler classrooms) Inclusion criteria: presence of at least 1 sandbox and 1 play area and of at least 12 available toddler places For the autumn of 1997 intervention group (24 DCCs, 43 classrooms, and 414 children), control group (23 DCCs, 23 classrooms, and 374 children). It is not clear what is the distribution and data for the autumn of 1996.
Interventions	Training session (1 day) with washing of hands, toy cleaning, window opening, sand pit cleaning, and repeated exhortations to hand wash. See Table 1 for details.
Outcomes	Laboratory: N/A Effectiveness: diarrhoea and coliform contamination (data not extracted) Colds (nasal discharge with at least 1 of the following: fever, sneezing, cough, sore throat, earache, malaise, irritability) URTI (cold of at least 2 days' duration) Surveillance was carried out by educators, annotating absences or illness on calendars. Researchers also filled in a phone questionnaire with answers by DCC directors. Safety: N/A
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators, and denominators)

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Carabin 1999 *(Continued)*

Notes: the authors conclude that the intervention reduced the incidence of colds (IRR 0.80, 95% CI 0.68 to 0.93). This was a confusingly written study with unclear interweaving of 2 study designs. For unclear reasons analysis was only carried out for the first autumn. Unclear why colds are not reported in the results. Cluster-coefficients and randomisation process were not described.

Support for the study was provided by the Rhone-Poulenc Rorer Canada Ltd.

Disclosure of interest: none mentioned.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Block randomisation of DCC according to region, but sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible (hygiene session plus educational material versus none)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Originally 52 eligible DCCs with 89 classrooms agreed to take part, but 5 dropped out (2 closed, 1 was sold, 2 either did not provide data or the data were "unreliable", and 6 classrooms had insufficient data). 43 children failing to attend DCC for at least 5 days in the autumn were also excluded. ITT analysis was carried out including an additional DCC whose director refused to let staff attend the training session. No correction made for clustering.
Selective reporting (reporting bias)	High risk	Denominators unclear and not explained

Chard 2019

Study characteristics

Methods	Cluster-RCT conducted amongst 100 randomly selected primary schools lacking functional WASH facilities in Saravane Province, Lao People's Democratic Republic. Schools were randomly assigned to either the intervention (n = 50) or comparison (n = 50) arm. Intervention schools received a school water supply, sanitation facilities, hand-washing facilities, drinking water filters, and behaviour change education and promotion. Comparison schools received the intervention after research activities had ended. At unannounced visits every 6 to 8 weeks, enumerators recorded pupils' roll-call absence, enrolment, attrition, progression to the next grade, and reported illness (diarrhoea, respiratory infection, conjunctivitis), and conducted structured observations to measure intervention fidelity and adherence. Stool samples were collected annually prior to de-worming and analysed for soil-transmitted helminth (STH) infection. In addition to our primary ITT analysis, we conducted secondary analyses to quantify the role of intervention fidelity and adherence on project impacts.
Participants	100 primary schools (50 intervention, 50 comparison) with a total of 3993 pupils were enrolled throughout the study period (intervention schools = 2021 pupils, control schools = 1972 pupils). Up to 40 pupils

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Chard 2019 *(Continued)*

	selected from grades 3 to 5 in each school using systematic stratified sampling, with grade and sex as the stratification variables. Pupils selected at baseline were followed throughout the entire study period; pupils who left the school due to abandonment or transfer were replaced at the beginning of the following academic year, maintaining equal grade and sex ratios when possible. Pupils who progressed from fifth to the sixth grade were replaced with pupils from grade 3 the following academic year.
Interventions	Water supply, sanitation facilities, hand-washing facilities, drinking water filters, and behaviour change education and promotion versus control. See Table 1 for details.
Outcomes	Primary impact of interest was pupil absence, measured by school-wide roll-call at each visit. Secondary health impacts included diarrhoea, symptoms of respiratory infection, and conjunctivitis/non-vision-related eye illness collected through pupil interviews. Pupils were considered to have symptoms of respiratory infection if they reported cough, runny nose, stuffy nose, or sore throat. No safety outcomes reported.
Notes	Funded by government and pharmaceutical industry. Competing interests: all authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/ coi_disclosure.pdf (available upon request from the corresponding author) and declare no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.
Allocation concealment (selection bias)	Low risk	Schools allocated prior to recruitment of individuals.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exclusions were due to participants leaving school, hence unlikely to cause bias.
Selective reporting (reporting bias)	Low risk	All specified outcomes reported.

Correa 2012

Study characteristics

Methods	Cluster-RCT in childcare facilities in Colombia from 16 April to 18 December 2008 (3 school terms) testing the effects of hand hygiene using an alcohol-based hand rub versus standard practice

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Correa 2012 *(Continued)*

Participants	42 childcare facilities in 6 towns in Colombia. A total of 1727 were enrolled (intervention group = 794 from 21 centres, control group = 933 from 21 centres). Inclusion criteria: licensed to care for 12 or more children aged 1 to 5 years for 8 hours a day, 5 times per week, and where availability of tap water was limited
Interventions	Intervention: alcohol-based hand wash as an addition to hand-washing Control: usual hand-washing practice See Table 1 for details.
Outcomes	ARI defined as: 2 or more of the following symptoms for at least 24 hours, lasting at least 2 days: runny, stuffy, or blocked nose or noisy breathing; cough; fever, hot sensation, or chills; and/or sore throat. Ear pain alone was considered an ARI.
Notes	This work was supported by a grant from the Global Development Network (New Delhi, India), "Fifth Global Research Project: Promoting Innovative Programs from the Developing World: Towards Realizing the Health MDG's in Africa and Asia," and the Bill and Melinda Gates Foundation (Seattle, Washington, United States). Authors declare to have no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"...using the random function in Microsoft Excel™ (Microsoft Corp., Redmond, Washington, United States), random numbers (1 or 2) were generated and allotted 1:1 within each group. Finally, a researcher flipped a coin to decide which number would correspond to either arm (heads = 1, intervention; tails = 2, control)."
Allocation concealment (selection bias)	Unclear risk	Method not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up similar in each group and not substantial
Selective reporting (reporting bias)	Unclear risk	No protocol available

Cowling 2008

Study characteristics

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Cowling 2008 *(Continued)*

Methods	Cluster-RCT carried out in Hong Kong SARS between February and September 2007. The study assessed the effects of non-pharmaceutical interventions on the household transmission of influenza over a 9-day period. ILI cases whose family contacts had been symptom-free for at least 2 weeks rapid-tested for influenza A and B were used and randomised to 3 interventions. Randomisation was carried out in 2 different schedules (2:1:1 for the first 100 households, and subsequently 8:1:1), but it is unclear why and how this was done.
Participants	A total of 350 of 944 originally enrolled participants representing 122 households were analysed (control group = 71 households with 205 household contacts, face mask = 21 households with 61 household contacts, HH = 30 households with 84 household contacts). Inclusion criteria: residents of Hong Kong aged at least 2 years, reporting at least 2 symptoms of ILI ((such as fever ≥ 38 degrees, cough, headache, coryza, sore throat, muscle aches and pains) and positive influenza A+B rapid test and living in a household with at least 2 other individuals, none of whom had ILI in the preceding 14 days Households were excluded because subsequent laboratory testing (culture) was negative. Attrition was not explained.
Interventions	Households were randomised to either wearing face masks with education (as the control group plus education about face mask use) or hand-washing with special medicated soap (with alcohol sanitiser) with education (as the control group plus education about hand-washing) or education about general healthy lifestyle and diet (control group). The soap was distributed in special containers that were weighed at the start and end of the study. Interventions visits to the households were done on average 1 day after randomisation of index case household. See Table 1 for details.
Outcomes	Laboratory: QuickVue RTI MDCK culture Samples were harvested using NTS, but the text refers to a second procedure from June 2007 onwards testing for non-influenza viruses, with no data reported. Effectiveness: secondary attack ratios (SAR): SAR is the proportion of household contacts of an index case who were subsequently ill with influenza (symptomatic contact individuals with at least 1 NTS positive for influenza by viral culture or PCR) 3 clinical definitions were used for secondary analysis: 1. Fever ≥ 38 degrees, or at least 2 of following symptoms: headache, coryza, sore throat, muscle aches and pains 2. At least 2 of the following S/S: fever ≥ 37.8 degrees, cough, headache, sore throat, muscle aches and pains 3. Fever ≥ 37.8 degrees plus cough or sore throat Safety: no harms were reported in any of the arms
Notes	The trial authors conclude that “The secondary attack ratios were lower than anticipated, and lower than reported in other countries, perhaps due to differing patterns of susceptibility, lack of significant antigenic drift in circulating influenza virus strains recently, and/or issues related to the symptomatic recruitment design. Lessons learnt from this pilot have informed changes for the main study in 2008”. Although billed as a pilot study, the text is highly confusing and at times contradictory. The intervention was delivered at a home visit up to 36 hours after the index case was seen in the outpatients. This is a long time and perhaps the reason for failure of the intervention. Practically, the intervention will have to be organised before even seeking medical care, i.e. people know to do it when the child gets sick at home. This work has received financial support from the US Centers for Disease Control and Prevention (grant no. 1 U01 CI000439-01), the Research Fund for the Control of Infectious Disease, Food and Health Bu-

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Cowling 2008 *(Continued)*

reau, Government of the Hong Kong SAR, and the Area of Excellence Scheme of the Hong Kong University Grants Committee (grant no. AoE/M-12/06).

Competing Interests: the authors have declared that no competing interests exist.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was computer generated by a biostatistician. Quote:"A pre-specified table of random numbers will be used to assign one of the three interventions to the household of the index case."
Allocation concealment (selection bias)	Low risk	The households of eligible study index patients were allocated to 3 groups in a 1:1:1 ratio under a block randomisation structure with randomly permuted block sizes of 18, 24, and 30 using a random-number generator. Allocation was concealed from treating physicians and clinics and implemented by study nurses at the time of the initial household visit.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people who administered the interventions were not blinded to the interventions, but participants were not informed of the specific nature of the interventions applied to other participating households.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropout was accounted for. Dropout from the randomised population was high: 32% in control group, 37.5% in hand hygiene group, and 39.4% in face mask and hand hygiene group. Reasons for dropout were distributed evenly across the 3 groups. Authors report follow-up as proportion of patients remaining in the study after initial dropout.
Selective reporting (reporting bias)	High risk	The choice of season, change in randomisation schedules, and unexplained dropouts amongst contacts; the use of QuickVue, which proved unreliable, reporting bias on non-influenza isolates resulted in a judgement of high risk of bias.

Cowling 2009

Study characteristics

Methods	Cluster-RCT
Participants	A total of 407 index cases and 794 household contacts were analysed. Of 407 enrolled households, 322 received the allocated interventions as follows: 1. control group = 112 households with 346 contacts (only 91 households analysed with 279 contacts); 2. hand hygiene = 106 households with 329 contacts (only 85 households analysed with 257 contacts); 3. face mask + hand hygiene = 104 households with 340 contacts (only 83 households analysed with 258 contacts).

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Cowling 2009 *(Continued)*

	Inclusion criteria: households in Hong Kong. Index cases from 45 outpatient clinics in both the private and public sectors across Hong Kong. They enrolled individuals who reported at least 2 symptoms of ARI (temperature 37.8 °C, cough, headache, sore throat, or myalgia); had symptom onset within 48 hours; and lived in a household with at least 2 other people, none of whom had reported ARI in the preceding 14 days. After giving informed consent, participants provided nasal and throat swab specimens. 2750 patients were eligible and tested between 2 January and 30 September 2008.
Interventions	Participants with a positive rapid-test result and their household contacts were randomly assigned to 1 of 3 study groups: control (lifestyle measures - 134 households), control plus enhanced hand hygiene only (136 households), and control plus face masks and enhanced hand hygiene (137 households) for all household members. No detailed description of the instructions was given to participants. See Table 1 for details.
Outcomes	Influenza virus infection in household contacts, as confirmed by RT-PCR or diagnosed clinically after 7 days "The primary outcome measure was the secondary attack ratio at the individual level: that is, the proportion of household contacts infected with influenza virus. We evaluated the secondary attack ratio using a laboratory definition (a household contact with a nose and throat swab specimen positive for influenza by RT-PCR) as the primary analysis and 2 secondary clinical definitions of influenza based on self-reported data from the symptom diaries as secondary analyses." Statistical analysis: adjusted for clustering Results: no statistically significant difference in secondary attack ratio between groups in total population. Statistically significant reduction in RT-PCR confirmed influenza virus infections in the household contacts in 154 households in which the intervention was applied within 36 hours of symptom onset in the index patient. Adherence to hand hygiene was between 44% and 62%. Adherence of index patient to wearing a face mask between 15% and 49%.
Notes	"In an unintentional deviation from that protocol, 49 of the 407 randomly allocated persons had a household contact with influenza symptoms at recruitment (a potential co-index patient). We also randomly assigned 6 of 407 persons who had symptoms for slightly more than 48 hours." The trial authors conclude that "Hand hygiene and face masks seemed to prevent household transmission of influenza virus when implemented within 36 hours of index patient symptom onset. These findings suggest that non-pharmaceutical interventions are important for mitigation of pandemic and interpandemic influenza". Primary funding source: Centers for Disease Control and Prevention. Potential conflicts of interest: none disclosed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was computer generated by a biostatistician. Quote:"A pre-specified table of random numbers will be used to assign one of the three interventions to the household of the index case."
Allocation concealment (selection bias)	Low risk	The households of eligible study index patients were allocated to 3 groups in a 1:1:1 ratio under a block randomisation structure with randomly permuted block sizes of 18, 24, and 30 using a random-number generator. Allocation was concealed from treating physicians and clinics and implemented by study nurses at the time of the initial household visit.
Blinding of participants and personnel (performance bias)	High risk	Quote: "Participants and personnel administering the interventions were not blinded to group assignment."

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Cowling 2009 *(Continued)*
All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated if the outcome assessor was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropout was accounted for. Dropout from the randomised population was high: 32% in control group, 37.5% in hand hygiene group, and 39.4% in face mask and hand hygiene group. Reasons for dropout were distributed evenly across the 3 groups. Trial authors report follow-up as proportion of patients remaining in the study after initial dropout.
Selective reporting (reporting bias)	Unclear risk	In general good reporting

DiVita 2011

Study characteristics	
Methods	The impact of hand-washing promotion on the risk of household transmission of influenza, ILI, and fever was tested in rural Bangladesh. ILI was defined as fever in children < 5 years old and fever with cough or sore throat in individuals > 5 years old. Households were randomised to intervention or control. The intervention group received hand-washing stations with soap and daily hand-washing motivation at critical times for pathogen transmission, such as after coughing or sneezing. Daily surveillance was conducted, and household members with fever were tested for influenza viruses by PCR. Secondary attack ratios (SAR) were calculated for influenza, ILI, and fever in each arm. Logistic regression with generalised estimating equations was used to estimate the significance of the SAR comparison whilst controlling for clustering by household.
Participants	The study included 233 patient index cases (intervention group = 100, control group 133) with 2540 household contacts (intervention group = 134, control group = 1226). Inclusion criteria: index case patients (individuals who developed ILI within the previous 2 days and were the only symptomatic person in their household) as well as their household contacts
Interventions	Hand-washing stations with soap and daily hand-washing motivation versus control. See Table 1 for details.
Outcomes	SAR were calculated for influenza, ILI, and fever. ILI was defined as fever in children < 5 years old and fever with cough or sore throat in individuals > 5 years old. No safety outcomes reported.
Notes	Funding source unknown. Disclosure of interest: none declared.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided

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DiVita 2011 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Insufficient details provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient details provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient details provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient details provided
Selective reporting (reporting bias)	Unclear risk	Insufficient details provided

Farr 1988a

Study characteristics	
Methods	6-month cluster-RCT, controlled, double-blind of the efficacy of virucidal nasal tissues in the prevention of natural cold, conducted in Charlottesville, Virginia, USA. Many of the families were enrolled because 1 or more family members worked at the State Farm Insurance Company; the remaining families were recruited from the Charlottesville community by advertisement in a local newspaper. Families were randomly assigned by the sponsoring company to receive boxes of treated tissues, placebo tissues, or no tissues. The randomisation was performed by computer. Study participants and investigators were unaware of the type of tissues each family was randomised to receive. Blinding efficacy was tested using a questionnaire: the mothers in each family were asked twice if she believed her family was using virucidal or placebo tissues. Participants in the treated and placebo groups were instructed to use only tissues received through the study, whilst families in the additional control group without tissues were allowed to continue their usual practice of personal hygiene. Each family member kept a daily listing of respiratory symptoms on a record card. A nurse epidemiologist visited each family monthly to encourage recording.
Participants	186 families, 58 in the active group, 59 in the placebo group, and 69 in the no-tissues group. A total of 302 families were originally recruited; 116 families who did not comply with the study protocol, lost their surveillance cards, could not complete the protocol were excluded from the analysis.
Interventions	Use of virucidal tissues versus placebo tissues versus no tissues. The treated tissues were impregnated with malic and citric acids and sodium lauryl sulphate, whilst placebo tissues contained saccharin. See Table 1 for details.
Outcomes	Laboratory: serological evidence: no Effectiveness: respiratory illness Safety: N/A
Notes	The authors concluded that virucidal tissues have only a small impact on the overall rate of natural acute respiratory illnesses. The total illness rate was lower in families using virucidal tissues than in both of the other study groups, but only the difference between active and placebo groups was statistically significant (3.4 illness per person versus 3.9 for placebo group, P = 0.04, and 3.6 for the no-tissue control group, P = 0.2, and overall 14% to 5% reduction). The questionnaire results suggest that some bias may have been present since a majority of mothers in the virucide group believed they were receiving the 'active' tissues. Another possible explanation of the low effectiveness of virucidal tissues

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Farr 1988a *(Continued)*

is poor compliance by children in use of the virucidal tissues. A well-designed and honestly reported study.

Funding source not reported.

Potential conflicts of interest: none disclosed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote:"The randomisation was performed by computer in each trial." However, method of sequence generation is not stated.
Allocation concealment (selection bias)	Unclear risk	Quote: "In trial I, families were randomly assigned by the sponsoring company to receive boxes of treated tissues, placebo tissues or no tissues." Quote: "Families with one or two children were randomised in one stratum, and families with three or more children were randomised in a second stratum in trial I." Concealment of allocation not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Study participants and investigators were unaware of the type of tissues which each family was randomised to receive in both trials. In trial I, the mother in each family was asked twice if she believed her family was using active or placebo tissues, first after three months and then at the end of the study."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Study participants and investigators were unaware of the type of tissues which each family was randomised to receive in both trials. In trial I, the mother in each family was asked twice if she believed her family was using active or placebo tissues, first after three months and then at the end of the study."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "A total of 116 of the 302 families were excluded from the analysis. Families were excluded if they lost their surveillance cards or did not conscientiously record data, did not comply with the study protocol, or simply could not complete the protocol for family reasons. It was discovered that families with five or more members had so many colds that it was not possible to distinguish primary and secondary illnesses. These large families were therefore excluded from the analysis in trial I and were excluded from enrolment in trial II."
Selective reporting (reporting bias)	Low risk	All indicated outcomes are reported.

Farr 1988b

Study characteristics

Methods	Six-month randomised, controlled, double-blind trial of the efficacy of virucidal nasal tissues in the prevention of natural cold, conducted in Charlottesville, Virginia, USA. Families were recruited from the Charlottesville community by advertisement in a local newspaper. Families were randomly assigned by the sponsoring company to receive either virucidal tissues or placebo-treated tissues. Stratified randomisation was performed by computer, and the strata were defined by total number in the family. Study participants and investigators were unaware of the type of tissues each family was randomised to receive. Each family member kept a daily listing of respiratory symptoms on a record card. A nurse

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Farr 1988b *(Continued)*

	epidemiologist visited each family monthly to encourage recording. In addition, a study monitor visited each family bimonthly to further encourage compliance and reporting of symptoms.
Participants	98 families, 58 in the active group and 40 in the placebo group. 231 families were initially recruited, 222 completed the trial, data of 98 families were analysed. The other families were excluded from the analysis because they complained of side effects (sneezing, etc.) or reported not using the tissues regularly. See Table 1 for details.
Interventions	Use of virucidal tissues versus placebo tissues. The treated tissues were impregnated with malic and citric acids and sodium lauryl sulphate, whilst the placebo tissues contained succinic acid. Participants in the treated and placebo groups were instructed to only use tissues received through the study.
Outcomes	Laboratory: serological evidence: no Effectiveness: respiratory illness Safety: N/A
Notes	The study suggests that virucidal tissues have only a small impact on the overall rate of natural acute respiratory illnesses. The total illness rate was lower in families using virucidal tissues than in the other study group, but the difference between active and placebo groups was not statistically significant. There was a small, non-significant drop in illness rates across families (5%). The tissues appeared to be ineffective as the drop was confined to primary illness unaffected by tissue use. The placebo (succinic acid) was not inert, and was associated with cough and nasal burning. This impacted on allocation concealment. A well-designed and honestly reported study marred by transparent allocation. Funding source not reported. Potential conflicts of interest: none disclosed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The randomisation was performed by computer in each trial." However, method of sequence generation is not stated.
Allocation concealment (selection bias)	Unclear risk	Quote: "In trial II, families were randomly assigned by the sponsor to receive either virucidal tissues or placebo treated tissues." Quote:"In trial II, stratified randomisation was again used, but this time the strata were defined by total number in the family (i.e., one stratum for two-member families, another stratum for three-member families, and a final one for four-member families)." Concealment of allocation not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote:"Study participants and investigators were unaware of the type of tissues which each family was randomised to receive in both trials."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote:"Study participants and investigators were unaware of the type of tissues which each family was randomised to receive in both trials."
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote:"A total of 222 (of 231) families completed trial II; 9 families were terminated early (table 1). In 124 families, one or more family members reported not using the tissues regularly and/or reported having significant side effects. The data from these families were not analysed, leaving 58 families (177 persons) and 40 families (114 persons) for analysis in the virucide and placebo groups, respectively."

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Farr 1988b *(Continued)*

Selective reporting (reporting bias)	Low risk	All indicated outcomes are reported.

Feldman 2016

Study characteristics	
Methods	Prospective cluster-RCT. Ships from a single, central naval base. Ships were stratified by vessel classes (corvette, fast missile boat, and patrol boat).
Participants	All people participating in security operations, routine exercises, and patrol at a single, central naval base were eligible. The actual number of participants in the groups is not reported.
Interventions	Chlorhexidine gluconate (CHG) dispensers in addition to soap-and-water hand-washing versus soap-and-water hand-washing. See Table 1 for details.
Outcomes	Laboratory: bacterial palm cultures from 30 sailors from each group using a modified bag broth technique with sterile brain-heart broth, at 0 and 4 months (sample participants) Effectiveness: Primary outcome: incidence of infectious diseases reported by the computerised patient records system using ICD-9 diagnoses and grouped into diarrhoeal, respiratory, and skin infections; the number of sick call visits; and the number of sick leave and light-duty days incurred by the sailors Secondary outcome: subclinical morbidity (i.e. symptoms of self-reported infectious diseases) Safety: not reported
Notes	No report on adherence Study was conducted between May and September 2014 (4 months follow-up). CHG availability onboard the ships did not reduce the transmission of infectious diseases or colonisation. Government funded (Israeli Defense Force Medical Corps). Potential conflicts of interest: none disclosed.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No description of randomisation
Allocation concealment (selection bias)	Unclear risk	No description of allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded. Self-reported outcomes
Blinding of outcome assessment (detection bias)	Unclear risk	No information if personnel collecting data for ICD-9 diagnosis were blinded

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Feldman 2016 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No participants flow chart, no attrition data
Selective reporting (reporting bias)	Unclear risk	No protocol to compare

Fretheim 2022a

Study characteristics	
Methods	Pragmatic RCT
Participants	3717 participants in Norway (glasses n = 1852; no glasses n = 1865) Inclusion criteria: 1. were at least 18 years of age; 2. did not regularly wear glasses; 3. owned or could borrow glasses that they could use (e.g. sun-glasses); 4. had not contracted COVID-19 in the 6 weeks prior to participation; 5. did not have COVID-19 symptoms when providing consent; 6. were willing to be randomised to wear, or not wear glasses outside their home when close to others for a 2-week period; 7. provided informed consent; and 8. contact lenses were allowed in the control group for those dependent on this visual aid. Exclusion criteria: 1. does regularly wear glasses (contact lenses are accepted); and 2. contracted COVID-19 after December 15th 2021.
Interventions	Intervention group: wearing eyeglasses (any type) when close to other people outside their home (on public transport, in shopping malls etc.), over a 14-day period. The control: encouraged not to wear glasses when close to others outside their home. See TIDieR Table (Table 1) for details.
Outcomes	Primary outcome 1. Any positive COVID-19 test result reported to the Norwegian Surveillance System for Communicable Diseases (MSIS), from day 3 to day 17 of the study period. Secondary outcomes 1. Any positive COVID-19 test result based on self-report, from day 1 to day 17 of the study period. 2. Episode of respiratory infection based on self-report of symptoms from day 1 to day 17 of the study period. Respiratory infection was defined as having 1 respiratory symptom (stuffed or runny nose, sore throat, cough, sneezing, heavy breathing) and fever, or 1 respiratory symptom and at least 2 more symptoms (body ache, muscular pain, fatigue, reduced appetite, stomach pain, headache, loss of smell). 3. Healthcare use for respiratory symptoms, self-reported, from day 1 to day 17 of the study period. 4. Healthcare use for injuries, self-reported, from day 1 to day 17 of the study period. 5. Healthcare use (all causes), self-reported, from day 1 to day 17 of the study period. 6. Healthcare use for respiratory symptoms as registered in Norwegian Patient Registry (NPR), from day 3 to day 28 of the study period.

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Fretheim 2022a *(Continued)*

	7. Healthcare use for injuries (from day 1 to day 21 as registered in NPR and the Norwegian Registry for Primary Health Care (KPR), from day 3 to day 28 of the study period. 8. Healthcare use (all causes) as registered in NPR and KPR from day 1 to day 21 of the study period.
Notes	The study did not report on the latter 4 outcomes due to lack of access to this data at the time of publication. Negative experiences of using the eyeglasses were reported: fogging, feeling uncomfortable and tiring, reduced vision, fall, feeling silly when wearing glasses indoor, headache. Funding: the costs of running the trial were covered by the Centre for Epidemic Interventions Research (CEIR), Norwegian Institute of Public Health. Competing interests: all authors declare: no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Automatically randomised after signing the consent form in the online recruitment platform (Nettskjema).
Allocation concealment (selection bias)	High risk	A digital recruitment platform (Nettskjema) was used to generate allocation. However, more participants in the intervention group wore face masks.
Blinding of participants and personnel (performance bias) All outcomes	High risk	An open-label study. Participants and investigators were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome is self-reported positive COVID-19 test result reported to the Norwegian Surveillance System for Communicable Diseases (MSIS). However, the public policy requiring confirmatory PCR-test had changed during the study conduct which may have affected case detection.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants flow chart was provided.
Selective reporting (reporting bias)	Low risk	No deviation from the published protocol.

Goodall 2014

Study characteristics

Methods	A 2X2 factorial RCT with 4 treatment arms 1. Vitamin D_3 and gargling 2. Placebo and gargling 3. Vitamin D_3 and no gargling 4. Placebo and no gargling
Participants	600 students from McMaster University, Hamilton, Ontario, Canada, randomised to the following. 1. Vitamin D and gargling (N = 150, analysed 135) 2. Vitamin D and no gargling (N = 150, 123 outcomes included in analysis)

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Goodall 2014 *(Continued)*

	3. Placebo and gargling (N = 150, 121 known outcomes included in analysis) 4. Placebo and no gargling (N = 150, 113 known outcomes included in analysis) Inclusion criteria: aged ≥ 17 years and lived with at least 1 student house mate. Exclusion criteria: students with contraindicated medical conditions (hypercalcaemia, parathyroid disorder, chronic kidney disease, use of anticonvulsants, malabsorption syndromes, sarcoidosis), who were currently or planning to become pregnant, who were taking ≥ 1000 international units (IU)/day vitamin D, or who were unable to swallow capsules
Interventions	See Table 1 for details.
Outcomes	Laboratory (influenza assessed via weekly self-collected nasal swabs; only swabs for symptomatic participants were assessed). Lab-confirmed influenza was determined by testing the Day 1 nasal swabs using an in-house enterovirus/rhinovirus PCR and, if negative, a commercial multiplex PCR able to detect 16 respiratory viruses and viral subtypes (xTAG RVP FAST, Luminex, Austin TX). Clinical URTI assessed via weekly online surveys. Clinical URTI is defined as the participant's perception of cold in conjunction with 1 or more symptoms (runny/stuffy nose, congestion, cough, sneezing, sore throat, muscle aches, or fever). When participants reported symptoms but were uncertain if they were ill, adjudication was applied by 2 clinicians. Safety: None assessed/reported by the investigators.
Notes	Study was conducted during 2 periods: September to October in 2010 and 2011. Partial governmental funding. Competing interests: the authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No description on how the randomisation sequence was generated
Allocation concealment (selection bias)	Low risk	Study used opaque, sealed, serially numbered envelopes. Envelopes were only accessed when both personnel were present.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Due to the nature of gargling with tap water, this intervention was not blinded. However, all other aspects of the study were blinded. Self-reported symptoms were adjudicated by 2 clinicians.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Except for gargling, all other participants and study personnel were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Study flow chart and reasons for lost to follow-up are provided, imputation used for missing outcomes.
Selective reporting (reporting bias)	Low risk	All planned study outcomes were reported and match the published study protocol.

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Gutiérrez-García 2022

Study characteristics	
Methods	Single-blind (analyst) randomised controlled trial carried out in a single centre in Mexico City during September to November 2020. Randomisation was through tokens in opaque envelopes but the trial was open to all except the data analysts. There were some imbalances in age groups post-randomisation at baseline in age and comorbidities
Participants	85 front line healthcare workers, unvaccinated and with no history of COVID infection in each arm. 6 and 1 were excluded from the analysis as they tested positive to CUVID within 14 days of recruitment. Follow-up was 2 weeks
Interventions	Neutral electrolysed water (SES) (pH 6.5 to 7.5) nasal and oral rinses 3 times daily and PPE versus PPE only for the prevention of SARS-CoV-2 infection. See Table 1 for details.
Outcomes	Laboratory RT-PCR no further described "according to the WHO guidelines", once only presumably with symptoms. Effectiveness COVID-19 disease confirmed by RT-PCR, between the 14th day since their recruitment and the 28th day of follow-up. The following are listed as COVID-19 signs and symptoms: dry cough, fever > 37.5℃, headache, myalgia, arthralgia, rhinorrhoea, conjunctivitis, pharyngodynia, odynophagia. 1 and 10 participants were positive in the intervention and control arms respectively. All 11 were nurses. Safety Local harms from SES applications – none reported
Notes	The authors conclude that quote: "the prophylactic protocol was demonstrated as a protective factor, in more than 90%, for developing the disease, and without adverse effects. Nasal and oral rinses with SES maybe an efficient alternative to reinforce the protective measures against COVID-19 disease and should be further investigated." Funding: no funding was received. Competing interests: the authors RGG, JCA and IDE declare that they have no competing interests. ACL, NMS and BPM state that they are employees at Esteripharma S.A. de C.V. company but did not participate in the decision to publish the results of the study, nor in the selection of the volunteers or in its development.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information provided.
Allocation concealment (selection bias)	High risk	Nurse or doctor chose one of two identical tokens that were placed inside an opaque plastic container. One token was labelled 'with SES' (treatment group) and the other 'without SES' (control group).
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded.
Blinding of outcome assessment (detection bias)	Low risk	Primary endpoint was the number of healthcare professionals, nurses, or physicians, with COVID-19 disease confirmed by

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Gutiérrez-García 2022 *(Continued)*

All outcomes		RT-PCR. Researchers that performed the statistical analyses were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal exclusions from the analysis.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported.

Gwaltney 1980

Study characteristics	
Methods	Study assessed the effectiveness of aqueous iodine applied to the fingers in blocking hand transmission of experimental infection with rhinovirus from 1 volunteer to another. Healthy, young adult volunteers were recruited from the general population at the University of Virginia, Charlottesville. Volunteers were not informed about the contents of the hand preparation until after the study. 2 experiments were conducted to evaluate the virucidal activity of aqueous iodine applied to the fingers immediately before viral contamination. Another 2 experiments were conducted to determine whether there was sufficient residual activity of aqueous iodine after 2 hours to interrupt viral spread by the hand route. Volunteers who were donors of virus for the hand exposures were challenged intranasally on 3 consecutive days with the rhinovirus strain HH. Recipients were randomly assigned to receive iodine or placebo. The donors contaminated their hands with nasal secretions by finger to nose contact before the exposure. Hand contact was made between a donor and a recipient by stroking of the fingers for 10 seconds. Donors and recipients wore masks during the exposure period.
Participants	15 and 20 volunteers in 2 experiments
Interventions	Treatment of fingers with iodine versus placebo. The virucidal preparation used was aqueous iodine (2% iodine and 4% potassium iodide). The placebo was an aqueous solution of food colours. See Table 1 for details.
Outcomes	Experimental rhinovirus infection reduced (P = 0.06) Laboratory: serological evidence Effectiveness: rhinovirus infection (based on serology, isolation, and clinical symptoms) with high-score clinical illness. Score was published elsewhere. Safety: N/A
Notes	Risk of bias: high (poor description of randomisation process, concealment, or allocation) Notes: the study suggests that aqueous iodine applied to the fingers was effective in blocking transmission by hand contact of experimental infection with rhinovirus for up to 2 hours after application (1 out 10 volunteers were infected compared to 6 out of 10 in the placebo preparation arm, P = 0.06 with Fisher's exact test). The effectiveness of iodine treatment of the fingers in interrupting viral transmission in volunteers recommends its use for attempting to block transmission of rhinovirus under natural conditions. Although the cosmetic properties of 2% aqueous iodine make it impractical for routine use, it can be used as an epidemiologic tool to study the importance of the hand transmission route and to develop an effective cosmetically acceptable hand preparation. A summarily reported study. Funding source not reported. Disclosure of interest: none mentioned.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

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Gwaltney 1980 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote:Quote: "The viricidal preparation used was aqueous iodine... . The placebo was an aqueous solution of food colors... mixed to resemble the color of iodine. An odor of iodine was given to the placebo... . Volunteers were not informed about the contents of the hand preparation until after the study."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not stated whether the outcome assessor was blinded or not.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information
Selective reporting (reporting bias)	Unclear risk	Insufficient information

Hartinger 2016

Study characteristics	
Methods	Communities were randomised to a comprehensive intervention was an improved solid-fuel stove, installation of a kitchen sink with running water, solar drinking water disinfection, education on handwashing, and separating animals from the kitchen environment.
Participants	534 children (267 in each group) in 51 communities (25 in intervention, 26 in control group). 250 children/households in the intervention group and 253 children/households in the control group were available for follow-up. Conducted in a rural farming area
Interventions	Environmental home-based intervention package consisting of improved solid-fuel stoves, kitchen sinks, solar disinfection of drinking water, and hygiene promotion. See Table 1 for details.
Outcomes	Laboratory: *Escherichia coli* (not relevant to this review) Effectiveness: weekly collection of daily diary data on illness. ARI was defined as child presenting cough or difficulty breathing, or both. ALRI was defined as child presenting cough or difficulty breathing, with a raised respiratory rate (> 50 per min in children aged 6 to 11 months and > 40 per min in children aged 12 months) on 2 consecutive measurements. Safety: none described in methods and none reported
Notes	The authors conclude that “combined home-based environmental interventions slightly reduced childhood diarrhoea, but the confidence interval included unity. Effects on growth and respiratory outcomes were not observed, despite high user compliance of the interventions. The absent effect on respiratory health might be due to insufficient household air quality improvements of the improved stoves and additional time needed to achieve attitudinal and behaviour change when providing composite interventions”. Well-reported trial. Age of children not reported. Funding: this work was supported by the UBS Optimus Foundation, Freiwillige Akademische Gesellschaft, Basel, Stiftung EmiliaGuggenheim-Schnurr, Basel.

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Hartinger 2016 *(Continued)*

Conflict of interest: the authors have no conflicts of interest to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Covariate-constrained randomisation is mentioned, but method not described.
Allocation concealment (selection bias)	Unclear risk	Method not mentioned
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data collected by field worker and recorded by parent. All would be aware of allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition rate, reasons stated, balanced between groups.
Selective reporting (reporting bias)	Low risk	It is unlikely that other outcomes were measured but not reported.

Helsingen 2021

Study characteristics

Methods	Non-inferiority open randomised trial carried out in May 25 to June 15 2020 during the first lockdown in Norway. Eligible individuals were randomised 1:1 stratified by fitness centre by a computerised random number generator to no access to fitness centre or access to fitness centre with “mitigation measures”
Participants	3825 people aged 18 to 65 with no risk factors for Covid 19 (diabetes, cardiovascular disease including hypertension, age > 65). 61 randomised participants (18 and 43, respectively) withdrew consent before start of the intervention with 3764 remaining
Interventions	The intervention consisted in gym access with: avoidance of body contact; 1 m distance between individuals at all times; 2 m distance for high intensity activities; disinfection of all work stations; cleaning of all equipment after use by participant; regular cleaning of facilities and access control by facility employees to ensure distance measures and avoid overcrowding; open changing rooms with showers and saunas remained closed; staff was present during all opening hours; lids on trash cans removed; individuals were instructed to stay home if they had any Covid-19 related symptoms, participants were advised to avoid touching their eyes, nose and mouth. See Table 1 for details.
Outcomes	Laboratory Self-administered (at times facilitated by HCW) NP, saliva or OP swabs in transport medium taken at day 14 to 15 from beginning sent to central lab. RT-RPC performed. Testing of antibodies (IGG) was carried out in late June with a mailed self-administered spot slide which was then mailed and analysed centrally. Effectiveness

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Helsingen 2021 *(Continued)*

	Primary: PCR positivity in both arms Co-primary: hospital admission in the two arms at 21 days (via data linkage) Secondary: proportion of participants with SARS-CoV-2 antibodies in the 2 study arms at 30 days. Testing also carried out for gym staff. Safety NR
Notes	The authors conclude that "Provided good hygiene and physical distancing measures and low population prevalence of SARS-CoV-2infection, there was no increased infection risk of SARS-CoV-2 in fitness centres in Oslo, Norway for individuals without Covid-19-relevant comorbidities." There was low and declining incidence on C19 in the Oslo area during the time of the trial as reported by the authors. The authors call the analysis set ITT but consent withdrawal individuals were not part of the analysis. There was marked difference in PCR uptake (88.7% in the training arm; 71.4% in the no-training arm) and no cycle thresholds are reported. Funding: this study was funded by the Norwegian Research Council, grant no. 312757. The grant paid for necessary equipment, study personnel and researchers. Competing interests: Dr. Lise M. Helsingen reports grants from Norwegian Research Council (grant no. 312757), during the conduct of the study. All other authors declare no competing interests in relation to this work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random-number generator
Allocation concealment (selection bias)	High risk	Allocation performed by one of the study authors
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	More women were compliant with SARS-CoV2 testing in the training arm as compared to the no-training arm, and compliant individuals were somewhat younger in the training arm compared to the non-training arm.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported

Hubner 2010

Study characteristics

Methods	A prospective, controlled, intervention-control group design to assess the epidemiological and economical impact of alcohol-based hand disinfectants use at workplace. Volunteers in public administra-

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Hubner 2010 *(Continued)*

	tions in the municipality of the city of Greifswald were randomised into 2 groups. Participants in the intervention group were provided with alcoholic hand disinfection, the control group was unchanged. In all, 1230 person-months were evaluated.
Participants	Employees (n = 134) from the administration of the Ernst-Moritz-Arndt University Greifswald, the municipality of Greifswald and the state of Mecklenburg-Pomerania, were recruited for the study and randomised to intervention (N = 67) or control (N = 67). Final analysis was performed on 64 from the intervention and 65 from the control group. Inclusion criteria: all administrative officers, who did not already apply hand disinfection at work, were considered for participation and were invited by email or mail (n = 850). The 134 participants declared their written consent to participate and completed a pre-study survey with demographic, social, health, and work-related questions to provide data for randomisation. Exclusion criteria: employees that were already using hand disinfectants at work
Interventions	Alcohol-based hand disinfectants use at workplace versus usual hygiene. See Table 1 for details.
Outcomes	Respiratory and gastrointestinal symptoms and days of work were recorded based on a monthly questionnaire over 1 year.
Notes	Funding source not mentioned. Competing interests: the authors declare a financial competing interest: GK is employed by Bode Chemie GmbH, Hamburg, Germany. NOH and AK received financial support for research from Bode Chemie in the past. All other authors declare no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up minimal and similar in 2 groups
Selective reporting (reporting bias)	Unclear risk	No protocol available

Huda 2012

Study characteristics

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Huda 2012 *(Continued)*

Methods	Poorly described cluster-RCT. Partial report of the SHEWA-B trial focused on changing 11 targeted behaviours in villages to measure the impact on diarrhoea and respiratory illness amongst children. Unit of randomisation is not clear, but was probably a village. A group of 10 to 17 households within a village were the participants, based on the household having at least 1 child under the age of 5.
Participants	A total of 1692 participants (intervention = 848, control = 844) at baseline and 1699 participants at 18 months (intervention = 849, control = 850) Households were eligible if they have a child < 5 years of age and a guardian agreed to participate.
Interventions	SHEWA-B programme targeting improved latrine coverage and usage, access to and use of arsenic-free water, and improved hygiene practices using soaps. See Table 1 for details.
Outcomes	Laboratory: none described in methods and none reported Effectiveness: ARI and diarrhoea. ARI defined as cough and fever or difficulty breathing and fever within 48 hours prior to interview. Safety: none described in methods and none reported
Notes	The authors conclude that quote: “The prevalence of childhood diarrhea and respiratory illness was similar in the intervention and control communities”. Poorly reported trial. This research activity was funded by the United Kingdom's Department for International Development (DFID). Disclosure of interest: none mentioned.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Mentions random-number tables, but not clear if this was for random selection or randomisation
Allocation concealment (selection bias)	Unclear risk	Method not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data on illness were collected by a resident of the village, who was likely to know treatment allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Not reported. No flow diagram
Selective reporting (reporting bias)	Unclear risk	Unlikely that other outcomes were measured and not reported

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Ibfelt 2015

Study characteristics	
Methods	Cluster-RCT in 12 daycare nurseries in Denmark. Centres in the intervention group had their linen and children's toys commercially cleaned and disinfected every 2 weeks. Control group centres had usual practice. Swabbing for bacteria and respiratory viruses was conducted at baseline and the end of the intervention period.
Participants	12 nurseries in Copenhagen (intervention = 6, control = 6) with a total of 587 children aged 6 months to 3 years Not clear how many children were in each group. Data on illness collected at the individual level, and on presence of bacteria and viruses at the cluster level.
Interventions	Washing and disinfection of toys and linen every 2 weeks for 3 months. See Table 1 for details.
Outcomes	Laboratory: counts of bacteria (not relevant to this review) and 11 respiratory viruses at baseline and end of intervention period, taken from swabs of 10 predefined locations in playroom (7 locations) and toilet area (3 locations). Viruses were influenza A and B; coronavirus NL63229E, OC43, and HKU1; parainfluenza virus 1, 2, 3, and 4; rhinovirus; RSV A/B; adenovirus; enterovirus; parechovirus; metapneumovirus; and bocavirus. Testing by PCR Effectiveness: illness counts in the children. Absence due to sickness recorded daily with reason categorised, but no definitions of illness provided. Safety: none mentioned in methods and none reported
Notes	The authors conclude that "Although cleaning and disinfection of toys every two weeks can decrease the microbial load in nurseries, it does not appear to reduce sickness absence among nursery children". The results of the disinfection are reported as follows: "The most prevalent virus was coronavirus (97% positive samples), followed by bocavirus (96%), adenovirus (73%) and rhinovirus (46%). The intervention reduced the presence of adenovirus, rhinovirus and RSV approximately two- to five-fold [odds ratio (OR) 2.4, 95% confidence interval (CI) 1.1-5.0 for adenovirus; OR 5.3, 95% CI 2.3-12.4 for rhinovirus; OR 4.1, 95% CI 1.5-11.2 for RSV] compared with the control group. On the other hand, metapneumovirus was found significantly less often in the control group than in the intervention group. The intervention had no effect on the detection of other viruses. The fomites with the highest presence of respiratory virus were pillows and sofas, followed by toys and playroom tables. When looking at the samples from the toys alone, there was a significant decrease following the intervention in the intervention group compared with the control group for rhinovirus (OR 3.8, 95% CI 1.3-10.5; P = 0.01) and RSV (OR 5.2, 95% CI 1.1-23.8; P = 0.04), but not adenovirus". This a poorly reported cluster-RCT. Its importance lies in the surface viral prevalence data (which could have been overestimated by PCR) and the finding that even in the presence of high viral prevalence, sickness was lower in the control (no surface disinfection) arm. This suggests the absence of other factors that could activate surface respiratory viruses. Funding: this work was supported by the Danish Council for Technology and Innovation under the Ministry of Science, Innovation and Higher Education as part of the Sundhed i Børneinstitutioner innovation consortium. Conflict of interest statement: Ecolab Denmark, Berendsen Denmark and 3M Denmark supplied materials and cleaning free of charge, but had no influence on the analysis of the data or the writing of the manuscript.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not mentioned

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Ibfelt 2015 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Method not mentioned
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Objective measure of bacterial and viral counts. However, illness reporting is unclear.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition or denominators given for results.
Selective reporting (reporting bias)	Low risk	Unlikely that other outcomes were measured but not reported

Ide 2014

Study characteristics	
Methods	Randomised, open-label, 2-group parallel study of 757 high school students (15 to 17 years of age) conducted for 90 days during the influenza epidemic season from 1 December 2011 to 28 February 2012, in 6 high schools in Shizuoka Prefecture, Japan. The green tea gargling group gargled 3 times a day with bottled green tea, and the water gargling group did the same with tap water. The water group was restricted from gargling with green tea.
Participants	A total of 747 students were enrolled (green tea gargling group = 384, water gargling group = 363) High school students (15 to 17 years of age) who attended 6 high schools in the Kakegawa and Ogasa districts of Shizuoka Prefecture, Japan
Interventions	See Table 1 for details.
Outcomes	Incidence of laboratory-confirmed influenza Incidence of clinically defined influenza infection Time for which the participant was free from clinically-defined influenza infection Clinically-defined influenza infection, specified as fever (≥ 37.8 °C) plus any 2 of the following additional symptoms: cough, sore throat, headache, or myalgia. Influenza infection with viral antigen was detected by immunochromatographic assay. No safety data reported.
Notes	Funding: this work was supported by Grants-in-Aid for Scientific Research (KAKENHI) Grant Number 23590887. Competing Interests: the authors have declared that no competing interests exist.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

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Ide 2014 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated permuted block randomised schema
Allocation concealment (selection bias)	Low risk	Randomised at the Data Management Center of Shizuoka General Hospital in Japan
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition
Selective reporting (reporting bias)	Unclear risk	Protocol not available

Ide 2016

Study characteristics	
Methods	Randomised controlled study in Japan. Participants were randomly allocated into the catechin-treated (epigallocatechin gallate-treated) or non-treated face mask groups for 60 days from January to March 2016. Incidence of laboratory-confirmed influenza infection was measured and compared between groups using Fisher's exact test. Multivariate analysis was performed to calculate adjusted ORs and associated 95% CIs.
Participants	Participants included workers in a nursing home, a rehabilitation facility, and a hospital. A total of 234 participants were eligible for the study (catechin group, n = 118; control group, n = 116).
Interventions	Catechin-treated mask versus non-treated face mask. See Table 1 for details.
Outcomes	Incidence of laboratory-confirmed influenza infection Laboratory-confirmed influenza infection with viral antigen detected by immunochromatographic assay performed when participants reported ILI. No safety outcomes reported.
Notes	Funding: this work was supported in part by a grant from the Japan Society for the Promotion of Science (JSPS), through the Grant-in-Aid for JSPS Fellows (No. 15J10190 to KI) and Grants-in-Aid for Scientific Research (C) (15K08924 to HY). Conflict of Interest: the authors declare that they have no conflicts of interest.
Risk of bias	
Bias	**Authors' judgement** / **Support for judgement**

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Ide 2016 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Computer-generated randomisation, but method not stated
Allocation concealment (selection bias)	Low risk	Central randomisation service at Data Management Centre of Shizouka General Hospital
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Attrition minimal
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition minimal
Selective reporting (reporting bias)	Low risk	Specified outcomes reported.

Jacobs 2009

Study characteristics	
Methods	Open-RCT lasting 77 days from January 2008 to test “superiority” of face masks in preventing "URTI". This term appears as an acronym in the introduction and is not explained. It is assumed that it stands for 'upper respiratory infections', but it is preceded in the text by the term 'common cold', which is also lacking a definition. Randomisation was carried out in blocks within each of 3 professional figures (physicians, nurses, and “co-medical” personnel).
Participants	33 HCWs mainly females aged around 34 to 37 in a tertiary healthcare hospital in Tokyo, Japan. HCW with quote: “predisposing conditions” (undefined) to “URTI” and those taking antibiotics were excluded. A baseline descriptive survey was carried out including “quality of life”. 1 participant dropped out at end of week 1, but no reason is reported nor the allocation arm. Analysis was performed on 32 participants (mask = 17, no mask = 15).
Interventions	Surgical mask MA-3 (Osu Sangyo, Japan) during all phases of hospital work (n = 17) or no mask (n = 15) (except when specifically required by hospital SOPs). See Table 1 for details.
Outcomes	Laboratory: N/A Effectiveness: URTI is defined on the basis of a symptoms score, with a score > 14 being a URTI according to Jackson’s 1958 criteria (“Jackson score”). These are not explained in text, although the symptoms are listed in Table 3 (any, sore throat, runny nose, stuffy nose, sneeze, cough, headache, ear ache, feel bad) together with their mean and scores SD by intervention arm. Safety: the text does not mention or report harms. These appear to be indistinguishable from URTI symptoms (e.g. headache which is reported as of significantly longer duration in the intervention arm). Compliance is self-reported as high (84.3% of participants).

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Jacobs 2009 *(Continued)*

Notes	The authors conclude that quote: “Face mask use in healthcare workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds. A larger study is needed to definitively establish non-inferiority of no mask use”. This is a small, badly reported trial. The purpose of trials is to test hypotheses not to prove or disprove 'superiority' of interventions. There is no power calculation, and CIs are not reported (although there is a mention in Discussion). No accurate definitions of a series of important variables (e.g. URTI, runny nose, etc.) are reported, and the Jackson scores are not explained, nor their use in Japanese personnel or language validated. Intervention arm data not extracted due to the uncertainty of its meaning. Funding source not mentioned. Conflicts of interest: none to report

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Open RCT, but sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	"Mask and no mask groups were formed using block randomisation of participants within their respective job categories: nurses, doctors, and co-medical personnel." Concealment of allocation not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study. Blinding not possible, as 1 group wore face masks
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 dropout in each group accounted for.Quote: "Analyses were performed following the principles of intention-to-treat."
Selective reporting (reporting bias)	High risk	NB: influenza vaccine coverage was 100% in mask group and only 81% in the non-mask-wearing group.

Kotch 1994

Study characteristics

Methods	Pair-matched, cluster-RCT conducted from 19 October 1988 to 23 May 1989 in 24 childcare centres in North Carolina, USA The trial tested the effects of a hand-washing and environment sterilising programme on diarrhoea (data not extracted) and ARIs. Child daycare centres had to care for 30 children or less, at least 5 of whom had to be in nappies, and intending to stay open for at least another 2 years. Randomisation is not described, nor are cluster coefficients reported.
Participants	389 children aged 3 years or less in daycare for at least 20 hours a week. There were some withdrawals, but attrition of participants is not stated, only that in the end data for 31 intervention classrooms and 36 control classrooms were available. 291 children aged up to 24 months and 80 over 24 months took part. The text is very confusing, as 371 seems to be the total of the number of families that took part.

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Kotch 1994 *(Continued)*

	No denominator breakdown by arm is reported, and numerators are only reported as new episodes per child-year.
Interventions	Structured hand-washing and environment (including surfaces, sinks, toilets, and toys) disinfecting programme with waterless disinfectant scrub. See Table 1 for details.
Outcomes	Laboratory: N/A Effectiveness: ARI (coughing, runny nose, wheezing, sore throat, or earache) Safety: N/A
Notes	Risk of bias: high (poor reporting of randomisation, outcomes, numerators and denominators) Note: the authors conclude that the fully adjusted RR for prevention of ARIs was 0.94 (−2.43 to 0.66). A poorly reported study. This study was supported in part by grant MCJ-373111 from the Maternal and Child Health Program (Title V. Social Security Act), Health Resources and Services Administration, Department of Health and Human Services. Cal Stat™ was contributed by Cal- gon Vestal Laboratories, a subsidiary of Merck and Co, Inc, St Louis, MO. Conflicts of interest: none to report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Pair-matched cluster-randomised, controlled trial", but sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	Centres were matched in pairs and then randomly allocated to either intervention or control programmes. Allocation concealment was not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible (intervention was training session)
Blinding of outcome assessment (detection bias) All outcomes	High risk	"The same staff who conducted the training unobtrusively recorded observations at 5-week intervals"
Incomplete outcome data (attrition bias) All outcomes	High risk	18 families were dropped, denominator not clear.
Selective reporting (reporting bias)	High risk	Denominators not clearly reported

Ladegaard 1999

Study characteristics

Methods	RCT with cluster-randomisation to intervention or control. Of 10 institutions, 2 were excluded because they wanted institutions to be comparable in uptake area (i.e. housing and income). Interventions were administered to children, parents, and teachers at the institutions.
Participants	Children 0 to 6 years old

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Ladegaard 1999 *(Continued)*

Interventions	Multifaceted: information, t-shirts to the children with: "Clean hands - yes, thank you", performance of a fairytale "The princess who did not want to wash her hands", exercise in hand-washing, importance of clean and fresh air. The aims of the intervention were to: 1. increase the hygiene education of the daycare teachers; 2. motivate the children by practical learning to have better hand hygiene; and 3. inform the parents about better hand hygiene. See Table 1 for details.
Outcomes	34% decrease in "sickness" (probably mostly gastroenteritis)
Notes	Risk of bias: only limited data available Note: the authors conclude that there was a 34% decrease in sickness in the intervention arm; this is probably overall sickness, as gastroenteritis is part of the outcomes (data not extracted). Only limited data available from translation by Jørgen Lous. Funding was received from a local part of the Danish Health Authority (Forebyggelsesrådet för Fyns Amt).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Randomisation by "lottery", the same as "flip the coin". Concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not possible
Incomplete outcome data (attrition bias) All outcomes	High risk	Total numbers of children included in each arm Not reported.
Selective reporting (reporting bias)	High risk	Limited data reported, in particular denominators missing.

Larson 2010

Study characteristics

Methods	Cluster block-randomised, controlled trial carried out between 20 November 2006 and 20 June 2008 in an upper Manhattan immigrant Latino neighbourhood (“19 month data collection period”). The study aimed at assessing the effects of education versus education and hand sanitiser use versus education and hand sanitiser use and common mask use against upper respiratory infections over a period of under 2 years. Follow-up was through an automated telephone system with a small financial incentive (USD 20) for those with 75% or more compliance. Those reporting an ILI received a visit within 48 hours for swabbing.

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Larson 2010 *(Continued)*

	An index case was someone who at the "onset day of illness nobody else in the household had been symptomatic within the previous five days". A secondary case for each episode quote: "was any member of the household who developed symptoms within five days following the index case"; "The secondary attack rate was defined as the number of secondary cases recorded within 5 days of the onset of symptoms in the index case divided by the number of household members minus one". The text implies that the unit of observation was the episode ("study subjects contributed more than one episode in which they were considered to be the index case").
Participants	617 households were randomised to the education group (n = 211), the hand-sanitiser group (n = 205), and the hand-sanitiser and mask group (n = 201). There were 2708 participants, mostly adult Latino immigrants to the USA. Recruitment and allocation were carried out by household. There had to be at least 3 people living in the household, with at least 1 being a preschool or elementary school child, speaking English or Spanish, having a telephone, willingness to complete symptom assessments and have bimonthly home visits, and not using alcohol-based hand sanitiser routinely. Intracluster correlation coefficients are reported on page 179 of the manuscript.
Interventions	Written Spanish or English language educational materials regarding the prevention and treatment of URTIs and influenza or the same educational materials and hand sanitiser (Purell, J&J), in large (8- and 4-ounce) and small (1-ounce) containers to be carried by individual household members to work or school, or the same interventions as well as regular surgical face masks (Procedure Face Masks for adults and children, Kimberly-Clark) with instructions for both the caretaker and the ill person to wear them when an ILI occurred in any household member. Replenishment of intervention stocks was done at the bimonthly home visit. Caretakers had to wear a mask for 7 days when within 3 feet of a symptomatic case. They were also encouraged to wear masks within 3 feet of any household member. Reinforcing phone calls were made 3 times in 6 days. The text clearly reports active influenza vaccine promotion during the bimonthly visits. ("The home visit to each household was made every 2 months to minimise study dropout, reinforce adherence to the assigned intervention, replenish product supplies and record use of supplies, answer questions, and correct ongoing misconceptions. At each visit, new educational materials regarding URTI prevention and treatment and influenza vaccination were distributed." (PDF page 3). Also just before the Discussion as follows: "Influenza vaccination rates: There was an increase between the baseline and exit interview in all three groups that reported 50% of more of members receiving influenza vaccine (pre- versus post-intervention for each group: 21.1% and 40.8% in the Education group, 19.0% and 57.1% in the hand sanitiser group, and 22.4% and 43.5% in the hand sanitiser and face mask group (P = 0.001). Additionally, those in the hand sanitiser group reported a significantly greater increase than the other 2 groups, controlling for baseline rates (P = 0.002)") Coverage was unequal across groups, no information on the progressive impact of the vaccine, or indeed the nature of the vaccine(s) is reported. Apparently the first season was mild and the vaccine mismatched, compliance with the trial interventions was low in Arm 3, and a local epidemic of *Staphylococcus aureus* meant that the control group started washing hands. The trial authors report no effect on reporting rates of vaccine coverage by arms, but with so many confounders who knows? See Table 1 for details.
Outcomes	Laboratory: PCR carried out on samples from deep nasal swabs for influenza and the most common other pathogens (RSV, rhinovirus, enterovirus, parainfluenza viruses, etc.). The text describing the results of the swabbing is confusing, but in general appears to be non-random "Households reported 669 episodes of ILI (0 to 5 per individual)". Of the 234 deep nasal swabs obtained, 33.3% (n = 78) tested positive for influenza: 43.6% (n = 34) were influenza A and 56.4% (n = 44) were influenza B. Amongst the 66.7% who tested negative for influenza, 30.8% (48/156) tested positive for other viruses: 7 for respiratory syncytial virus, 9 for parainfluenza, 11 for enterovirus, 10 for rhinovirus, 6 for adenovirus, and 5 for metapneumovirus. Swabs were not obtained from the remaining 435 reported ILI episodes for the fol-

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Larson 2010 *(Continued)*

	lowing reasons: 72.0% (n = 313) did not meet the CDC definition of an ILI and were therefore included in the URTI symptom count; 21.4% of episodes (n = 93) were reported after 48 hours of ILI onset or the participant refused to be swabbed; and the research staff were unable to reach the participant in 6.7% of episodes (n = 29). As no definition of URTI is given, it is unclear what kind of biases were introduced by the non-swabbing of the 313/435 "not meeting CDC definition". Effectiveness: ILI (CDC definition): "temperature of 37.8°C or more and cough and/or sore throat in the absence of a known cause other than influenza" URTI only referred to as "Viral upper respiratory infections (URTIs)". Safety: N/A
Notes	The authors conclude that quote: "the Hand Sanitizer group was significantly more likely to report that no household member had symptoms (P,0.01), but there were no significant differences in rates of infection by intervention group in multivariate analyses. Knowledge improved significantly more in the Hand Sanitizer group (P,0.0001). The proportion of households that reported >50% of members receiving influenza vaccine increased during the study (P.0.001). Despite the fact that compliance with mask wearing was poor, mask wearing as well as increased crowding, lower education levels of caretakers, and index cases 0–5 years of age (compared with adults) were associated with significantly lower secondary transmission rates (all P,0.02). In this population, there was no detectable additional benefit of hand sanitiser or face masks over targeted education on overall rates of URTIs, but mask wearing was associated with reduced secondary transmission and should be encouraged during outbreak situations. During the study period, community concern about methicillin-resistant *Staphylococcus aureus* was occurring, perhaps contributing to the use of hand sanitiser in the Education control group, and diluting the intervention's measurable impact". The study is at high risk of bias. Randomisation and reasons for dropout are not described. Differentials in cluster characteristics across arms point to randomisation not having worked, and the confounding effects of a post randomisation staphylococcal scare are difficult to judge. Symptom-driven follow-up gives no idea of the effects on asymptomatic ILI/influenza. Poor definitions (URTI?). There are unexplained dropouts, and the analysis plan is unclear. Finally, the very small number of cases of influenza and an unclear swabbing attrition may introduce further elements of confounding. Funding: this study was funded by grant #1 U01 CI000442-01, "Stopping URIs and Flu in the Family: The Stuffy Trial." Conflicts of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Cluster block randomised, controlled trial", but sequence generation not reported
Allocation concealment (selection bias)	Unclear risk	Quote:"Households were block randomised into one of three groups" Allocation concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of participants and personnel was not possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Blinding of outcome assessment is not stated.

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Larson 2010 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	In control group households (n = 211), 26 dropped out and 37 did not consent. In hand-sanitiser group households (n = 205), 21 dropped out and 36 did not consent. In hand-sanitiser and face mask group households (n = 201), 19 dropped out and 35 did not consent. Reasons for dropout were not described.
Selective reporting (reporting bias)	Unclear risk	617 of 772 eligible households were randomised.

Little 2015

Study characteristics	
Methods	Individuals sharing a household by mailed invitation through general practices in England were recruited. After consent, participants were randomised online by an automated computer-generated random-number program to receive either no access or access to a bespoke automated web-based intervention that maximised hand-washing intention, monitored hand-washing behaviour, provided tailored feedback, reinforced helpful attitudes and norms, and addressed negative beliefs. Participants were enrolled into an additional cohort (randomised to receive intervention or no intervention) to assess whether the baseline questionnaire on hand-washing would affect hand-washing behaviour. Participants were not masked to intervention allocation, but statistical analysis commands were constructed masked to group. The primary outcome was number of episodes of RTIs in index participants in a modified intention-to-treat population of randomly assigned participants who completed follow-up at 16 weeks.
Participants	344 physician offices were recruited over a wide area of England, and 20,066 participants were enrolled and randomised to intervention (N = 16,086) and control (N = 10,026). Modified ITT was performed on 16,908 participants who completed the follow-up questionnaire at 16 weeks (intervention = 8241 and control = 8667). Inclusion criteria: adult patients (aged 18 years or older) identified from computerised lists in general practitioner (GP) practices in England, for whom there was at least 1 other individual living in the household who was willing to report illness to the index person Exclusion criteria: patients with severe mental problems (e.g. major uncontrolled depression or schizophrenia, dementia, or severe mental impairment) or who were terminally ill, and those reporting a skin complaint that would restrict hand-washing
Interventions	Automated web-based intervention that maximised hand-washing intention, monitored hand-washing behaviour, provided tailored feedback, reinforced helpful attitudes and norms, and addressed negative beliefs. Control no access to intervention web pages. See Table 1 for details.
Outcomes	The primary outcome was the number of index individuals that reported 1 or more RTIs (including ILI) at 16 weeks. Secondary: duration of symptoms, transmission of respiratory infections, gastrointestinal infections, attendance at the practice, and use of health service resources Infections self-reported by participants. RTI defined as 2 symptoms of an RTI for at least 1 day or 1 symptom for 2 consecutive days. Definition of ILI was a high temperature (feeling very hot or very cold; or measured temperature > 37.5 °C), a respiratory symptom (sore throat, cough, or runny nose), and a systemic symptom (headache, severe fatigue, severe muscle aches, or severe malaise).

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Little 2015 *(Continued)*

	No safety outcomes reported.
Notes	Government funded. The study was funded by the Medical Research Council (study number 09/800/22). Declaration of interests: the authors declare no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were automatically randomly assigned by the intervention software, but sequence generation not described.
Allocation concealment (selection bias)	Low risk	Participants were automatically randomly assigned by the intervention software.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	High risk	High attrition that was different in the 2 groups
Selective reporting (reporting bias)	Low risk	Specified outcomes reported.

Loeb 2009

Study characteristics

Methods	Open non-inferiority RCT carried out to compare the surgical mask with the N95 respirator in protecting healthcare workers against influenza. The trial was carried out between 2008 (enrolment started in September and follow-up on 12 January 2009) and 23 April 2009 (when all HCWs caring for febrile patients were told to wear an N95 respirator) because of the appearance of novel A/H1N1). The trial trigger was the beginning of the influenza season, defined as isolation of 2 or more viruses in a district in the same week. Following the 2003 SARS outbreak, all Ontario nurses caring for febrile patients (38 °C or more and new onset cough or SOB) had to wear surgical masks. The randomisation (carried out in blocks of 4 by centre) then consisted of either confirmation to same-maker surgical mask wear or N95 respirator wear. Investigators and laboratory staff were blind to allocation status, but for obvious reasons (the visible difference in interventions), participants were unblinded. “The criterion for non-inferiority was met if the lower limit of the 95% confidence interval (CI) for the reduction in incidence (N95 respirator minus surgical group) was greater than -9%”. So this is the non-inferiority margin. It is assumed that the “minus surgical group” means minus surgical mask group.
Participants	Consenting nurses (n = 446 randomised) aged a mean of 36.2 years working full time (≥ 37 hours/week) in 23 acute units (a mix of paediatric, A&E, and acute medical units) in 8 hospitals in Ontario, Canada. 225 were randomised to the surgical mask and 221 to the N95 respirator. There were 13 and 11 dropouts, respectively from each arm (all accounted for), plus 21 and 19 lost to follow-up; 11 in each arm gave no reason, the others are accounted for. There were no deaths. The final total of 212 and 210 was included in the analysis. Table 1 reports the demographic data of participants by arm, which appear comparable.

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Loeb 2009 *(Continued)*

Interventions	Surgical masks (as standard wear by the standard distributor) or fit–tested N95 respirator. All nurses wore gloves or gowns in the presence of a febrile patient. See Table 1 for details.
Outcomes	Laboratory RT-PCR paired sera with 4-fold antibody rise from baseline (only for unvaccinated) nurses Effectiveness: follow-up (lasting a mean of around 97 days for both arms) was carried out twice-weekly on a web-based instrument. Nurses with new symptoms were asked to swab a nostril if any of the following signs or symptoms had developed: fever (temperature ≥ 38 °C), cough, nasal congestion, sore throat, headache, sinus problems, muscle aches, fatigue, earache, ear infection, or chills. The text defines influenza with laboratory confirmation, and separately reports criteria for swab triggering and a definition of ILI ("Influenza-like illness was defined as the presence of cough and fever: a temperature ≥ 38°C"). But this is not formally linked to influenza in the text, as it appears that primary focus was the detection of laboratory-confirmed influenza (either by RT-PCR or serology). Additional outcome data sought were work-related absenteeism and physician visits for respiratory illness. Secondary outcomes included detection of the following non-influenza viruses by PCR: parainfluenza virus types 1, 2, 3, and 4; respiratory syncytial virus types A and B; adenovirus; metapneumovirus; rhinovirus-enterovirus; and coronaviruses OC43, 229E, SARS, NL63, and HKU1. Audits to assess nurse compliance with the interventions were carried out in the room of each patient cared for. The text reports that 50 and 48 nurses in the surgical mask and N95 groups, respectively, had laboratory confirmation of influenza infection, indicating non-inferiority. Interestingly, non-inferiority seemed to be applicable both to seasonal viruses and nH1N1 viruses (as 8% and 11.9% were serologically positive to nH1N1). This finding is explained either by seeding or cross reaction with seasonal H1N1. Equivalent conclusions could be drawn for nurses with complete follow-up. Non-inferiority was applicable also to other ILI agents identified. None of the 52 individuals with positive isolates met the criteria for ILI. All cases of ILI were confirmed as having influenza (9 and 2 respectively). This means that all the 11 cases of ILI had influenza, but that most of those with a laboratory diagnosis of influenza did not have cough and fever. For example, the text reports that "Of the 44 nurses in each group who had influenza diagnosed by serology, 29 (65.9%) in the surgical mask group and 31 (70.5%) in the N95 respirator group had no symptoms". By implication, of the 88 nurses with antibody rises, 28 had symptoms of some kind, i.e. two-thirds were asymptomatic. Absenteeism was 1 versus 39 episodes in the mask versus respirator arms. No episodes of LRTI were recorded. The number of family contacts with ILI were the same for each arm (45 versus 47). Physician visits were similar in both groups. Safety: no AEs are reported
Notes	The authors conclude that "Among nurses in Ontario tertiary care hospitals, use of a surgical mask compared with a N95 respirator resulted in non-inferior rates of laboratory-confirmed influenza". This a well-designed and conducted trial with credible conclusions. The only comment is that the focus in the analysis on influenza (symptomatic and asymptomatic) is not well-described, although the rationale is clear (interruption of transmission). Funding/Support: this study was supported by the Public Health Agency of Canada. Financial disclosures: none reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation was performed centrally ....", but method of sequence generation not described.

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Loeb 2009 *(Continued)*

Allocation concealment (selection bias)	Low risk	"...by an independent clinical trials coordinating group such that investigators were blind to the randomisation procedure and group assignment and was stratified by centre in permuted blocks of 4 participants."
Blinding of participants and personnel (performance bias) All outcomes	High risk	"It was not possible to conceal the identity of the N95 respirator or the surgical mask since manipulating these devices would interfere with their function"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessment blinded: "Laboratory personnel conducting hemagglutinin inhibition assays, polymerase chain reaction (PCR), and viral culture for influenza were blinded to allocation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	21 of 225 randomised to mask group and 19 of 221 randomised to N95 group were lost to follow-up, reasons reported. Study stopped early: Quote: We had planned to stop the study at the end of influenza season. However, because of the 2009 influenza A(H1N1) pandemic, the study was stopped on April 23, 2009, when the Ontario Ministry of Health and Long-Term Care recommended N95 respirators for all healthcare workers taking care of patients with febrile respiratory illness."
Selective reporting (reporting bias)	Low risk	All outcomes reported.

Longini 1988

Study characteristics	
Methods	Cluster-controlled, double-blind, randomised trial to assess the efficacy of virucidal tissues in interrupting family transmission of rhinovirus and influenza virus. The study was carried out in the community of Tecumseh, Michigan, USA during the period of 25 November 1984 to 28 April 1985. However, the authors only report results for the period of 13 January to 23 March 1985, when a high circulation of influenza A H3N2 and rhinovirus was detected.
Participants	296 households were enrolled, but 5 households were eliminated from the analysis for "technical reasons". The analysis was carried out in households with 3 to 5 members. The authors report data on 143 households randomised to virucidal tissues and 148 to placebo tissue. The average age in households was around 22, and the difference between arms was not significant. Randomisation was carried out by the sponsor, and tissues were pre-packed in coded boxes with no other identifying features and delivered to households at the beginning of the study period.
Interventions	Disposable 3-layered virucidal tissues (citric and malic acids with sodium lauryl sulphate in the middle layer) or placebo (succinic acid in the middle layer) tissues. They were used to blow the nose and for coughing or sneezing into. Households were also stratified by level of tissue use. Tissue use was significantly higher in the intervention arm (82% versus 71%). See Table 1 for details.
Outcomes	Laboratory: yes - viral culture from nasal and throat swabs from symptomatic participants Effectiveness: ARI (with a proportion of laboratory-confirmed diagnosis in non-randomly chosen participants with symptoms lasting 2 days or more) Follow-up and surveillance was carried out using a telephone questionnaire. Safety: N/A
Notes	Risk of bias: high (inappropriate choice of placebo) Note: the authors conclude that virucidal tissues were up to 36.9% effective in preventing transmission of ARIs as measured by secondary attack rates (18.7% versus 11.8%). This finding was not statistical-

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Longini 1988 *(Continued)*

ly significant, but may well have been affected by the lack of do-nothing community controls. This a well-designed, well-written study despite the unexplained attrition of 5 families, the lack of reporting of cluster coefficients, and the differential in tissue use between the 2 arms, which raises questions about the robustness of double-blinding. Particularly notable is the discussion on the low generalisability of results from the study from the placebo arm given that even the inert barrier of the tissues is likely to have limited spread. Also, the lengths to which the authors went to obtain allocation concealment and maintenance of double-blind conditions.

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Declaration of interests: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Treated and placebo tissues were randomly assigned ..." Sequence generation not reported
Allocation concealment (selection bias)	Low risk	Quote:"Treated and placebo tissues were randomly assigned by the sponsor to 296 participating households stratified by household size, such that roughly half the households would receive treated tissues. Thus, the investigators were unaware of the assignment of treated tissues."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Treated and placebo tissues were randomly assigned by the sponsor to the randomly assigned 296 households stratified by household size... The type of tissue was identified by code, and the boxes in which tissues were contained were not marked with any specific identifiers. Therefore, the study was double-blinded."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote:"The investigators were unaware of the assignment of the treated tissues"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	296 households eligible. "The final sample used for analysis consisted of 143 households in the treatment group and 148 households in the placebo group."
Selective reporting (reporting bias)	High risk	Quote:"The analysis of secondary spread was restricted to households of three to five members for technical reasons, which eliminated five households." "The two groups were almost identical in composition."

Luby 2005

Study characteristics

Methods	Partly double-blind, cluster-RCT carried out during 15 April 2002 to 5 April 2003 in Karachi, Pakistan. The trial assessed the effects of mother and child hand-washing on the incidence of respiratory infections, impetigo (data not extracted), and diarrhoea (data not extracted). Randomisation took place by computer-generated random numbers in 3 phases. 1. 25 neighbourhoods were assigned to hand-washing and 11 to standard practice. 2. 300 households were assigned to using antiseptic soap. 3. 300 households were assigned to using plain soap.

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Luby 2005 *(Continued)*

4. 306 households were assigned to standard practice.
5. 1523 children younger than 15 years were assigned to using antiseptic soap.
6. 1640 children younger than 15 years were assigned to using plain soap.
7. 1528 children younger than 15 years were assigned to standard practice.

Soaps were of identical weight, colour, and smell and were packed centrally with a coded packing case matched to households containing 96 bars. Neither field workers nor participants were aware of the content. Control arm households were visited with the same frequency as intervention household but were given books and pens. Codes were held centrally by the manufacturer and broken after the end of the trial to allow analysis.

Participants	Householders of slums in Karachi. Of the 1523 children younger then 15 years assigned to using antiseptic soap, 117 dropped out (1 died, 51 were born in, and 65 aged out) = 1406; 504 were aged less than 5. Of 1640 children younger then 15 years assigned to using plain soap, 117 dropped out (3 died, 44 were born in, and 70 aged out) = 1523; 517 were aged less than 5. Of 1528 children younger then 15 years assigned to standard practice, 125 dropped out (3 died, 40 were born in, and 82 aged out) = 1403; 489 were aged less than 5.
Interventions	Instruction programme and antibacterial soap containing 1.2% triclocarban, or ordinary soap to be used throughout the day by householders, or standard procedure. See Table 1 for details.
Outcomes	Laboratory: N/A Effectiveness: 1. Number of new respiratory illness per person per week 2. Pneumonia (cough or difficulty in breathing with a respiratory rate of > 60 min in children less than 60 days old, > 50 min in those less than 1 year old, and > 40 min for those aged 1 to 5 years) Follow-up was weekly with household interview and direct observation. Children aged less than 5 were weighed, and the report presents stratification of results by child weight. Safety: N/A
Notes	Risk of bias: low (cluster coefficients and analysis by unit of randomisation provided) Note: the authors conclude that "handwashing" neighbourhoods has significantly fewer episodes of respiratory disease than controls (e.g. 50% less cough). "Handwashing" children aged less than 5 had 50% fewer episodes of pneumonia than controls (−65% to −35%). However, there was no difference in respiratory illness between types of soap. The report is confusing, with a shifting focus between children age groups. The impression reading is of an often rewritten manuscript. There is some loss of data (e.g. in the results by weight, i.e. risk group) because of lack of clarity on denominators. Despite this, the trial is a landmark. Funding: most of the funding for this study was provided by Procter and Gamble, manufacturer of Safeguard Bar Soap. The balance of the funding was provided by the Centers for Disease Control and Prevention. Conflict of interest statement: S Luby was supported by the grant from the Procter & Gamble company that funded this study. W Billhimer is an employee of the Procter & Gamble company. The other authors declare that they have no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation took place by computer-generated random numbers in 3 phases.
Allocation concealment (selection bias)	Low risk	Quote:"One of the investigators (SL) who did not participate in recruiting neighbourhoods or households programmed a spreadsheet to randomly gen-

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Luby 2005 *(Continued)*

		erate the integers of a 1 or a 2. He applied the random numbers sequentially to the list of neighbourhoods. Neighbourhoods with a 1 were assigned to control, and those with a 2 were assigned to handwashing promotion. Random assignment continued until neighbourhoods consisted of at least 600 handwashing promotion households and 300 control households were assigned."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote:"The antibacterial soap ... contained 1-2% triclocarban as an antibacterial substance. The plain soap was identical to the antibacterial soap except that it did not contain triclocarban... . Neither the fieldworkers nor the families knew whether soaps were antibacterial or plain."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote:"Neither the fieldworkers nor the families knew whether soaps were antibacterial or plain."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	89% of the study population followed up, but no data on the clusters.
Selective reporting (reporting bias)	Low risk	Quote:"At baseline, households in the three intervention groups were similar."

MacIntyre 2009

Study characteristics	
Methods	Prospective cluster-RCT carried out in Sydney, Australia, to assess the use of surgical masks, P2 masks, and no masks in preventing ILI in households. The study was carried out during the 2 winter seasons of 2006 and 2007 (August to the end of October 2006 and June to the end of October 2007). “Gaussian random effects were incorporated in the model to account for the natural clustering of persons in households"
Participants	290 adults from 145 families. 47 households (94 enrolled adults and 180 children) were randomised to the surgical mask group, 46 (92 enrolled adults and 172 children) to the P2 mask group, and 52 (104 enrolled adults and 192 children) to the no-mask (control) group.
Interventions	Use of surgical masks and P2 mask versus no mask. The P2 mask is described as very cumbersome. See Table 1 for details.
Outcomes	Laboratory: serological evidence Effectiveness: ILI (described as fever, history of fever or feeling feverish in the past week, myalgia, arthralgia, sore throat, cough, sneezing, runny nose, nasal congestion, headache) However, a positive laboratory finding for influenza converts the ILI definition into one of influenza. Safety: N/A
Notes	The study authors conclude that adherence to mask use significantly reduced the risk for ILI-associated infection, but < 50% of participants wore masks most of the time. They concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory disease. Compliance was by self-report, therefore likely to be an underestimate. The primary outcome was ILI or lab-positive illness. This showed no effect. Sensitivity analysis by adherence showed that under the assumption that the incubation period is equal to 1 day (the most probable value for the 2 most common viruses isolated, influenza (21) and rhinovirus (26)), adherent use of P2 or surgical masks significantly reduces the risk for ILI infection, with a hazard ratio = 0.26 (95% CI 0.09 to 0.77; P = 0.015). No other covariate was significant. Under the less likely assumption that the incubation period is equal to 2 days, the quantified effect of complying with P2 or surgical mask use remains strong, although borderline significant; hazard ratio was 0.32 (95% CI

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MacIntyre 2009 *(Continued)*

0.11 to 0.98; P = 0.046). The study was underpowered to determine if there was a difference in efficacy between P2 and surgical masks (Table 5). The study conclusion appears to be a post hoc data exploration. Regardless of this, the study message is that respirator use in a family setting is unlikely to be effective as compliance is difficult unless there is a situation of real impending risk.

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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Participating households were randomised to 1 of 3 arms by a secure computerised randomisation process", but sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Study participants and trial staff were not blinded, as it is not technically possible to blind the mask type to which participants were randomised."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"However, laboratory staff were blinded to the arm of randomisation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	143 of 145 randomised families were analysed; 2 families in the control group were lost to follow-up during the study, for which no reasons were given.
Selective reporting (reporting bias)	Low risk	No differences between groups at baseline

MacIntyre 2011

Study characteristics

Methods	A cluster-RCT of 1441 HCWs in 15 Beijing hospitals was performed during the 2008 to 2009 winter. Participants wore masks or respirators during the entire work shift for 4 weeks. Outcomes included CRI, ILI, laboratory-confirmed respiratory virus infection, and influenza. A convenience no-mask/respirator group of 481 health workers from 9 hospitals was compared.
Participants	Participants (N = 1441) were hospital HCWs aged > 18 years from the emergency departments and respiratory wards of 15 hospitals. These wards were selected as high-risk settings in which repeated and multiple exposures to respiratory infections are expected.

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MacIntyre 2011 *(Continued)*

	Participants were randomised to medical mask (N = 492 staff from 5 hospitals), N95 fit-tested masks (N = 461 staff from 5 hospitals), and N95 non-fit-tested mask (N = 488 staff from 5 hospitals).
Interventions	Fit-tested N95 respirators versus non-fit-tested N95 respirators versus medical masks. See Table 1 for details.
Outcomes	Clinical respiratory illness, defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom (i.e. cough, runny nose, etc.) Laboratory-confirmed viral respiratory infection (detection of adenoviruses, human metapneumovirus, coronavirus 229E/NL63, parainfluenza viruses 1, 2, and 3, influenza viruses A and B, respiratory syncytial virus A and B, rhinovirus A or B, and coronavirus OC43/HKU1 by multiplex PCR) Laboratory-confirmed influenza A or B Adherence with mask or respirator use. Reported problems associated with using the masks or respirators
Notes	Control arm not randomised so has been ignored. Funding source unknown. Conflict of interests: Raina MacIntyre receives funding from influenza vaccine manufacturers GSK and CSL Biotherapies for investigator-driven research. She has also been on advisory boards for Wyeth, GSK and Merck. Dr Simon Cauchemez received consulting fees from MacIntyre et al. 178 [a] 2011 Blackwell Publishing Ltd, Influenza and Other Respiratory Viruses, 5, 170–179 Sanofi-Pasteur MSD on the modelling of varicella zoster virus. The remaining authors declare that they have no competing interests. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. Prior to the start of this study, NMF acted as a consultant for Roche, Novartis and GSK Biologicals (ceasing in 2007).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation process (using a secure computerised randomisation program), but sequence generation not described
Allocation concealment (selection bias)	Low risk	Hospitals randomised prior to inclusion of participants.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Low risk	Specified outcomes reported.

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MacIntyre 2013

Study characteristics	
Methods	A cluster-RCT
Participants	A total of 1669 nurses and doctors from 68 emergency departments and respiratory wards of 19 Beijing hospitals were included. Inclusion criteria: any nurse or doctor aged 18 years or older who worked full time in the emergency or respiratory wards was eligible. Exclusion: HCWs if they (1) were unable or refused to consent; (2) had beards, long moustaches, or long facial hair stubble; (3) had a current respiratory illness, rhinitis, and/or allergy; or (4) worked part time or did not work in the aforementioned wards or departments Final analysis was performed on 572 staff and 24 wards in medical mask group, 516 staff and 20 wards in the targeted N95 mask group, and 581 staff and 24 wards in the N95 mask group.
Interventions	Quote: "Masks used in the study were the 3M Standard Tie-On Surgical Mask (catalog number mask 1817; 3M, St. Paul, MN) and the 3M Health Care N95 Particulate Respirator (catalog number 1860; 3M)... . Participants wore the mask or respirator on every shift after being shown how to fit and wear it. Participants were supplied daily with either three masks for the medical mask arm or two N95 respirators. Participants using N95 respirators underwent a fit testing procedure using a 3M FT-30 Bitrex Fit Test Kit according to the manufacturer's instructions (3M)." See Table 1 for details.
Outcomes	Laboratory: 1. Laboratory-confirmed viral respiratory infection in symptomatic participants, defined as detection of adenoviruses; human metapneumovirus; coronaviruses 229E/NL63 and OC43/HKU1; parainfluenza viruses 1, 2, and 3; influenza viruses A and B; respiratory syncytial viruses A and B; or rhinoviruses A/B by nucleic acid testing (NAT) using a commercial multiplex polymerase chain reaction (Seegen, Inc., Seoul, Korea). 2. Laboratory-confirmed influenza A or B in symptomatic participants. 3. Laboratory-confirmed bacterial colonisation in symptomatic participants, defined as detection of *Streptococcus pneumoniae*, *Legionella*, *Bordetella pertussis*, chlamydia, *Mycoplasma pneumoniae*, or *Haemophilus influenzae* type B by multiplex polymerase chain reaction (Seegen, Inc.). Effectiveness: CRI, defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom. ILI, defined as fever (38 °C) plus 1 respiratory symptom Safety: adverse effects measured using a semi-structured questionnaire. Investigators stated that there was higher reported adverse effects and discomfort of N95 respirators compared with the other 2 arms. In terms of comfort, 52% (297 of 571) of the medical mask arm reported no problems, compared with 62% (317 of 512) of the targeted arm and 38% (217 of 574) of the N95 arm (P < 0.001).
Notes	Compliance with the product was highest in the targeted N95 arm (82%; 422 of 516), then the medical mask arm (66%; 380 of 572), and the N95 arm (57%; 333 of 581); these differences were statistically significant (P < 0.001). The period study conducted: 28 December 2009 to 7 February 2010 Funding: unclear Declaration of interests: none declared.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"using a secure computerized randomization program", but sequence generation not described

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MacIntyre 2013 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Outcome was objectively assessed with lab confirmation in addition to clinical illness.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Laboratory outcomes are reported for all subjects (with at least one respiratory symptom or fever) tested, and then for the subset meeting the CRI definition"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up. Flow chart and text match, investigators conducted ITT and PP analysis. All the outcomes were accounted for amongst all participants.
Selective reporting (reporting bias)	Low risk	All outcomes were reported as planned.

MacIntyre 2015

Study characteristics	
Methods	A cluster-RCT of cloth masks compared with medical masks in healthcare workers in 14 secondary-/tertiary-level hospitals in Hanoi, Vietnam. Hospital wards were randomised to: medical masks, cloth masks, or a control group (usual practice, which included mask wearing). Participants used the mask on every shift for 4 consecutive weeks.
Participants	1607 hospital HCWs aged ≥ 18 years working full time in selected high-risk wards. Medical mask group (n = 580 HCWs), cloth mask group (n = 569 HCWs), control group (n = 458 HCWs)
Interventions	Medical masks, cloth masks, or a control group. See Table 1 for details.
Outcomes	Clinical respiratory illness, influenza-like illness, and laboratory-confirmed respiratory virus infection 1. Clinical respiratory illness, defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom 2. Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom 3. Laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex reverse transcriptase PCR (RT-PCR) for 17 respiratory viruses. Adverse events associated with mask use
Notes	Government funded. Competing interests: CRM has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator-driven research. 3M has also contributed masks and respirators for investigator-driven clinical trials. CRM has received research grants and laboratory testing as in-kind support from Pfizer, GSK and Bio-CSL for investigator-driven research. HS had a NHMRC Australian-based Public Health Training Fellowship at the time of the study (1012631). She has also received funding from vaccine manufacturers GSK, bio-CSL and Sanofi Pasteur for investigator-driven research and presentations. AAC used filtration testing of masks for his PhD thesis conducted by 3M Australia.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

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MacIntyre 2015 *(Continued)*

Random sequence generation (selection bias)	Low risk	Epi info V.6 was used to generate a randomisation allocation.
Allocation concealment (selection bias)	Low risk	74 wards randomised prior to recruitment of individuals.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Low risk	Specified endpoints reported.

MacIntyre 2016

Study characteristics	
Methods	Cluster-RCT to examine medical mask use as source control for people with respiratory illness in 6 major hospitals in 2 districts of Beijing, China. Index cases with ILI were randomly allocated to medical mask (n = 123) and control arms (n = 122). Since 43 index cases in the control arm also used a mask during the study period, an as-treated post hoc analysis was performed by comparing outcomes amongst household members of index cases who used a mask (mask group) with household members of index cases who did not use a mask (no mask group).
Participants	245 index cases with ILI (medical mask = 123, control group = 122) and 597 household contacts (medical mask = 302, control group = 295)
Interventions	Medical mask versus no mask (control). See Table 1 for details.
Outcomes	Clinical respiratory illness, ILI, and laboratory-confirmed viral respiratory infection 1. Clinical respiratory illness, defined as 2 or more respiratory symptoms (cough, nasal congestion, runny nose, sore throat, or sneezes) or 1 respiratory symptom and a systemic symptom (chill, lethargy, loss of appetite, abdominal pain, muscle or joint aches). 2. ILI, defined as fever ≥ 38 °C plus 1 respiratory symptom. 3. Laboratory-confirmed viral respiratory infection, defined as detection of adenoviruses, human metapneumovirus, coronaviruses 229E/NL63 and OC43/HKU1, parainfluenza viruses 1, 2, and 3, influenza viruses A and B, respiratory syncytial virus A and B, or rhinovirus A/B by nucleic acid testing using a commercial multiplex PCR. No safety outcomes reported.
Notes	Government funded. Competing interests: all authors have completed the Unified Competing Interests form (available on request from the corresponding author) and declare that: CRM has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator driven research. 3M have also contributed supplies of masks and respirators for investigator-driven clinical trials. She has received re-

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MacIntyre 2016 *(Continued)*

search grants and laboratory testing as in-kind support from Pfizer, GSK and Bio-CSL for investigator-driven research. HS had an NHMRC Australian based Public Health Training Fellowship at the time of the study (1012631). She has also received funding from vaccine manufacturers GSK, bio-CSL and Saniofi Pasteur for investigator-driven research and presentations. AAC had testing of filtration of masks by 3M for PhD.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random allocation sequence using Microsoft Excel
Allocation concealment (selection bias)	High risk	Doctors enrolled the participants randomly to intervention and control arms.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Clinical endpoints assessed unblinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Low risk	Specified outcomes reported.

McConeghy 2017

Study characteristics

Methods	Pilot study of comprehensive intervention (education, cleaning of surfaces, audit and feedback) to staff of nursing homes versus usual care. Pair-matched cluster-randomised design with only 5 clusters (nursing homes) in each group
Participants	10 nursing homes in Colorado, USA Intervention group = 481 long-stay residents and control group = 380 'Long-stay' defined as resident at least 90 days prior to baseline, or recently readmitted after previous long stay.
Interventions	A multifaceted hand-washing/surface-cleaning intervention comprised of 1) 1-hour online educational module focused on how to prevent infections; 2) provided with an “essential bundle” of 7 products, ranging from hand sanitiser gel and foam to antiviral facial tissues, disinfecting spray, and hand and face wipe and recommendation to use 4 skin cream and wipe products; 3) audit and feedback system. See Table 1 for details.
Outcomes	Laboratory: surface cultures mentioned in Methods, but no results given Effectiveness: LRTI, all infections, hospitalisation, use of antibiotics (not relevant to this review)

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McConeghy 2017 *(Continued)*

	Safety: none mentioned in Methods and no results given
Notes	The authors conclude that Quote: "This multifaceted hand-washing and surface cleaning intervention was designed to reduce infection rates among nursing homes residents. In our 10-facility randomized, matched pair pilot study, we observed program compliance and satisfaction along with reductions in surface bacterial counts, but did not observe a statistically significant reduction in infection rates, antimicrobial use, or hospitalizations". Very poorly reported study with results not explained, summarised in Table 3 as RDs. Denominators and attrition are unclear. This work was supported by Kimberly-Clark Corporation (Contract # 14792008). Declaration of interests: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method not described
Allocation concealment (selection bias)	Unclear risk	Method not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Illness and absenteeism reported by treating staff.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition given. Data were collected from e-medical record at baseline, but not clear whether illness data during the study were collected by the same method.
Selective reporting (reporting bias)	High risk	Upper respiratory tract infection was mentioned in the Methods (intervention presumably would target these), but only LRTI and overall infection reported.

Millar 2016

Study characteristics

Methods	Cluster-RCT, open-label study, factorial design
Participants	Around 30,000 healthy, male army trainees aged 18 to 42 years at Fort Benning, Georgia were included. Inclusion criteria: trainees assigned to 1 of the 6 selected training battalions, trainees who present with an SSTI at the clinic or the hospital, provide informed consent. Exclusion criteria: fails to meet inclusion criteria. No denominator breakdown by arm is reported.
Interventions	Promotion of hand-washing in addition to a once-weekly application of chlorhexidine-based body wash. See Table 1 for details.
Outcomes	This study was nested in a large field-based RCT and utilised clinic-based medical records. Laboratory: none

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Millar 2016 *(Continued)*

	Effectiveness: incidence of ARI at 20 months. The case definition was any occurrence of the following ICD-9 symptom or disease-specific codes: 460 to 466, 480 to 488, and specifically 465.9, 482.9, 486, and 487.1. Safety: adverse effects neither planned nor reported by the investigators
Notes	The period study conducted: May 2010 to January 2012 Government funded. Declaration of interests: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	quote: "computer-generated random numbers to 1 of the 3 study groups"
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	The study was open-label and self-reporting of ARI. It is planned as secondary objective of an original trial. Data abstractors were blinded to group assignment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data abstractors were blinded to group assignment.
Incomplete outcome data (attrition bias) All outcomes	High risk	There is a statistically significant difference between attrition rates in the 3 groups. The reasons for attrition are briefly reported in Table 1 of the original study (Ellis and colleagues 2014), but are unlikely to be related to the outcomes of this study. ARI cases were captured utilising clinic-based medical records, but this outcome is not prespecified in the protocol.
Selective reporting (reporting bias)	High risk	The study was conducted for another purpose. According to the study protocol, the outcomes of interest in the current report were not mentioned as outcomes when the study was planned. ARI is not prespecified as an outcome in the protocol published on ClinicalTrials.gov.

Miyaki 2011

Study characteristics

Methods	A quasi-cluster-RCT
Participants	A total of 15,134 assigned to intervention (N = 6634 workers) and control (N = 8500 workers) Inclusion criteria: all general employees (aged 19 to 72 years in 2009) of 2 sibling companies of a major car industry in Kanagawa Prefecture, Japan. All workers who regularly reported to the workplace were included, regardless of treatment for chronic diseases. All employees have the same health insurance plan and were followed up in the same way.
Interventions	Quote: "The intervention involved asking workers whose family members developed an influenza-like illness (ILI) to stay at home. If any co-habiting family members showed signs of influenza-like illness

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Miyaki 2011 *(Continued)*

	(ILI), employees ... were asked to stay at home voluntarily until 5 days has passed since the resolution of the ILS symptoms or 2 days after alleviation of fever." See Table 1 for details.
Outcomes	Workroom: influenza A test kit (rapid test) Effectiveness: assess the effectiveness of household quarantine in reducing the incidence of influenza A H1N1. ILI was defined as a body temperature greater than 38 °C or more than 1 °C above the normal temperature accompanied with more than 2 of these symptoms: nasal mucus, pharyngeal pain, cough, chills or heat sensation Safety: the incidence of influenza A H1N1 amongst workers who were told to stay home if a family member developed ILI was higher (relative risk of 2.17; P < 0.001) compared to control group. No other safety measures/harms reported. Compliance: quote: "our intervention was not compulsory; we only asked the employees to leave the workplace for a while on full pay, and we succeeded in getting all workers' agreement. In our case, explaining that the home waiting policy might be beneficial to the whole workers and help to avoid stopping the manufacturing lines (explaining it is for the benefit of the public) and guaranteeing payment during the leave (financial support) helped them to obey our request."
Notes	Period study conducted: 1 July 2009 to 19 February 2010 Unfunded There are no conflicts of interest to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information given.
Allocation concealment (selection bias)	Unclear risk	No information given.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of the intervention (stay at home) was confirmed in the intervention group, where all workers agree as they were financially supported during absences due to ILI.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Company doctors diagnosed the disease through a positive result of an influenza A test or clinical symptoms", but not clear if they were blinded to assignment; however, the diagnostic process is meticulous and objectively confirmed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All cases are included in the analysis, and none were lost to follow-up.
Selective reporting (reporting bias)	Unclear risk	Although all outcomes of interest are clearly specified, described, and followed up, and text and numbers checked out well and based on the outcome stated for the study, there is no published protocol to match the planned vs the reported outcomes.

Morton 2004

Study characteristics

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Morton 2004 *(Continued)*

Methods	Cross-over study to evaluate the effectiveness of an alcohol gel as an adjunct to regular hand-washing for decreasing absenteeism amongst elementary children by reducing specific communicable diseases such cold, flu, and conjunctivitis. The study was conducted in an elementary school in New England, USA. In the cross-over design, classrooms in each grade level were randomised to begin as the experimental group (alcohol gel) or the control group (regular hand-washing). A study protocol for hand hygiene was introduced following the germ unit education. The hand-washing product was a soap-and-water alternative that is approximately 60% ethyl alcohol. In phase 1 (46 days) children in 9 classrooms were in the experimental group, and children in 8 classrooms were in the control group. After a 1-week washout period when no children had access to the alcohol gel, phase 2 (47 days) started, and the classroom that had participated before as experimental group passed into the control group and vice versa. Data were collected by the parents, who informed the secretary or the school nurse of the reasons for a child's absence, including symptoms of any illness. Respiratory illnesses were defined by symptoms of URTI.
Participants	253 children, 120 girls and 133 boys, from kindergarten to 3rd grade. Of the eligible 285 students, 32 children dropped out (10 due to skin irritation and 22 because of lack of parental consent). No denominator breakdown by arm is reported because the study used a cross-over design.
Interventions	Use of an alcohol gel as an adjunct to regular hand-washing and educational programme versus regular hand-washing and educational programme. See Table 1 for details.
Outcomes	Laboratory: no Effectiveness: days of absences from school for respiratory illness Safety: N/A
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators and denominators) Note: the authors conclude that significantly fewer children became ill whilst using the alcohol gel as an adjunct to regular hand-washing than when using regular hand-washing only (decreased school absenteeism of 43% with the use of alcohol gel on top of hand-washing). The authors also described, as a limitation of the study, the fact that the school nurse served as the data collector, which could be perceived as bias in measurement of the outcome variable. Randomisation and allocation are not described; no cluster coefficients were reported; and attrition was not taken into consideration during the analysis. Unit of randomisation and analysis are different. No reporting by arm. No ORs, no CIs reported. Funding: Maine Administrative School District #35 in Eliot, Maine, and South Berwick, Maine. Conlicts of interest: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "A cross-over design was used. In the crossover design, classrooms in each grade level were randomized to begin as the experimental group (regular hand washing)."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote:"The school nurse served as the data collector for the duration of the study. This could be perceived as bias in the measurement of the outcome variable, absenteeism related to infectious illness."

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Morton 2004 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information
Selective reporting (reporting bias)	Unclear risk	Insufficient information

Najnin 2019

Study characteristics	
Methods	Cluster-RCT, parallel assignment
Participants	Residents of the high-risk, cholera-prone study areas. Low-income communities in Mirpur area of urban Dhaka defined by low per capita income, poor sanitation, unsafe water use, sharing of water source, and poor living conditions. 90 geographic clusters were included, with 30-metre buffer zones. A total of 7842 households, with 52,237 individuals analysed Vaccine-only area: data were analysed for 1965 households consisting of 13,148 individuals Vaccine-plus-behaviour-change area: data were analysed for 3886 households consisting of 25,566 individuals Control area: data were analysed for 1991 households consisting of 13,523 individuals Study criteria from published protocol: Inclusion criteria: apparently healthy residents of selected vaccination sites, aged 1 year and above, non-pregnant women, written informed consent Exclusion criteria: age less than 1 year and pregnant women
Interventions	Hand-washing and water treatment promotion. See Table 1 for details.
Outcomes	Laboratory: none used Effectiveness: prevalence of respiratory illness. People were classified as having respiratory illness if they reported having fever plus either cough or nasal congestion or fever plus breathing difficulty in the past 2 days of unannounced home visits: in each intervention group and amongst those who had soap/soapy water with water present in the hand-washing station (35% of all groups combined) versus those without this (regardless of the intervention group). Planned secondary outcome: prevalence of reported respiratory illness during 2-year intervention period Safety: no adverse effects planned or reported
Notes	The period study conducted: 2011 to 2013 Funding: government and private Bill & Melinda Gates Foundation Conlicts of interest: none declared.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation sequence was used to allocate 90 geographical clusters to 1 of 3 groups. Before randomisation, clusters were strat-

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Najnin 2019 *(Continued)*

		ified blocked into 2 categories according to the distance to the hospital. (parent article: Lancet. 2015 Oct 3;386(10001):1362-1371)
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	All trial participants and investigators were aware of group assignment. Several in and out migrations across all groups before, after, and during outcome monitoring, and large number of changes in intervention areas
Blinding of outcome assessment (detection bias) All outcomes	High risk	Several in and out migrations across all groups before, after, and during outcome monitoring, and large number of changes in intervention areas
Incomplete outcome data (attrition bias) All outcomes	High risk	High migration movement. This could have distorted the baseline characteristics even more. Very hard to assess because the numbers in the index paper are different from the parent paper (Qadri 2015). In addition to that, for each intervention, data were analysed for 15% to 30% of those allocated on start date. Each group started with approximately 80,000 people; the number analysed is much lower (237,216 people were in the study area on start date of outcome monitoring, the total number analysed across all groups was 52,237). No info about data on migrated individuals or on those who changed intervention areas was dealt with? Also data for prevalence of ARI adjusted for age and wealth were not shown. The outcome is addressed in the 2 days preceding an unannounced visit. This means that if there was a respiratory illness in the past week it would not have been reported. Moreover, these monthly unannounced visits were done to a different set of participants in each group!
Selective reporting (reporting bias)	High risk	Published protocol does not include respiratory illness as an outcome.

Nicholson 2014

Study characteristics	
Methods	Cluster-RCT
Participants	70 low-income communities in Mumbai, India (35 communities per arm) were randomised to intervention arm (N = 1025) and control arm (N = 1026). Households located in low-income urban communities in west and south Mumbai, India. Each household contains 1 target child in the first year of a municipal school (typically aged 5 years).
Interventions	Combination of hand-washing promotion with provision of free soap aimed at 5-year-olds with provision of free soap. See Table 1 for details.
Outcomes	Laboratory: none reported Effectiveness: Primary outcomes: episodes of diarrhoea, ARIs, and school absences amongst target children, and episodes of diarrhoea and ARIs among their families Secondary outcomes: episodes of eye infections, vomiting, abscesses or boils, headaches, and earache

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Nicholson 2014 *(Continued)*

	Operational defiinitions for all the illnesses were taken from *Black's Medical Dictionary* (MacPherson 1999). ARIs as "pneumonia, cough, fever, chest pain and shortness of breath, cold, inflammation of any or all of the airways, that is, nose, sinuses, throat, larynx, trachea and bronchi" Safety: no safety measures planned or reported by the investigators
Notes	The period study conducted: 22 October 2007 to 2 August 2008 Funding: multinational corporate company (Unilever plc.) Conlicts of interest: none declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Coin tossing used, which could have led to a large imbalance.
Allocation concealment (selection bias)	Low risk	"a coin toss was used to assign one community in each pair to intervention and one to control"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants knew to which arm they had been recruited. Households were removed from the study if they provided no data for 5 consecutive weeks.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data collectors were independent of the behaviour change intervention. Each was assigned exclusively to either households in the intervention group or to control households. However, communities, where very low literacy levels exist, were replaced after randomisation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Data for non-completers were available and similar across groups. ITT and PP were performed. However, households were removed from the study if they provided no data for 5 consecutive weeks.
Selective reporting (reporting bias)	Unclear risk	No information to judge

Pandejpong 2012

Study characteristics

Methods	Cluster-RCT, single study centre
Participants	Children (total number = 1437) were randomised to alcohol hand gel every 60 minutes (N = 452 children), every 120 minutes (N = 447 children), and once before lunch (N = 540 children). Inclusion criteria: all children in a large private school in suburban Bangkok, Thailand, all ages, both genders with parental consent to participate. Exclusion criteria: an allergy to alcohol hand gel
Interventions	3 disinfection interventions: Alcohol hand gel applied every 60 minutes vs every 120 minutes vs once before lunch (3 groups). The current school standard for hand hygiene (q lunch group). See Table 1 for details.
Outcomes	Laboratory: none

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Pandejpong 2012 *(Continued)*

	Effectiveness: Primary: rates of absenteeism from physician-confirmed ILI Secondary: rate of absenteeism caused by total reported ILI (with and without a doctor's confirmation) In case the child was sick but did not see a doctor, the parents were asked to report any of the following symptoms: runny nose or cough, fever or chills, sore throat, headache, diarrhoea, and presence of hand, foot, or mouth ulcers. If 2 or more of these symptoms were reported, then the child's illness was documented as an ILI. Safety: investigators reported that no adverse reaction to the alcohol hand gel was reported in any participants
Notes	The period study conducted: December 2009 to February 2010 Funding: Royal College of Physicians of Thailand Conflict of interest: none to report

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Parents and teachers are aware of the assignment. Teachers were responsible for recording the absenteeism case record forms. Parents would report child sickness. No diagnostic tests, even in the case of physician-confirmed ILI
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome is physician-confirmed ILI.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "No students were lost to follow-up or discontinued the intervention during the study period."
Selective reporting (reporting bias)	Low risk	All outcomes were reported.

Priest 2014

Study characteristics

Methods	A cluster-RCT
Participants	Study included children aged 5 to 11 years at 68 primary schools in New Zealand. Schools were randomised to hand sanitiser + education session arm (34 schools and 8859 children) and education session arm (34 schools and 7386 children). Inclusion criteria:

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Priest 2014 *(Continued)*

	School-level inclusion: at least 100 children of primary school age (school years 1 to 6; children will generally range in age from 5 years to 11 years) at November 2008. Schools that are not currently using hand-sanitiser products or are willing to not use them for the period of the trial. Schools are within the City boundaries of Christchurch, Dunedin, or Invercargill in New Zealand. The principal of the school consents to the school being included in the trial. Not ''special schools'' (e.g. schools for children with deafness or disability) and either not currently using hand-sanitiser products or willing to not use them for the period of the trial if they were randomised to the control group were eligible to participate in the trial. Student-level inclusion (follow-up children): children were eligible to participate in the follow-up group, for whom more detailed information on absences was collected, if they attended a school year 1 to 6 class in 1 of the included schools at the beginning of the second school term in 2009 (the end of April), and their caregivers completed the consent form indicating that they were willing to be telephoned following their child's absences and that they were able to take part in telephone interviews in English Exclusion criteria: School-level exclusion: special needs schools Student-level exclusion (follow-up children): children of the principal investigators and study personnel of the trial. Or, children of families that the principal of the primary school directs us not to approach
Interventions	Hand sanitiser provision (in addition to hand hygiene education session also provided to control group) in schoolchildren. See Table 1 for details.
Outcomes	Laboratory: none Effectiveness: Primary outcome: the incidence rate of absence episodes from school (reported by the parents during telephone calls) due to any illness during the study period (winter term) Secondary outcomes: assessing whether hand sanitiser was effective in reducing the: 1. incidence rate of respiratory illness absence episodes, 2. incidence rate of gastrointestinal illness absence episodes, 3. incidence rate of absence for any reason, 4. length of illness episode, 5. length of illness absence episode, and 6. incidence rate of subsequent illness amongst other children or adults in the household. Definition of respiratory illness: at least 2 of the following caregiver-reported symptoms for 1 day, or 1 of the following symptoms for 2 days (but not fever alone): runny nose, stuffy or blocked nose or noisy breathing, cough, fever, sore throat, or sneezing Safety: examined whether the use of hand sanitiser was associated with an increased risk of any skin reactions during the intervention period. Skin reactions: dryness, redness, flakiness, itchiness, eczema, and any other skin reactions
Notes	The period study conducted: 27 April to 25 September 2009 Government funded: Health Research Council of New Zealand Competing Interests: the authors have declared that no competing interests exist. All authors affirm that they are not involved in any other trials on the same or a related intervention.

Risk of bias

Bias	Authors' judgement	Support for judgement

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Priest 2014 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "Stata/MP 10.1 for Windows was used to generate the random numbers"
Allocation concealment (selection bias)	Low risk	Done by trial statistician provided with school codes and district and randomised the schools to either "A" or "B"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Outcome assessors were blinded to the group allocation until the analysis was completed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors were blinded to the group allocation until the analysis was completed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study flow diagram gives a clear account on follow-up, with numbers of those lost to follow-up and those who discontinued the intervention along with the reasons for doing so. No child was excluded from the analysis. Only PP analysis was reported.
Selective reporting (reporting bias)	Low risk	All outcomes stated in the published protocol were reported in the study. The exception was quote: "1 planned secondary outcome (that is irrelevant to our study) that was not collected and 2 collected secondary outcomes that were not planned in the original protocol".

Radonovich 2019

Study characteristics	
Methods	Cluster-RCT, multicentre, pragmatic effectiveness trial
Participants	Study included 280 clusters randomly assigned to N95 respirators (189 clusters and 1993 HCPs) and medical masks (191 clusters and 2058 HCPs). All participants in a cluster worked in the same outpatient clinic or outpatient setting. All participants were permitted to participate for 1 or more years and gave written consent for each year of participation. Inclusion criteria: healthcare workers in outpatient settings serving adult and paediatric patients with a high prevalence of acute respiratory illness. Participants were aged at least 18 years and employed at 1 of the 7 participating health systems, and self-identified as routinely positioned within 6 feet (1.83 m) of patients. Participants were full-time employees (defined as direct patient care for approximately ≥ 24 hours weekly) and worked primarily at the study site (defined as ≥ 75% of working hours). Exclusion criteria: medical conditions precluding safe participation or anatomic features that could interfere with respirator fit, such as facial hair or third-trimester pregnancy. Participants self-identified race and sex using fixed categories; these variables were collected because facial anthropometrics related to race and sex may influence N95 respirator fit.
Interventions	Fit-tested N95 respirators versus medical masks when near patients with respiratory illness. See Table 1 for details.
Outcomes	Laboratory. Primary outcome: the incidence of laboratory-confirmed influenza, defined as: 1. detection of influenza A or B virus by RT-PCR in an upper respiratory specimen collected within 7 days of symptom onset; 2. detection of influenza from a randomly obtained swab from an asymptomatic participant; and

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Radonovich 2019 *(Continued)*

3. influenza seroconversion (symptomatic or asymptomatic), defined as at least a 4-fold rise in haemagglutination inhibition antibody titres to influenza A or B virus between pre-season and postseason serological samples deemed not attributable to vaccination.

Effectiveness. Secondary outcomes: the incidence of 4 measures of viral respiratory illness or infection as follows:

1. acute respiratory illness with or without laboratory confirmation;
2. laboratory-detected respiratory infection, defined as detection of a respiratory pathogen by PCR or serological evidence of infection with a respiratory pathogen during the study surveillance period(s), which was added to the protocol prior to data analysis;
3. laboratory-confirmed respiratory illness, identified as previously described (defined as self-reported acute respiratory illness plus the presence of at least PCR–confirmed viral pathogen in a specimen collected from the upper respiratory tract within 7 days of the reported symptoms and/or at least a 4-fold rise from pre-intervention to postintervention serum antibody titres to influenza A or B virus; and
4. influenza-like illness, defined as temperature of at least 100 °F (37.8 °C) plus cough and/or a sore throat, with or without laboratory confirmation.

Safety: no serious study-related adverse events were reported. 19 participants reported skin irritation or worsening acne during years 3 and 4 at 1 site in the N95 respirator group.

Notes

The study was conducted from September 2011 to May 2015, with final follow-up on 28 June 2016.

Compliance: adherence was reported on daily surveys 22,330 times in the N95 respirator group and 23,315 times in the medical mask group. Quote: “Always” was reported 14,566 (65.2%) times in the N95 respirator group and 15,186 (65.1%) times in the medical mask group; “sometimes” 5407 (24.2%) times in the N95 respirator group and 5853 (25.1%) times in the medical mask group; “never” 2272 (10.2%) times in the N95 respirator group and 2207 (9.5%) times in the medical mask group; and “did not recall” 85 (0.4%) times in the N95 respirator group and 69 (0.3%) times in the medical mask group. Participant-reported adherence could not be assessed in 784 participants (31.2%) in the N95 respirator group and 822 (30.8%) in the medical mask group (P = 0.84) because of lack of response to surveys or lack of adherence opportunities (i.e. participants did not encounter an individual with respiratory signs or symptoms). Analysed post hoc, participant adherence was reported as always or sometimes 89.4% of the time in the N95 respirator group and 90.2% of the time in the medical mask group.

Government funded.
Conflict of interest disclosures: Dr Bessesen reported receiving grants from the Department of Veterans Affairs during the conduct of the study. Dr Brown reported receiving grants from the US Department of Veterans Affairs during the conduct of the study. Dr Cummings reported receiving grants from the Centers for Disease Control and Prevention, the National Institutes of Health, and MedImmune outside the submitted work and the Biomedical Advanced Research and Development Authority during the conduct of the study. Ms Los reported receiving grants from Centers for Disease Control and Prevention, the Veterans Health Administration, and the Biodefense Advanced Research and Development Agency during the conduct of the study. Dr Gibert reported receiving financial support for the conduct of the study, including research personnel, from the Veterans Health Administration during the conduct of the study. Dr Gorse reported receiving grants from the US Department of Veterans Affairs during the conduct of the study. Dr Nyquist reported receiving grants from the Centers for Disease Control and Prevention/Division of Healthcare Quality Promotion, the National Institute for Occupational Safety and Health, and the Veterans Health Administration during the conduct of the study; personal fees and nonfinancial support from Sequirus outside the submitted work; and serving on a policy making committee regarding infectious disease for the American Academy of Pediatrics Committee on Infectious Diseases. Dr Reich reported receiving grants from Veterans Health Administration during the conduct of the study. Dr Rodriguez-Barradas reported receiving grants from Veterans Affairs Central Office during the conduct of the study. Dr Perl reported receiving grants from the Centers for Disease Control and Prevention and Biomedical Advanced Research and Development Authority during the conduct of the study and grants from Medimmune outside the submitted work. No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement

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Radonovich 2019 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated random sequences by an individual not involved in the study implementation and data analyses. Used stratified randomisation
Allocation concealment (selection bias)	Low risk	Used constrained randomisation
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The participants cannot be blinded, but it seems that all the measures otherwise were the same with meticulous follow-up. Besides, the primary outcome was lab based (an objective outcome), which is unlikely to be affected by of lack of blinding. Investigators were blinded to the randomisation until completion of the study and analysis.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Primary outcome is laboratory-confirmed diagnosis.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Missing outcomes were imputed using standard multiple imputation techniques, creating multiple imputed data sets with no missing values for each analysis"
Selective reporting (reporting bias)	Low risk	Reported study outcomes matched the published protocol. Every outcome was accounted for.

Ram 2015

Study characteristics	
Methods	RCT
Participants	377 household compounds (index cases) completed the study. Control arm has 184 compounds with 1607 contacts, and intervention group has 193 compounds with 1814 contacts. Final analysis was performed on 193 index cases and 1661 contacts in the intervention group and 184 index cases and 1498 contacts in the control group. In 2009, index case-patients with symptom onset within 7 days preceding enrolment were eligible. Eligibility criteria changed in 2010 to include index case-patient with symptom onset within 48 hours preceding enrolment. Inclusion criteria: 1. Individuals ≥ 5 years old: ILI, defined as history of fever and either cough or sore throat with fever onset within the previous 24 hours. 2. Individuals < 5 years old: any child with acute fever with onset within the previous 24 hours. 3. Return to home within 24 hours of presentation to Upazilla Health Complex, Jahurul Islam Medical College Hospital or the local pharmacies, i.e. the index case cannot be admitted for treatment. If admitted, the patient would not be eligible. 4. No fever in any bari resident during the 7 days preceding the patient's presentation to hospital (see definition below). 5. At least 2 individuals (in addition to the index case-patient) who intend to reside in the bari during the subsequent 20 days. 6. Residence within 30 minutes travel time (1-way) from the Upazilla Health Complex or Jahurul Islam Medical College Hospital or the local pharmacy. Exclusion criteria: compounds were excluded if any compound member(s) was reported to have fever within 3 days before index case-patient enrolment. At another time point, compounds were excluded

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Ram 2015 *(Continued)*

	if any primary household member was reported to have fever (fever occurring within 48 hours prior to enrolment recorded).
Interventions	Promoting intensive hand-washing in households to prevent transmission of ILI. See Table 1 for details.
Outcomes	Laboratory: PCR for influenza A and B, with further subtyping of influenza A isolates for all ILI amongst contacts Effectiveness: incidence of ILI. An age-based definition of ILI was used as follows. 1. For individuals > 5 years old, ILI was defined as history of fever with cough or sore throat. 2. For children < 5 years old, ILI was defined as fever (the authors used this relatively liberal case definition in order to include influenza cases with atypical presentations in children). Safety: no safety data planned or reported by investigators
Notes	Inclusion/exclusion criteria changed 3 times during the study conduct. The period study conducted: June 2009 to December 2010 Government funded Competing interests: the authors have declared that no competing interests exist.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation, with a block size of 4, in order to promote random and even allocation of household compounds to the 2 treatment arms. The list of random assignments was generated by an investigator with no contact with the participants.
Allocation concealment (selection bias)	Low risk	Once baseline data collection was complete, the data collector notified the field research officer, who consulted the block randomisation list to make the assignment of the household compound to intervention or control.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Relied on symptom reporting from the head of family. Inclusion/exclusion criteria changed 3 times during the study conduct. Given the provision of a hand-washing station as part of the intervention, it was not possible to ensure blinding of participants, intervention staff, or data collectors.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Relied on symptom reporting from the head of family. Inclusion/exclusion criteria changed 3 times during the conduct of the study. Given the provision of a hand-washing station as part of the intervention, it was not possible to ensure blinding of participants, intervention staff, or data collectors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow chart followed all households an individuals from recruitment to analysis.
Selective reporting (reporting bias)	Low risk	The specified outcomes are clearly accounted for Investigators report all outcomes for each modified enrolment.

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Roberts 2000

Study characteristics	
Methods	Open cluster-RCT carried out between March and November 1996 (the Southern Hemisphere winter season) in 23 childcare centres caring for a minimum of 50 children 10 hours a day, 5 days a week in Australia. The study assessed the effects of an Australian national hand-washing programme compared to standard procedure. Randomisation was according to a random-number table, and cluster coefficients are reported.
Participants	Children (299 in the intervention arm and 259 in the control arm) aged 3 or younger attending the centres at least 3 days a week. Attrition was 51 children in the intervention arm and 72 children in the control arm due mainly to staff leaving the centres.
Interventions	Hand-washing programme with training for staff and children. It is unclear whether any extra hand-cleansing agents were used, as GloGerm (?) is mentioned when it was used in a preliminary study. See Table 1 for details.
Outcomes	Laboratory: N/A Effectiveness: ARI (runny nose, cough, and blocked nose) Follow-up was via a parental phone interview every 2 weeks. Safety: N/A
Notes	Risk of bias: low (cluster coefficients and analysis by unit of randomisation) Note: the authors conclude that although there was no overall decrease in respiratory illness (RR 0.95, 95% CI 0.89 to 1.01), in children up to 24 months the decrease was statistically significant (RR 0.90, 95% CI 0.83 to 0.97). The authors speculated that this was because maximum benefits are likely from this age group due to their limited ability to wipe their nose and hands without a structured programme. Analyses by 3 compliance levels are also reported. A so-so reported and well-conducted trial. This work was supported by a grant from the Commonwealth Department of Family Services and Health, Research and Development Scheme. Conflict of interest: none to report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was according to a random-number table.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The observer was not informed of the content of the training sessions or the intervention status of the centres."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Recruitment rate 88% (23 of 26 CCCs); loss to follow-up not clear, as no denominator given
Selective reporting (reporting bias)	Low risk	Centres were comparable at baseline.

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Sandora 2005

Study characteristics	
Methods	Single-blind, cluster-RCT carried around the Boston area, USA, in the period of November 2002 to April 2003. The trial tested the effects of using a hand sanitiser and a programme of instruction on the transmissions of GI infections (data not extracted) and ARIs in families. Units of randomisation were child-care centres and were carried out on enrolment by an investigator using random block size generated by computer. Assignment was single-blind (i.e. investigator blinded to the status of the centre). Cluster correlation was 0.01.
Participants	292 families with 1 or more children aged 6 months to 5 years who were in child care for 10 or more hours a week 155 children in 14 centres were allocated to the intervention arm and 137 children in 12 centres to the control arm**.** The mean age was 3 to 2.7 years. Attrition was respectively 15 (3 lost to follow-up and 12 who discontinued the intervention) and 19 (8 lost to follow-up and 11 who discontinued the intervention). ITT analysis was carried out.
Interventions	Alcohol-based hand sanitiser with biweekly hand hygiene educational materials over 5 months versus biweekly educational material on healthy diet. See Table 1 for details.
Outcomes	Effectiveness: ARI (2 of the following symptoms for 1 day or 1 of the following symptoms for 2 days: runny nose, cough, sneezing, stuffy or blocked nose, fever, sore throat). An illness episode had to be separated by 2 symptom-free days from a previous episode. A secondary illness was when it followed a similar illness in another family member by 2 to 7 days. Follow-up was by means of biweekly phone calls to caregivers. Safety: dry skin (71 reports), stinging (11 reports), bad smell (7 reports), dislike (2 reports), allergic reaction (2 reports), slippery feel (1 report), and irritation (20 reports).
Notes	Risk of bias: low Note: the authors conclude that although the rate of GI illnesses was significantly lower in the intervention group, the IRR was not significantly different for ARIs (0.97, 95% CI 0.72 to 1.30). Compliance and droplet route spread may account for this apparent lack of effect. A well-reported trial. Study funds and hand sanitiser were provided by GOJO Industries, Inc (Akron, OH). No conflict of interest declared.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "Random assignments were generated by computer using a permuted-blocks design with random block sizes."
Allocation concealment (selection bias)	Low risk	Low riskUnclear riskHigh risk
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Teachers in the intervention classrooms were responsible for encouraging the use of the disinfecting wipes and hand sanitizer according to the study protocol ... Given that no placebo was provided and sanitizer use was recorded, neither families nor data collectors could be blinded as to the group assignment of the family."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "Given that no placebo was provided and sanitizer use was recorded, neither families nor data collectors could be blinded as to the group assignment of the family."

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Sandora 2005 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was 15 in intervention arm (3 lost to follow-up and 12 who discontinued the intervention) and 19 in the control arm (8 lost to follow-up and 11 who discontinued the intervention). ITT analysis was carried out.
Selective reporting (reporting bias)	Unclear risk	Well-reported

Sandora 2008

Study characteristics	
Methods	Cluster-RCT carried out in a single elementary school system located in Avon, Ohio, USA to assess the effectiveness of a multifactorial infection-control intervention, including alcohol-based hand sanitiser and surface disinfection, in reducing absenteeism caused by gastrointestinal and respiratory illnesses amongst elementary school students. The study also aimed to describe the viral and bacterial contamination of common surfaces in the school classroom and to assess the impact of an environmental disinfectant on the presence of selected viruses and bacteria on these surfaces. Clustering was described as "teams of 3-4 classes depending on the class year".
Participants	A total of 363 students in 15 different classrooms were eligible to participate and received letters about the study. A sample of 285 of these students provided written informed consent and were randomly assigned to the intervention group (146) or to the control group (139) and contributed to final analysis. No students were lost to follow-up or discontinued the intervention during the study period. Baseline demographic characteristics were similar in the intervention and control groups. Most families were white and non-Hispanic and in excellent or very good health at baseline.
Interventions	Alcohol-based hand sanitiser to use at school and quaternary ammonium wipes to disinfect classroom surfaces daily for 8 weeks versus usual hand-washing and cleaning practices. See Table 1 for details.
Outcomes	Laboratory: Serological evidence: no Swabs for bacteria and viruses from 3 types of classroom surfaces were taken. Effectiveness: Respiratory illness defined as days absent as measured by a (blinded) school worker who routinely recorded reason for absenteeism either for gastrointestinal or respiratory causes. Safety: N/A
Notes	The authors conclude that the multifaceted intervention that included alcohol-based hand sanitiser use and disinfection of common classroom surfaces reduced absenteeism from gastrointestinal illness amongst elementary school students. The intervention did not impact on absenteeism from respiratory illness. In addition, norovirus was detected less frequently on classroom surfaces in the group receiving the intervention. The study is of good quality with low risk of bias. The authors checked compliance by counting discarded wipes. Reasons given for the apparent lack of effect against ARIs but good effect on GI illness are that disinfecting the classroom surfaces (daily at lunchtime with alkali) was important, as were the alcohol wipes. The authors measured the norovirus concentration on surfaces and found this to be reduced. Other reasons may be that droplets are not affected by this method, or that contamination of hands by respiratory infections is likely to be continuous (in orofaecal transmission is mostly at the time of defecation). Study funds, hand-sanitiser, and disinfecting wipes were provided by The Clorox Company (Oakland, CA).

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Sandora 2008 *(Continued)*

	Financial disclosures: Drs Sandora and Goldmann received a consulting fee from The Clorox Company for their efforts in designing and conducting this study; Dr Shihh as indicated she has no financial relationships relevant to this article to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The allocation sequence was generated by computer ..."
Allocation concealment (selection bias)	Unclear risk	Quote: "...and teams were assigned to study groups by a study investigator (Dr Shih)." Blinding of allocation cannot be guaranteed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: " All of the students absences were recorded in the usual fashion by the school employee who normally answers this dedicated telephone line. This employee was blinded to the group assignment of the child."
Incomplete outcome data (attrition bias) All outcomes	Low risk	No students were lost to follow-up or discontinued the intervention during the study period.
Selective reporting (reporting bias)	Unclear risk	Well-reported

Satomura 2005

Study characteristics

Methods	RCT. Randomisation was achieved by simple computer-generated random digit. Allocation was concealed using sealed, opaque envelopes. Not clear if there was a central randomisation centre. Post hoc exchange of envelopes was prevented by writing both the name of each participant and the number on the envelope he/she drew before breaking the seal. Participants were not blinded to the intervention; however, disease incidence was determined by 1 study physician who was not informed of the results of assignment. Analysis was done based on the intention-to-treat principle. The study targeted community healthcare all over Japan and was conducted between December 2002 and March 2003 for a follow-up period of 60 days.
Participants	387 participants at 18 sites were recruited, 384 were included in the analysis: water gargling (N = 122), povidone-iodine gargling (N = 132), and control (N = 130). Follow-up was completed on 338 participants. Attrition was fully explained for URTI analysis; however, 2 participants were not accounted for in the ILI analysis. 46 participants did not complete the follow-up due to either discontinuation of diary use (n = 9) or contracting ILI (n = 37). Of the 37 participants with ILI, 11 were in the povidone-iodine group, 12 in the water group, and 14 in the control group. Analysis was performed on 35 participants (Kitamura 2007 [Kitamura 2007]).
Interventions	Participants were randomised to 1 of the following: water gargling, n = 122 (20 mL of water for about 15 seconds 3 times consecutively, at least 3 times a day); povidone-iodine gargling, n = 133 (20 mL of 15 to

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Satomura 2005 *(Continued)*

	30 times diluted 7% povidone-iodine (as indicated by the manufacturer) in the same way as water gargling); and control, n = 132 (retain their previous gargling habits). All groups were asked to fill a daily gargling diary (standardised form to record: gargling habits, hand-washing, and influenza complaints). The frequency of gargling in the water group was higher (3.6); the frequency of hand-washing was similar amongst the 3 groups. URTI symptom was classified according to Jackson methods. Diary recording was continued throughout the follow-up period and for 1 week after the onset of URTI. ILI was reported separately. See Table 1 for details.
Outcomes	Laboratory: none Effectiveness: Primary outcome: incidence of first URTI. Index cases were defined as all of the following conditions: 1. both nasal and pharyngeal symptoms, 2. severity of at least 1 symptom increased by 2 grades or more, and 3. worsening of a symptom of 1 increment or more for > 3 days. Secondary outcome: severity of URTI of the incident cases was assessed by grading each symptom during the initial 7 days after the onset of URTI in numeric scores: none = 0, mild = 1, moderate = 2, and severe = 3 ILI was defined as both developing a fever of 38 °C or higher and worsening arthralgia in addition to some respiratory symptoms (Kitamura 2007). Safety: no harm was reported. However, 2 participants in the povidone-iodine group switched to water gargling (analysed in their assignment group).
Notes	The authors concluded that simple water gargling is effective in preventing URTIs amongst healthy people. However, no statistically significant difference was observed against ILIs. The study was well-conducted; blinding would have added to the validity of the results. In addition, the study was not powered enough to detect a statistically significant preventative effect against ILI. The study demonstrates that in addition to hand-washing, simple gargling even with water can reduce URTI, but not ILI. However, during periods of endemic influenza, multiple inexpensive and simple modalities (hand-washing, masks, gargling) can be utilised together to reduce infection and transmission. Overall, the reporting of the 2 combined studies together is highly confusing. In the first study (Satomura 2005), the main outcome is URTI defined as fever and arthralgia. The second study (which is a presentation of further data from the 2005 publication in the guise of a short report) introduces the outcome ILI with a definition similar to that of URTI in the first study but referring to the earlier outcome as common cold. Also of note is reporting of significance without confidence intervals. Overall, this potentially important study should be repeated with a larger denominator. Unclear risk of bias because of confused reporting and absence of double-blinding. Partial financial support was provided by the Suzuken Memorial Foundation (2002) and Uehara Memorial Foundation (2003) (trial registry, ISRCTN67680497). No financial conflict of interest was reported by the authors of this paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Group assignment was based on simple computer-generated random digits..."
Allocation concealment (selection bias)	Low risk	Quote: "By an individual drawing of sealed opaque envelopes, subjects were randomly assigned to the following three groups" Quote: "allocation was completely concealed from study administrators"

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Satomura 2005 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "To prevent post hoc exchange of the envelopes, local administrators wrote down both the name of each subject and the number on the envelope he/she drew before breaking the seal."
Incomplete outcome data (attrition bias) All outcomes	Low risk	338 of 385 randomised followed up; reasons reported.
Selective reporting (reporting bias)	Unclear risk	Confusing reporting

Savolainen-Kopra 2012

Study characteristics	
Methods	Open cluster-RCT, 3-arm intervention trial
Participants	A total of 21 clusters (683 individuals) were randomised to implement hand hygiene with soap and water (257 individuals), alcohol-based hand rub (202 individuals), or control (224 individuals). The study was conducted in distinct office work units in 6 corporations in the Helsinki Region that together employed some 10,000 staff. All employees (age ≥ 18 years, both genders) were contacted by email survey. Inclusion criteria: quote: "Volunteers working in defined units" Exclusion criteria: quote:"Persons with open wounds or chronic eczema in hands" The designated 21 study clusters were identified as operationally distinct working units, each containing at least 50 people.
Interventions	Hand hygiene with soap and water and standardised instructions on how to limit the transmission of infections. Usual hand hygiene (control). See Table 1 for details.
Outcomes	Laboratory: Quote: "Between November 2008 and May 2010, the seven occupational health clinics serving the six participating corporations were advised to collect, using standard techniques, two to three respiratory samples per week from typical RTI patients and also faecal samples from a few representative patients with gastrointestinal symptoms when a GIT outbreak was suspected. The samples could originate from the study participants and also from work units not included in the study. In the laboratory, viral nucleic acids were extracted with well-characterized commercial kits and tested by validated real-time PCR methods to detect influenza A and B viruses, respiratory syncytial virus, parainfluenza virus types 1, 2, and 3, adenoviruses, human rhinoviruses and human enteroviruses from respiratory specimens, and norovirus from faecal specimens (detailed descriptions of the test procedures are available from the authors)." Effectiveness: Predefined primary endpoints: 1. Number of reported infection episodes in a cluster per total reported weeks. 2. Number of reported sick leave episodes in a cluster per total reported weeks. Secondary endpoints and outcome measures:

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Savolainen-Kopra 2012 *(Continued)*

	1. Number of days with reported symptoms of RTI and/or GTI in a cluster within a time frame of 100 reporting weeks. 2. Number of days-off due to own RTI or GTI in a cluster within a time frame of 100 reporting weeks. Safety: reported 0 adverse events
Notes	The period study conducted: January 2009 to May 2010 Government funded. Competing interests: the authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Low risk	Quote:"clusters were matched and randomized prior to onset of the interventions"
Blinding of participants and personnel (performance bias) All outcomes	High risk	The interventions were not blinded to any party involved (i.e. the study group, participants, or the occupational health services). Subjective reporting of disease episodes
Blinding of outcome assessment (detection bias) All outcomes	High risk	Subjective reporting of disease episodes
Incomplete outcome data (attrition bias) All outcomes	High risk	24% loss to follow-up. However, new recruiting in most clusters; the total number of reporting participants at the end of the trial was 91.7% compared to that at the beginning. Attrition was reported, and 76% of volunteers who started reporting continued to do so until the end of the study. Because of new recruiting in most clusters, the total number of reporting participants at the end of the trial was 626, or 91.7%, compared to that at the beginning. This means that 15.7% of the participants were replaced during the study!!! Raw data on the effects of the interventions on the occurrence of respiratory infections and vomiting/diarrhoea diseases were not reported. Zero adverse effects were reported.
Selective reporting (reporting bias)	Low risk	All planned outcomes were reported.

Simmerman 2011

Study characteristics

Methods	Randomised controlled study
Participants	Study recruited 348 households and 885 members and randomised them as follows: 1. Control (index household = 119, with 302 family members) 2. Hand-washing (index household = 119, with 292 family members) 3. Hand-washing and face mask (index household = 110, with 291 family members)

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Simmerman 2011 *(Continued)*

	The household members of children (index cases) presenting with ILI at the outpatient department of the Queen Sirikit National Institute of Child Health (QSNICH) in Bangkok, the largest public paediatric hospital in Thailand Inclusion criteria: For index cases: children aged 1 month through 15 years, residents of the Bangkok metropolitan area, and had an onset of illness < 48 hours before respiratory specimens tested positive for influenza by an RIDT that was later confirmed by qualitative real-time RT-PCR (rRT-PCR) Eligible index cases' households must have had at least 2 other members aged ≥ 1 month who planned to sleep inside the house for a period of at least 21 days from the time of enrolment. Exclusion criteria: For index cases: children at high risk for severe influenza complications (e.g. chronic lung disease, renal disease, and long-term aspirin therapy) and those treated with influenza antiviral medications Excluded households: those with any member reporting an ILI that preceded the index case by 7 days or less and households where any member had received influenza vaccination during the preceding 12 months
Interventions	Hand-washing, or hand-washing plus paper surgical face mask, or control. See Table 1 for details.
Outcomes	Laboratory: To identify index cases: QuickVue Influenza A+B rapid diagnostic kit (Quidel Co., San Diego, CA, USA), followed by rRT-PCR for influenza viral RNA Index cases and contacts tested with nasal swab and throat swab both processed for rRT-PCR. 2 blood samples for antibody seroconversion collected on Days 1 and 21 (seroconversion defined as a fourfold rise in HI titre between paired sera for any of the antigens assayed). Effectiveness: Laboratory-confirmed secondary influenza virus infections amongst household members described as the secondary attack rate (SAR). A secondary influenza virus infection was defined as a positive rRT-PCR result on Days 3 or 7 or a fourfold rise in influenza HI antibody titres with the virus type and subtype matching the index case. SAR for ILI defined by the WHO as fever plus cough or sore throat, based on self-reported symptoms. Safety: no safety measures planned or reported by the investigators Adherence: participants in the control arm reported an average of 3.9 hand-washing episodes/day (on Day 7), whilst participants in the hand-washing arm reported an average of 4.7 hand-washing episodes/day (95% CI 4.3 to 5.0; P = 0.002 compared to controls), and participants in the hand-washing plus face mask arm reported 4.9 episodes/day (95% CI 4.5 to 5.3; P < 0.001 compared to controls). In the intervention arms, parents had the highest reported daily hand-washing frequency (5.7, 95% CI 5.3 to 6.0) followed by others (4.8, 95% CI 4.3 to 5.3), siblings (4.3, 95% CI 3.7 to 4.8), and the index cases (4.1, 95% CI 3.8 to 4.4). There was no difference in the average amount of soap used in a week in the hand-washing arm (54 mL per person) and the hand-washing plus face mask arm (58.1 mL per person) (P = 0.15). 289 participants in the hand-washing plus face mask arm used an average of 12 masks per person per week (median 11, IQR 7 to 16) and reported wearing a face mask a mean of 211 minutes/day (IQR 17 to 317 minutes/day). Parents wore their masks for a median of 153 (IQR 40 to 411) minutes per day, far more than other relations (median 59; IQR 9 to 266), the index patients themselves (median 35; IQR 4 to 197), or their siblings (median 17; IQR 6 to 107). The study authors note that differences in average usage may be an attenuated measure of appropriate use in relation to the actual unmeasured exposure risk such as proximity to the index case.
Notes	The period study conducted: April 2008 and August 2009

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Simmerman 2011 *(Continued)*

Government funded.

BJC has received research funding from MedImmune Inc. No other declarations are reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was achieved using a block randomization method using a list of blocks each with 12 household IDs, four of which were assigned to each of the three study arms."
Allocation concealment (selection bias)	Unclear risk	Quote: "A study coordinator assigned each household to one study arm after consent was obtained"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Recruiting clinicians were blinded to the allocation of the specific intervention. The participants were not blinded, but it is unlikely that the outcome would have been affected by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The primary outcome is a laboratory-confirmed influenza.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Household flow chart provided with reasons for exclusions, all numbers provided. Analysis was done by ITT and PP.
Selective reporting (reporting bias)	Low risk	All outcomes are accounted for in the ITT analysis of the results.

Stebbins 2011

Study characteristics

Methods	Cluster-RCT, open-label
Participants	Study included 3360 students from 10 Pittsburgh elementary schools. Intervention arm (5 schools, 1695 people) and control arm (5 schools, 1665 people) No inclusion or exclusion criteria were provided.
Interventions	Training in hand and respiratory (cough) hygiene. Hand-sanitiser was provided and encouraged to be used regularly. See Table 1 for details.
Outcomes	Laboratory: Primary outcome: laboratory-confirmed influenza (RT-PCR) amongst children presenting with ILIs leading to their absence from school 2 nasal swabs were obtained using test manufacturer-approved sterile Dacron swabs. 1 swab was employed for influenza testing using the QuickVue Influenza A+B test (Quidel Corp, San Diego, CA). The second nasal swab was delivered on cold pack to the University of Pittsburgh Medical Center Clinical Virology Laboratory, Pittsburgh, PA for RT-PCR testing (performed within 48 hours). The RT-PCR used viral nucleic acid extract (EasyMag; bioMerieux, Durham, NC) and primer/probe sequences for influenza A, influenza B, and influenza A H1 and H3

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Stebbins 2011 *(Continued)*

	subtypes (CDC, Atlanta GA). Effectiveness: Secondary outcome: absence episodes and cumulative days of absence due to ILI, any illness, and all causes Safety: none mentioned
Notes	The period study conducted: 1 November 2007 through 24 April 2008 Funding: this research was supported by Cooperative Agreement number 5UCI000435-02 from the Centers for Disease Control and Prevention (CDC). DC and DB received support from the NIH MIDAS program (1U01-GM070708). DC holds a Career Award at the Scientific Interface from the Burroughs Welcome Fund. No other conflicts declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "constrained randomization algorithm"
Allocation concealment (selection bias)	Low risk	Quote: "Random allocation of schools to two arms was created by Dr. Cummings and concealed until intervention assignment". "At the beginning of the school year parents and guardians were given the opportunity to decline participation"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	In 76% and 78% of illness in intervention and control group were laboratory confirmed. ILI is objectively defined.
Incomplete outcome data (attrition bias) All outcomes	High risk	Only episodes of identified causes were analysed. Causes of absence episodes in 66% of the study participants were not identified (2092 in the intervention group and 2232 in the control group). The parents could be contacted in only 34% cases of absence. About half of them had an illness, and in one-third of these cases the illness met the criteria of ILI (361 cases (33%)). Of these, 279 (77%) were tested for influenza.
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge

Suess 2012

Study characteristics

Methods	Cluster-RCT, open-label, parallel design
Participants	Study sample included 84 households randomised as follows: 1. 30 control (index cases = 30, household contact = 82) 2. 26 mask group (index cases = 26, household contact = 69)

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Suess 2012 *(Continued)*

	3. 28 mask and hand hygiene group (index cases = 28, household contact = 67) Inclusion criteria: patients presenting to general practitioners or family physicians at the study sites within 2 days of symptom onset; had a positive rapid antigen test for influenza (later to be confirmed by quantitative RT-PCR (qRT-PCR); and was at least 2 years old. Index cases also had to be the only household member suffering from respiratory disease within 14 days prior to symptom onset. Exclusion criteria were pregnancy, severely reduced health status, and HIV infection. 1-person households were also not eligible or inclusion.
Interventions	Quote: "facemask and practising intensified hand hygiene (MH group), wearing facemask only (M group) and none of the 2 (control group)". See Table 1 for details.
Outcomes	Primary outcomes: SAR of laboratory-confirmed (qRT-PCR) influenza infection amongst household members (secondary infection cases) presenting with ILI within the observation period (8 days from the date of onset). ILI was defined as fever (> 38.0 °C) + cough or sore throat. Nasal wash specimens (or if these were not possible, nasal swabs) from all participating household members Effectiveness: Secondary outcomes: laboratory-confirmed influenza infection in a household contact (secondary infection cases). The study authors defined a symptomatic secondary influenza virus infection as a laboratory-confirmed influenza infection in a household member who developed fever (> 38.0 °C), cough, or sore throat during the observation period. They termed all other secondary cases as subclinical. A secondary outcome measure was the occurrence of ILI as defined by WHO as fever plus cough or sore throat. Safety: study reported that the majority of participants (107/172, 62%) did not report any problems with mask-wearing. This proportion was significantly higher in the group of adults (71/100, 71%) compared to the group of children (36/72, 50%) (P = 0.005). The main problem reported by participants (adults as well as children) was "heat/humidity" (18/34, 53% of children; 10/29, 35% of adults) (P = 0.1), followed by "pain" and "shortness of breath" when wearing a face mask.
Notes	Period study conducted: November 2009 to April 2011 Adherence: in general, daily adherence was good, reaching a plateau of over 50% in nearly all groups (M and MH groups; 2009/10 and 2010/11) from the third day on (by then the intervention had been implemented in all households). A gradual decline towards lower adherence began around the sixth day of the index patient's illness. Government funded. The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "prepared lists of random numbers with Microsoft Excel 2003 (Mircosoft™ Cooperation, Seattle, USA) which were divided between the three intervention groups. Each participating physician received a list of random numbers with the interventions represented in a 1:1:1 ratio"
Allocation concealment (selection bias)	Low risk	Quote: "the participating physician received a list of random numbers with the interventions represented in a 1:1:1 ratio. Eligible index patients were randomly assigned a number, which was then communicated to the study center. The resulting intervention was only communicated to the households with the physicians. Intervention material was given to the study sites in closed boxes marked only with the randomisation number. Recruiting physicians were not aware of the allocation of the numbers to the interventions and the boxes for the three intervention arms looked identical. After randomisation, participants were given their box by the physician's assistants"

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Suess 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Outcomes are very objective and therefore unlikely to be influenced by lack of blinding. In addition, Quote: "physicians (as well as laboratory personnel) blinded from the randomisation results".
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: physicians (as well as laboratory personnel) blinded from the randomisation results". Outcomes are very objective and therefore unlikely to be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up. Daily follow-up home visits over the short period of data collection (8 days)
Selective reporting (reporting bias)	Low risk	The follow-up period is very short (8 days) with very good coverage, and the criteria for defining the outcome are highly objective. All planned outcomes were reported.

Swarthout 2020

Study characteristics	
Methods	Cluster randomised open-label controlled trial carried out over 18 months in Kenyan geographically near villages to test the effect of a package of measures on pregnant mothers and then on prevalence of ARIs in their young children
Participants	7246 pregnant women in 702 clusters were enrolled, with 6960 children in year 1 and 7088 in year 2 children with available ARI data. The mean ages of index children and siblings younger than 3 years were 14.2 months (SD: 6.77 months) and 22.9 months (SD: 5.70 months) for years 1 and 2, respectively. The cluster-level intra-cluster correlation coefficient for ARIs was 0.026 for both years. There were 2212 households with 2279 children lost to follow-up by year 2 for unspecified reasons
Interventions	There were 6 intervention groups: chlorinated drinking water (W), improved sanitation (S), handwashing with soap (H), combined WSH, improved nutrition (N) through counselling lipid based nutrient supplementation (LNS) combined WSHN There were 2 control groups passive control (no promotional visits), a double-sized active control (monthly visits to measure mid–upper arm circumference) All were done through health promoters with follow up 1 or 2 years after intervention. See Table 1 for details.
Outcomes	Laboratory NR Effectiveness Prevalence of ARIs in children (defined as cough or difficulty breathing, including panting or wheezing, within 7 days before the interview - in children younger than 3 years). Secondary outcomes included difficulty breathing, including panting or wheezing, in the past 7 days (a more specific indicator of respiratory infection than a cough alone); ARI symptoms presenting with fever in the past 7 days (a potentially more severe infection); and facilitator observed runny nose. As this was a rare outcome, caregiver-reported runny nose was analysed post hoc Safety NR
Notes	Quote: "The authors conclude that Water, sanitation, and handwashing interventions with behaviour change messaging did not reduce ARIs. Nutrition counselling and LNS modestly reduced ARI symptoms compared with controls in year 1 [prevalence ratio (PR): 0.87, 95% confidence interval (CI): 0.77–0.99], but no effect in the combined WSHN group weakens this finding" Financial support: this work was supported by the Bill & Melinda Gates Foundation (OPPGD759).

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Swarthout 2020 *(Continued)*

The authors declare no further competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random-number generator
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition balanced across groups and < 20%
Selective reporting (reporting bias)	High risk	None of the outcomes reported were prespecified in the trial registry

Talaat 2011

Study characteristics

Methods	Cluster-RCT
Participants	Children (N = 44,451) in the first 3 primary grades from 60 governmental elementary schools in Cairo, Egypt were included and randomised to 30 schools in the intervention arm (N = 20,882 students) and 30 control schools (N = 23,569 students). No exclusion criteria provided.
Interventions	Students were required to wash their hands at least twice during the school days for about 45 seconds, followed by proper rinsing and drying on a clean towel. Campaign material was developed, and posters were placed near sinks in the classroom and playground to encourage hand-washing with soap and water upon arriving at school, before and after meals, using the bathroom, and after coughing and sneezing. See Table 1 for details.
Outcomes	Laboratory: point-of-care influenza A and B viruses using QuickVue (QuickVue; Quidel Corp., San Diego, CA, USA). School nurses collected nasal swabs from children who visited the school clinic with ILI, and only for students who had prior written approval of a parent. Effectiveness: rates of absenteeism caused by ILI and laboratory-confirmed influenza. ILI defined as fever > 38 °C and either cough or sore throat. Safety: none planned or reported by the investigators
Notes	The period study conducted: 16 February to 12 May 2008

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Talaat 2011 *(Continued)*

Funding: this work was supported by the Centers of Diseases Prevention and Control, Work Unit no. 6000.000.000.E0016.

No interests declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "computer-generated random number table"
Allocation concealment (selection bias)	Unclear risk	No information given.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The participants and study personnel were not blinded, although lack of blinding is unlikely to have influenced the outcome. Laboratory-confirmed influenza was only conducted only for students who had prior written approval of a parent.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: “Differential interest of study teams may have contributed to the low rate of testing in students who were absent because of ILI in the control schools compared to the intervention schools (12% vs 22%)”
Incomplete outcome data (attrition bias) All outcomes	High risk	No flow chart of clusters flow during the study period. No information on withdrawal. Differential interest of study teams may have contributed to the low rate of testing in students who were absent because of ILI in the control schools compared to the intervention schools (12% vs 22%) incomplete or loss of data. The total number ILI episodes could be an underestimate, as there is no proactive method to look for symptoms of ILI amongst the students; it depends on the student being absent or in class with symptoms that are picked up by the teachers at school.
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge

Teesing 2021

Study characteristics

Methods	Cluster - trial taking place in 66 nursing homes units (33 nursing homes) in the Netherlands during October to December 2016 with 2 follow-up periods (January to April 2017, May to October 2017). Randomisation was carried out by computer and there were some post-randomisation imbalances: the intervention arm had more small and medium-sized nursing homes (< 88 beds, 88 to 118 beds) and the control arm had more large nursing homes (> 118 beds).
Participants	Nursing home staff whose compliance was measured with direct observation according to the WHO-defined HH moments and recorded in a novel app. “The nurses were blinded by giving distinct names to the lessons (The New Way of Working) and the observations (HANDSOME), so that they appeared to be different projects. Nurses were told that the observers were registering the frequency of health care activities (in general)”. Staff worked in 66 nursing home units, 36 (976 beds, median 25 per unit) in the intervention arm, and 30 (886 beds, median 28 per unit) in the control arm. During the trial 8 (12%) units left the study during the follow-up for various reasons: 6 intervention units (four during Follow-up 1 and 2 during Follow-up 2) and 2 control units (both during Follow-up 2)

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Teesing 2021 *(Continued)*

Interventions	Hand hygiene (HH) enhancement activities versus no activities. Activities for staff were: an e-learning session, 3 live lessons, posters, and a photo competition. See Table 1 for details.
Outcomes	Laboratory NR Effectiveness Incidence of gastroenteritis*, influenza-like illness (ILI), assumed pneumonia*, urinary tract infections (UTIs)*, and infections caused MRSA* in residents *Data not extracted Safety NR
Notes	The authors conclude that quote: "This study, similarly to comparable studies, could not conclusively demonstrate the effectiveness of an HH intervention in reducing HAIs among residents of nursing homes, despite the use of clearly defined outcome measures, a standardized illness incident reporting instrument, and directly observed HH in a multicenter cluster-RCT. This could be due to an insufficient increase in HH compliance and/or other factors in the nursing home environment that need to be addressed concurrently in order to decrease illness rates" The trend of ILI incidence reflects that of the outside community at a higher level. This is probably due to ascertainment bias in the nursing homes in the trial. The trend is seasonal and could be accounted for by visitor transmission. Funding: this study was funded by the Netherlands Organization for Health Research and Development (ZonMw). Non-financial support was received from Essity during the conduct of the study. Competing interests: the authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random-number generator
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Nurses blinded but participants and other staff members not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Staff members of nursing homes in the intervention arm were potentially extra alert to infections and more motivated to register them.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Participant flow diagram not reported.
Selective reporting (reporting bias)	Unclear risk	Insufficient information available

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Temime 2018

Study characteristics	
Methods	2-arm cluster-RCT
Participants	All residents and staff of 27 privately held chains of nursing homes owned by Korian. 26 nursing homes (13 per arm), with an average of 80 residents per nursing home, were included in the study.
Interventions	Quote: "The intervention was based on a bundle of HH-related measures aimed at NH staff, residents, visitors, and outside care providers. These measures included facilitated access to handrub solution using pocket-sized containers and new dispensers, a campaign to promote HH with posters and event organization, the formation of local work groups in each NH to work on HH guidelines, and staff education using e-learning on infection control and HH training performed by the same nurse for all NHs." See Table 1 for details.
Outcomes	Laboratory: none used Effectiveness: Primary outcomes: incidence rate of ARIs and AGE reported in the context of episodes of clustered cases, defined as at least 5 cases within 4 days amongst nursing home residents or staff. ARIs were defined as the combination of at least 1 respiratory symptom with 1 symptom of systemic infection. AGE was defined as the sudden onset of diarrhoea or vomiting in the absence of a non-infectious aetiology. Secondary endpoints were mortality rate, hospitalisation rate, and antibiotic prescription rate (measured in defined daily doses (DDDs) per 100 resident days). Safety: no adverse event surveillance planned or reported by the investigators
Notes	The period study conducted: 1 April 2014 to 1 April 2015 Funding: private (Institute of Ageing Well Korian (Institut du bien vieillir Korian), which runs the nursing homes included in the study) Conflicts of interest: none to report.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	"simple" randomisation is used
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "we suspected that underreporting occurred. The data were verified qualitatively after the end of the intervention through individual phone interviews with each participating NH. Based on these interviews, ARI clustered cases episodes had actually occurred in 12 out of 13 control NHs; however, only 1 had been notified to health authorities. No unreported clustered cases episodes were identified in the intervention NHs"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data were collected at NH level and reported to centralised by the NH group headquarters in Paris through computerised databases. There was underreporting of ARI and AGE in the control groups. The trial authors suspected that underreporting occurred. Primary outcome: high risk. Secondary outcomes: low risk

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Temime 2018 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	For the primary outcome, there was underreporting of ARI and AGE in the control groups; no study flow chart was provided; and no reporting on any exclusions. Surveillance is based on voluntary and standardised notifications to health authorities of any AGE or ARI clustered case episode.
Selective reporting (reporting bias)	Low risk	Reported outcomes match planned outcomes published in the protocol.

Turner 2004a

Study characteristics	
Methods	Double-blind RCT conducted by Hill Top Research, Inc., Winnipeg, Canada, to assess the efficacy of acids with virucidal activity for the inactivation of virus and prevention of experimental rhinovirus colds. Participants in good health, aged 18 to 60, were recruited from Winnipeg and surrounding communities for participation. Qualified participants were randomised to treatment with vehicle (62% ethanol, 1% ammonium lauryl sulphate, and 1% Klucel), vehicle containing 3.5% salicylic acid, or vehicle containing 1% salicylic acid and 3.5% pyroglutamic acid. The volunteers' hands were disinfected, and then test product was applied to both hands of participant. 15 minutes after application, the fingerprints of each hand were contaminated with rhinovirus type 39. The volunteers touched conjunctiva and the nasal mucosa only with the right hand. Viral contamination of the fingers was assessed in the left hands of the volunteers, and viral infection was assessed by culture of nasal lavage specimens and blood samples.
Participants	85 volunteers; 31 control group, 27 used vehicle with 3.5% salicylic acid, 27 used vehicle with 1% salicylic acid and 3.5% pyroglutamic acid
Interventions	Use of salicylic acid versus salicylic acid and pyroglutamic acid versus "placebo" substance. See Table 1 for details.
Outcomes	Laboratory: yes Effectiveness: rhinovirus type 39 infection Safety: N/A
Notes	Risk of bias: unclear (no description of randomisation process, concealment or allocation) Note: the authors concluded that organic acids commonly used in over-the-counter skin care and cosmetic products have substantial virucidal activity against rhinovirus. These preparations provided effective residual antiviral activity on the hands. The virucidal effect of these hand treatments resulted in a reduction in the incidence of rhinovirus infection in the treated volunteers (P = 0.025). The utility of this observation in the natural setting remains to be determined. The volunteers were not allowed to use their hands in the interval between the hand treatment and the virus challenge, so the effect of normal use of the hands on the virucidal activity of these organic acids is not known. Similarly, the virus challenge method used in these experiments may not simulate the natural setting in all aspects. The effect of nasal secretions that would be transferred with the virus in the natural setting on the activity of the acids or on the transmission of virus was not tested in the model. We are unsure as to the practical significance of this study and the generalisability of its results to the real world. Poorly reported study Funding for this study was provided by the Procter & Gamble Co., Cincinnati, Ohio. No interests declared.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

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Turner 2004a *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Quote: "randomised" Sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "double blind", but no description
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "double blind", but no description
Incomplete outcome data (attrition bias) All outcomes	Low risk	All accounted for (short study).
Selective reporting (reporting bias)	High risk	Poorly reported

Turner 2004b

Study characteristics	
Methods	Double-blind RCT conducted by Hill Top Research, Inc., Winnipeg, Canada, to assess the residual virucidal activity of a skin cleanser wipe and its effectiveness in preventing experimental rhinovirus colds. Participants in good health, aged 18 to 60 years, were recruited from Winnipeg and surrounding communities for participation. The residual activity of a skin cleanser wipe containing 4% pyroglutamic acid formulated with 0.1% benzalkonium chloride was tested. The negative control treatment was 62% ethanol. Benzalkonium chloride had been previously tested and was found to have no virucidal activity. Volunteers were randomly assigned to use the control preparation or the active preparation. The study material was applied to hands with a towelette. 15 minutes later, when the fingers were completely dry, the fingertips of each hand of the control participants and the volunteers in the active treatment group were contaminated with rhinovirus type 39. An additional volunteer in the active group was challenged with virus 1 hour after application, and the final group of volunteers was challenged 3 hours after application. Viral infection was assessed by culture of nasal lavage specimens and blood samples.
Participants	122 volunteers; 30 in control group, 92 in active group (30 tested after 15 minutes, 30 after 1 hour, 32 after 2 hours)
Interventions	Use of a skin cleanser wipe containing 4% pyroglutamic acid formulated with 0.1% benzalkonium chloride versus skin cleanser wipe containing ethanol. See Table 1 for details.
Outcomes	Laboratory: yes Effectiveness: rhinovirus type 39 infection Safety: N/A
Notes	Risk of bias: unclear (no description of randomisation process, concealment or allocation) Funding for this study was provided by the Procter & Gamble Co., Cincinnati, Ohio. No interests declared.

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Turner 2004b *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised" Sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "double blind", but no description given
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "double blind", but no description given
Incomplete outcome data (attrition bias) All outcomes	Low risk	All accounted for (short study).
Selective reporting (reporting bias)	High risk	Poorly reported

Turner 2012

Study characteristics	
Methods	Randomised controlled clinical trial
Participants	A total of 212 participants were enrolled (116 in the treatment group, 96 in the control group). Healthy adult volunteers aged > 18 years from the University of Virginia community Written informed consent was obtained, and volunteers were compensated for participation. Exclusion: individuals with skin conditions that would interfere with safety evaluations or medical conditions that could impact the person's well-being or affect study results, and those whose occupations required frequent hand-washing
Interventions	Antiviral hand treatment containing 2% citric acid, 2% malic acid, and 62% ethanol (n = 116) or to a no-treatment control group (n = 96). The hand treatment was applied every 3 hours and after hand-washing whilst the participants were awake. See Table 1 for details.
Outcomes	Laboratory: PCR using AmpliTaq Gold DNA Polymerase from Applied Biosystems Effectiveness: reduction of rhinovirus-induced common colds; comparison of the number of RV-associated illnesses per 100 participants in the control group with that in the treatment group over 9 weeks. Definitions: a common cold illness was defined as the presence of any of the symptoms of nasal obstruction, rhinorrhoea, sore throat, or cough on at least 3 consecutive days. Illnesses separated by at least 3 symptom-free days were considered to be separate illnesses. Rhinovirus infection was defined as the detection of RV in nasal lavage. All volunteers were seen weekly for nasal lavage, and specimens were assayed by PCR for the presence of RV. PCR–positive specimens separated by at least 8 days and at least 1 negative PCR specimen were considered to be separate infections. RV-associated illnesses were based on detection of RV either at the time of the illness or at the first weekly visit after the illness.

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Turner 2012 *(Continued)*

	Safety: hand irritation occurred in 11 of the 116 volunteers (9%) in the treatment group, which met protocol criteria for removal from the study. An additional 8 participants who did not meet these protocol criteria voluntarily withdrew due to hand irritation. There was no hand irritation in the control group. No other adverse effects of the study treatment were noted.
Notes	The period study conducted: August 2009 to November 2009 Funding: The Dial Corporation - a Henkel Company, Scottsdale, Arizona, USA Potential conflicts of interest: R. B. T. is a consultant to Henkel and received grant funding to conduct these studies. All other authors are current or former employees of Henkel. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A randomization code generated using commercially available software was provided by the sponsor"
Allocation concealment (selection bias)	Low risk	Quote: "staff at the study site assigned sequential subject numbers as they enrolled volunteers into the study, and treatment assignment was determined by the subject number."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The outcomes are unlikely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Personnel who conducted the laboratory assays were blinded to study groups and to whether the specimen was from a routine or illness related visit"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition (and reasons for it) was reported. Study outcomes reported as ITT and PP.
Selective reporting (reporting bias)	Low risk	All planned outcomes in study protocol were reported on.

White 2001

Study characteristics

Methods	Double-blind, placebo-controlled, cluster-RCT that took place in 3 schools in California during March to April 1999. The study assessed the incremental value of using an alcohol hand rub together with water-and-soap hand-washing. Both arms were administered an educational programme beginning 2 weeks prior to start of the trial. Randomisation was by classroom, and the placebo hand rub was indistinguishable from the active ingredient. Details of randomisation are not given.
Participants	Of the 72 classes originally recruited, lack of compliance (use of supplementary product at least 3 times a day) reduced the classes to 32 (16 in both arms) and a total of 769 participants aged 5 to 12 (381 students who received the sanitiser, and 388 who received the placebo).

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White 2001 *(Continued)*

Interventions	Pump-activated antiseptic hand rub with benzalkonium chloride (SAB) (Woodward Laboratories) or inert placebo that "virtually" looked the same in batches of 4 colour-coded bottles. School staff, parents, and participants were blinded. See Table 1 for details.
Outcomes	Laboratory: testing of virucidal and bactericidal activity of the active compound Effectiveness: ARI (cough, sneezing, sinus trouble, bronchitis, fever, red eye, headache, mononucleosis, acute exacerbations of asthma) Gastrointestinal and other illnesses (data not extracted) Follow-up and observation was carried out by classroom staff, and illnesses were described by parents. Safety: 7 students dropped out because of mild sensitivity to the rub
Notes	Risk of bias: high (no description of randomisation; partial reporting of outcomes, numerators and denominators) Note: the authors conclude that addition of the rub led to a 30% to 38% decrease of illness and absenteeism (RR for illness absence incidence 0.69, RR for absence duration 0.71). Very high attrition, unclear randomisation procedure, educational programme and use of placebo hand rub make generalisability of the results debatable. No confidence intervals reported. This study was supported by an Orange County School Nurses Organization Health Promotion Grant. No interests declared.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised trial", but sequence generation not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "To distinguish content, both the active and placebo formulations were distributed in four color-coded groups of 1oz spritz bottles. The content were and distribution patters were only know to the researchers and were indecipherable by the school staff or students."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Teachers were responsible for recording attendance for each day during the study"
Incomplete outcome data (attrition bias) All outcomes	High risk	Partial reporting of outcomes, numerators and denominators
Selective reporting (reporting bias)	High risk	Poor reporting

Yeung 2011

Study characteristics

Methods	Clustered-RCT of a hand hygiene intervention involving pocket-sized containers of alcohol-based hand rub for the control of infections in long-term care facilities. Staff hand hygiene adherence was directly observed, and residents' infections necessitating hospitalisation were recorded. After a 3-month pre-intervention period, long-term care facilities (LTCFs) were randomised to receive pocket-sized containers of alcohol-based gel, reminder materials, and education for all HCWs (treatment group) or to re-

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Yeung 2011 *(Continued)*

	ceive basic life support education and workshops for all HCWs (control group). A 2-week intervention period (1 to 15 April 2007) was followed by 7 months of postintervention observations.
Participants	6 out of 7 community-based, private or semiprivate, residential LTCFs in Hong Kong agreed to participate and were randomised to: 1. hand hygiene group (3 LTCFs, 73 nursing staff and 244 residents analysed); or 2. control group (3 LTCFs, 115 nursing staff and 379 residents analysed). All were nursing homes serving an elderly population. All LTCFs were situated in different regions of Hong Kong, including urban and rural areas. The targets of the intervention were all full- and part-time HCWs at these LTCFs. The LTCFs employed 3 types of HCWs: nurses, nursing assistants, and physiotherapists.
Interventions	Pocket-sized containers of alcohol-based gel, reminder materials, and education (intervention group) or basic life-support education and workshop (control group). See Table 1 for details.
Outcomes	Rates of infection (requiring hospitalisation) Outbreaks Death due to infection Diagnoses of infection coded into 6 categories, all of which were common endemic infections in LTCFs: 1. pneumonia, 2. urinary tract infection, 3. septicaemia, 4. skin or soft-tissue infection (including cellulitis or pressure sores), 5. gastroenteritis, and 6. fever. Infections recorded in death certificates were also included, regardless of whether the resident had been hospitalised. The causes of death were categorised as due to infection, not due to infection, or unknown. If the primary or the secondary diagnosis on the death certificate belonged to 1 of the 6 endemic infection categories, the death was coded as due to infection. No safety outcomes reported.
Notes	University and industry funded.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded study

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Yeung 2011 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Unclear risk	No protocol available

Young 2021

Study characteristics	
Methods	Cluster-randomised, controlled trial of daily contact testing in students and staff at secondary schools and colleges in England to show whether daily contact testing increases school attendance and to assess the impact of daily contact testing on SARS-CoV-2 transmission within schools.
Participants	201 schools, of which 99 were randomly assigned to self-isolation of school-based COVID-19 contacts for 10 days (control) and 102 to voluntary daily lateral flow device (LFD) testing for 7 days with LFD-negative contacts remaining at school (intervention)
Interventions	All schools in the intervention and control groups followed the national policy of offering twice weekly asymptomatic testing with LFDs. Individuals with positive LFD results were required to self-isolate immediately and requested to obtain a confirmatory PCR test within 2 days. Those with indicator symptoms of possible COVID-19 (new cough, fever, loss or change in taste or smell) were required to self-isolate along with their household and obtain an urgent PCR test. If a student or staff member tested positive by LFD or PCR, close contacts (hereafter referred to as contacts) were identified by schools using national guidelines. Those in close contact with a case less than 48 hours before symptom onset (or a positive test if asymptomatic) were required to self-isolate for 10 days. At schools in the intervention group, contacts were offered daily contact testing as an alternative to self-isolation, provided the contact was school-based (i.e. with a staff member or student), the contact did not have indicator symptoms of COVID-19, and contacts were able to attend for on-site testing at school. See Table 1 for details.
Outcomes	Laboratory PCR confirmed infections Effectiveness COVID-19-related school absence and symptomatic PCR-confirmed COVID-19. Safety NR
Notes	The authors conclude that quote: “Daily contact testing of school-based contacts was non-inferior to self-isolation for control of COVID-19 transmission, with similar rates of symptomatic infections among students and staff with both approaches." Funding: UK Government Department of Health and Social Care. Declaration of interests: DWE reports lecture fees from Gilead outside the submitted work. VB, RO, and DC are consultants employed by Department of Health and Social Care as part of Deloitte’s broader project work supporting the delivery of NHS Test and Trace. TF reports honoraria from Qatar National Research Fund outside the submitted work. All other authors declare no competing interests. Potential conflicts of interest: all authors report no conflicts of interest relevant to this article.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer random-number generator

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Young 2021 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Insufficient information reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Participant flow diagram reported showing high attrition at different rates in the 2 groups
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported

Zomer 2015

Study characteristics	
Methods	Cluster-RCT
Participants	71 daycare centres (36 intervention DCCs, and 35 control) in Rotterdam-Rijnmond, Gouda and Leiden in the Netherlands Study enrolled 545 children (intervention = 278, control = 267). Inclusion/exclusion criteria: children who attended the DCC at least 2 days a week; were aged between 6 months and 3.5 years at start of the trial; intended to attend the DCC throughout the study period; and if their parents consented, were Dutch-speaking, and had access to email or regular post. Children were excluded if they had a chronic illness or medication that predisposed them to infection, a sibling taking part in the trial (i.e. 1 child per family could be included), or if they started attending CCC after the beginning of the trial).
Interventions	4 components: 1. HH products, paper towel dispensers, soap, alcohol-based hand sanitiser, and hand cream were provided for 6 months. 2. Training and a booklet outlining the training. 3. 2 team training sessions aimed at specific HH improvement activities. 4. Posters and stickers for caregivers and children as reminders. See Table 1 for details.
Outcomes	Laboratory: none Effectiveness: incidence of respiratory infections in children monitored by parents. The common cold was defined as a blocked or runny nose with at least 1 of the following symptoms: coughing, sneezing, fever, sore throat, or earache. Safety: none planned or reported by the investigators
Notes	The period study conducted: September 2011 to April 2012

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Zomer 2015 *(Continued)*

Funding: mixed. The Netherlands Organisation for Health Research and Development (ZonMw). Dispensers and refills were sponsored by SCA Hygiene Products, Sweden.

Declaration of interest: none.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Stratified randomization is performed by assigning each DCC to one of six strata based on size (i.e. small < 46 children per day versus large ≥ 46 children per day) and geographic location (i.e. highly urban versus urban versus slightly/non-urban). DCCs are assigned to either intervention or control group by means of computer generation with a 1:1 ratio in each of the strata"
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Outcome is subjective.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Symptoms were reported by parents, no validation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Very few children were excluded or lost to follow-up (reasons for exclusions provided).
Selective reporting (reporting bias)	Low risk	All planned outcomes are reported. However, between published protocol and the paper, secondary outcomes became the primary outcome in the published paper!

AEs: adverse events
AFH: Armed Forces Hospital
AGE: acute gastroenteritis
AgNPs: ARGOVIT silver nanoparticles
ALRI: acute lower respiratory infection
ARI: acute respiratory infection
ASR: adverse skin reactions
A&E: accident and emergency
BIPAP: bilevel positive airway pressure
CCC: childcare centre
CDC: Centers for Disease Control and Prevention
CG: control group
CHG: chlorhexidine gluconate
CI: confidence interval
CMF: citric acid: malic acid: sodium lauryl sulphate (a virucidal mixture added to tissue paper)
CoV: coronavirus
cluster-RCT: cluster-randomised controlled trial
CRI: clinical respiratory illness
CXR: chest X-ray
DCC: daycare centre
EG: experimental group
FRI: febrile respiratory illness
FU: follow up
GI: gastrointestinal

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GTI: gastrointestinal infection
GP: general practitioner
HCW: healthcare worker
HFH: Hanoi French Hospital
HH: hand hygiene
HR: high risk
HSG: hand sanitiser group
ICD-9: International Classification of Disease, 9th Revision, Clinical Modification
IgG: immunoglobulin G
ICU: intensive care unit
ILI: influenza-like illness
IQR: interquartile range
IRR: incident rate ratio
ITT: intention-to-treat
KSA: Kingdom of Saudi Arabia
LFD: lateral flow device
LNS: lipid based nutrient supplementation
LRTI: lower respiratory tract infection
LTCF: long-term care facility
m: metre
MCU: medical convalescent unit
MDCK: Madin Darby canine kidney cell line
M group: face mask group
MH group: face mask and hand hygiene group
MS: monkey-derived cell line
N/A: not applicable
NAT: nucleic acid testing
NH: nursing home
NICU: neonatal intensive care unit
NOS: Newcastle-Ottawa Scales
NP: non-pharmaceutical
NR: not reported
NTS: nasal and throat swab
OR: odds ratio
PCR: polymerase chain reaction
PCU: physical conditioning unit
POCT: point-of-care testing
PP: per protocol
PPE: personal protective equipment
QNAF: Qatar National Research Fund
RCT: randomised controlled trial
RDS: respiratory distress syndrome
RI: respiratory infection
RIDT: rapid influenza diagnostic test
RNA: ribonucleic acid
RR: risk ratio
rRT-PCR: real-time reverse transcription-polymerase chain reaction
RTI: respiratory tract infection
RT-PCR: reverse-transcriptase polymerase chain reaction
RSV: respiratory syncytial virus
RV: rhinovirus
SAB: surfactant, allantoin, and benzalkonium chloride
SAR: secondary attack rate
SARS: severe acute respiratory syndrome
SCBU: special care baby unit
SD: standard deviation
SES: electrolysed water
SHEWA-B: Sanitation, Hygiene Education and Water Supply in Bangladesh
SOB: shortness of breath
SOPs: standard operating procedures
S/S: signs/symptoms
SSTI: skin and soft-tissue infection

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STH: soil-transmitted helminth
SWG: soap and water group
TIDieR: Template for Intervention Description and Replication
UHR-I: ultra high-risk infection
UHR-S: ultra high-risk SARS
URI: upper respiratory infection
URTI: upper respiratory tract infection
WBC: white blood cell
WHO: World Health Organization
WSH: water, sanitation, and handwashing (combined)

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abou El Hassan 2004	Topic completely extraneous
Ahmadian 2022	Excluded as study is an experiment that did not measure any of our outcomes of interest.
Amirav 2005	Randomised controlled trial of aerosol treatment
Anderson 2004	Mathematical model with interesting discussion of interaction between public health measures
Anonymous 2002	News item
Anonymous 2004	News item
Anonymous 2005a	News item
Anonymous 2005b	News item
Anonymous 2005c	News item
Apisarnthanarak 2009	Intervention bundle not broken down.
Apisarnthanarak 2010	Participants took antivirals.
Aragon 2005	Descriptive paper (non-comparative). Has no viral outcomes
Azor-Martinez 2014	Results reported as respiratory and gastrointestinal infections. No extractable respiratory data
Barros 1999	Correlational study between incidence of URTI and factors such as overcrowding
Bauer 2009	Historical comparison with RSV gammaglobulin amongst interventions
Bell 2004	Has unpublished entry exit screening data and extensive references but no comparative data
Bellissimo-Rodrigues 2009	Intervention is chlorhexidine.
Ben-Abraham 2002	Exclude - bacterial illness only
Black 1981	Diarrhoea only outcome
Borkow 2010	No human beings involved.
Bouadma 2010	Hospital-based ventilator routine

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Study	Reason for exclusion
Bowen 2007	Outcomes of composite infections. Respiratory infections are not reported separately.
Breugelmans 2004	Description of risk factors in aircraft
Cai 2009	Compliance study
Cantagalli 2010	Outcome outside inclusion criteria
Carbonell-Estrany 2008	Immunoglobulin intervention and descriptive review
Carter 2002	News item
Castillo-Chavez 2003	Editorial
Cava 2005a	Survey of quarantinees' views
Cava 2005b	Personal experiences of quarantine
CDC 2003a	Case reports
CDC 2003b	No data presented.
Chai 2005	Letter - about MRSA
Chami 2012	Outcomes of composite infections. Respiratory infections are not reported separately.
Chaovavanich 2004	Case report
Chau 2003	No original retrievable data. Mathematical model fitting expected to observed cases with quarantine in the SARS of Hong Kong
Chau 2008	Audit of infection control procedures and compliance with guidelines
Chen 2007	An assessment of the impact of different hand-washing teaching methods. No clinical outcomes
Chen 2022	Not a RCT.
Cheng 2010	Confounded by antiviral use for postexposure prophylaxis
Chia 2005	Knowledge survey
Clynes 2010	Letters
Costa 2021	No clinical outcome assessed
Cowling 2007	Epidemiology, non-comparative, non-interventions study
Cyril Vitug 2021	Is a treatment for COVID-19 infection
Dalakoti 2022	Excluded as study is an experiment that did not measure any of our outcomes of interest.
Daniels 2010	Commentary
Daugherty 2008	No free data presented.

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Study	Reason for exclusion
Davies 1994	Antibody titres as outcomes with so many biases that interpretation of study is problematic
Day 1993	No acute respiratory infection outcome data
Day 2006	Mathematical model; no new data
Dell'Omodarme 2005	Probabilistic and Bayesian mathematical model of screening at entry
Denbak 2018	Outcomes of composite infections. Respiratory infections are not reported separately.
Desenclos 2004	Description of transmission
DiGiovanni 2004	Qualitative study of compliance factors in quarantine
Doebbeling 1992	RCT respiratory data not present. Only 3 viruses isolated in total with no viral typing available.
Dwosh 2003	Case series
Edmonds 2010	Lab study
Egger 2022	Excluded as study is an experiment that did not measure any of our outcomes of interest.
Fendler 2002	Cohort study badly biased with differential health profiles and healthcare workers dependency in intervention and control semi-cohorts. No attempt to adjust for confounders was made. No denominators available.
Ferrer 2021	Is a treatment (not something to interrupt transmission)
Flint 2003	Description of spread in aircraft and non-comparative data
Fung 2004	Non-comparative
Garcia 2010	Commentary
Gaydos 2001	Editorial linked to Ryan 2001. (Ryan 2001 was an included trial in a previous version of this review (2011). Non-RCTs were removed in this 2020 update).
Gensini 2004	Interesting historical review
Gharebaghi 2020	Study on the prevention of ventilator associated pneumonia in mechanical ventilatory patients
Girou 2002	Non-clinical outcomes
Giuliano 2021	Outcome is hospital aquired pneumonia which is a syndrome with multiple aetiologies, mainly bacterial and mycotic
Glass 2006	Mathematical model - no original data presented
Goel 2007	Non-comparative study
Gomersall 2006	Non-comparative study
Gore 2001	Summary of Dyer 2000. (Dyer 2000 was a prospective, cluster open-label cross-over cohort study included in the previous version of this review (2011). Non-RCTs were removed in this 2020 update).

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Study	Reason for exclusion
Gostin 2003	Not an analytical study
Gralton 2010	Review
Guinan 2002	It would appear that 9 classes took part and "acted as their own controls", but it is not clear if there was cross-over of classes or not. In addition, the outcome is combined gastrointestinal/respiratory. The clue lies in the presence of a nested economic analysis which shows considerable savings in time for staff and pupils if the soap is used: in other words this is a (covert) publicity study.
Gupta 2005	Economic model - no new data
Gwaltney 1982	No breakdown of cases given by arm.
Han 2003	Non-comparative
Hayden 1985	This is an RCT with laboratory-induced colds, small numbers, and uncertain numerators, but almost certainly because of the unique laboratory conditions (placebo tissues not being a placebo at all) of impossible generalisation. It was a pilot to the far bigger trial by Farr 1988a; Farr 1988b.
Hendley 1988	Inappropriate intervention
Hens 2009	Model
Heymann 2009	Already included in review as Heymann 2004. (Heymann 2004 was a controlled before and after study included in the previous version of this review (2011). Non-RCTs were removed in this 2020 update).
Hilburn 2003	No ARI/viral outcomes (e.g. URTIs)
Hilmarsson 2007	Animal study
Hirsch 2006	Study tested pharmacological interventions.
Ho 2003	Descriptive review
Hsieh 2007	Mathematical model
Hugonnet 2007	Letter without any data
Jiang 2003	Two papers that are probably different versions of the same paper: Jiang SP, Huang LW, Wang JF, Wu W, Yin SM, Chen WX, et al. A study of the architectural factors and the infection rates of health-care workers in isolation units for severe acute respiratory syndrome. Chung-Hua Chieh Ho Ho Hu Hsi Tsa Chih [Chinese Journal of Tuberculosis & Respiratory Diseases]. 26(10):594-7, 2003 Oct
Johnson 2009	Outcomes are non-clinical.
Jones 2005	Historical account
Karakaya 2021	Outcome is ventilator associated pneumonia which is a syndrome with multiple aetiologies, mainly bacterial and mycotic
Kawyannejad 2020	Trial on mouthwash for VAP patients with no viral infection outcomes
Kaydos-Daniels 2004	Not an analytical study
Kelso 2009	Model

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Study	Reason for exclusion
Khaw 2008	Assessing the efficacy of O_2 delivery
Kilabuko 2007	Aetiological study
Kosugi 2004	Non-comparative study
Lam 2004	Outcomes were generic (infection rates). No laboratory data available for viral diagnosis.
Lange 2004	No data presented.
Larson 2004a	Inappropriate outcomes
Larson 2004b	Inappropriate outcomes
Larson 2005	Cluster-RCT comparing the effects of 2 hand hygiene regimens on infection rates and skin condition and microbial counts of nurses' hands in neonatal intensive care units. Outcomes were generic (e.g. pneumonia and microbial counts of participants' skin). No laboratory data available for viral diagnosis.
Lau 2004	Attitude survey
Lau 2005	Herbal remedy effectiveness assessment
Lee 2005	Descriptive study of risk and protective factors of transmission in households. No assignment took place.
Lee 2010	Cohort study; unclear numbers were vaccinated against influenza
Lennell 2008	Measured absenteeism due to non-specific infection
Lim 2022	Not a RCT.
Lipsitch 2003	Mathematical model fit to evidence
Luckingham 1984	Historical report on Tucson experience during Spanish flu pandemic
Ma 2004	Case-control study of risk factors for SARS
MacIntyre 2010	Commentary on Cowling 2009
Malaczek 2022	Excluded as study is an experiment that did not measure any of our outcomes of interest.
Malone 2009	Model
Marin 1991	Viral resistance study
McSweeny 2007	Historical description
Meister 2022	Excluded as this is a treatment trial (all participants had COVID).
Mielke 2009	Review
Mikolajczyk 2008	No intervention
Mo 2022	Not a RCT.

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Study	Reason for exclusion
Monsma 1992	Non-comparative study
Montero-Vilchez 2022	Excluded as study is an experiment that did not measure any of our outcomes of interest.
Munoz-Basagoiti 2022	Excluded as this is a report of another study.
Nandrup-Bus 2009	The trial had only 2 clusters.
Nishiura 2009	Model
O'Callaghan 1993	Letter linked to Isaacs 1991. (Isaacs 1991 was a retrospective and prospective cohort study included in a previous version of this review (2011). Non-RCTs were removed in the 2020 update).
Olsen 2003	Description of transmission
Ooi 2005	Descriptive study, but with interesting organisational chart
Orellano 2010	Confounded by antiviral use
Panchabhai 2009	Pharma intervention
Pang 2004	Descriptive study of Beijing outbreak. Some duplicate data in common with Pang 2003. (Pang 2003 was an eclogical study included in a previous version of this review (2011). Non-RCTs were removed in the 2020 update).
Patel 2012	Although within each district the participating schools and households were randomly selected, the allocation of districts to the intervention and comparison arms was not randomly assigned.
Pittet 2000	Analysis of relationship between hand-washing compliance campaign and nosocomial bacterial infections (e.g. MRSA)
Prasad 2004	Letter about retrospective cohort - behavioural
Rabenau 2005	In vitro test of several disinfectants
Reynolds 2008	Describes the psychological effects of quarantine
Richardson 2010	Non-clinical study
Riley 2003	Mathematical model fit to evidence
Rodriguez 2009	A “reasonable attempt at minimizing bias” (see inclusion criteria) does not include absenteeism
Rosen 2006	Non-specific outcome. Measured absenteeism
Rosenthal 2005	Outcomes were generic (e.g. pneumonia, URTIs). No laboratory data available for viral diagnosis.
Safiulin 1972	Non-comparative set of studies with no clinical outcomes
Sanchez Barrueco 2022	Excluded as this is a treatment trial (all participants had COVID)
Sandrock 2008	Review
Sattar 2000	Experiment assessing virucidal activity of fingertip surface - no clinical outcome data

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Study	Reason for exclusion
Schull 2007	Describes the impact of SARS in a Toronto study
Seal 2010	Lab study
Seale 2009	Study looking at whether using respirators in A&E department is feasible
Seneviratne 2021	Not an intervention to reduce transmission and they did not look at ARIs or other clinically relevant outcomes
Sevinc Gul 2022	Excluded as this is a treatment trial (all participants had COVID)
Sizun 1996	This is a review; no original data presented.
Slayton 2016	Compares hand-washing plus (antibacterial) towel versus hand-washing without towel
Stebbins 2009	Attitude survey
Stedman-Smith 2015	Composite outcome. No data on separate respiratory illnesses reported.
Stoner 2007	No study data available.
Stukel 2008	Impact of the SARS disruption on care/mortality for other pathologies (e.g. acute myocardial infarction). There are no interventions, and outcomes are unrelated to acute respiratory infections.
Svoboda 2004	Descriptive study with before-and-after data but shifting denominators
Tracht 2010	Model
Ueno 1990	Experimental study. No clinical intervention
Uhari 1999	No respiratory illness data to be extracted
van der Sande 2008	Laboratory study without any clinical outcomes
Vessey 2007	Composite outcome. No data on separate respiratory illnesses reported.
Viscusi 2009a	Lab study
Viscusi 2009b	Lab study
Wang 2003	Descriptive study
Wang 2005	Case-control study of susceptibility factors
Weber 2004	Editorial linked to Larson 2004a
Wen 2010	Lab study
White 2005	Redundant publication of White 2003. (White 2003 was a prospective, open, cohort study included in a previous version of this review (2011). Non-RCTs were removed in the 2020 update).
Wilczynski 1997	Clinical trial of the effects of breastfeeding
Wilder-Smith 2003	Description of risk factors in aircraft

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Study	Reason for exclusion
Wilder-Smith 2005	Descriptive review
Wong 2005	Attitude survey
Yen 2010	Model
Yu 2004	Description of transmission
Zamora 2006	Head-to-head comparison of 2 sets of PPEs with no controls and no clinical outcomes
Zhai 2007	Non-comparative study
Zhao 2003	CCT of SARS treatment

A&E: accident and emergency
ARI: acute respiratory infection
CCT: controlled clinical trial
MRSA: methicillin-resistant *Staphylococcus aureus*
RCT: randomised controlled trial
RSV: respiratory syncytial virus
PPE: personal protective equipment
SARS: severe acute respiratory syndrome
URTI: upper respiratory tract infection
VAP: ventilator associated pneumonia

Characteristics of studies awaiting classification *[ordered by study ID]*

Contreras 2022

Methods	Follow-up of the WASH Benefits Bangladesh cluster-randomised controlled trial. Access to and reported use of latrines was high in both arms, and latrine quality was significantly improved by the intervention, while use of child faeces management tools was low. A random subset of households from the sanitation and control arms was enrolled into a longitudinal substudy, which measured child health with quarterly visits between 1 to 3.5 years after implementation.
Participants	9800 observations on children < 5 years through intention-to-treat analysis using generalised linear models with robust standard errors. 720 households (360 per arm) from the parent trial were enrolled and made 9800 child observations between June 2014 and December 2016.
Interventions	Multicomponent sanitation intervention including periods with differing intensity of behavioural promotion: water, sanitation, hygiene, and nutrition interventions. The sanitation intervention included provision of or upgrades to improved latrines, sani-scoops for faeces removal, children's potties, and in-person behavioural promotion. Promotion was intensive up to 2 years after intervention initiation, decreased in intensity between years 2 to 3, and stopped after 3 years. The study period included approximately 1 year of high-intensity promotion, 1 year of low-intensity promotion, and 6 months with no promotion.
Outcomes	Diarrhoea and ARI, at 1 to 2 years after intervention implementation to 3.5 years (follow-up). Outcomes were caregiver-reported and there were limited data collected after promotion ceased.
Notes	Trial registration: ClinicalTrials.gov; NCT01590095; https://clinicaltrials.gov/ct2/show/NCT01590095

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Croke 2022

Methods	Cluster-randomised trial assessing the effect of a national water, sanitation, and hygiene program on adherence with COVID-19 policies in Congo. The trial is a follow-up of the Villages et Ecoles Assainis programme which was running prior to the COVID-19 pandemic.
Participants	332 communities were randomly assigned to the Villages et Ecoles Assainis program or control. (590/1312; 45%) individuals who owned phones were surveyed by phone 3 times between May 2020 to August 2021.
Interventions	Large-scale water and sanitation programme not described in detail.
Outcomes	Primary outcomes were COVID symptoms, non- COVID illness symptoms, child health, psychological well-being, and vaccine acceptance. Secondary outcomes included COVID-19 preventive behaviour and knowledge, and perceptions of governmental performance, including COVID response. All outcomes were self-reported. COVID symptoms were defined as the number of household members in the past week with fever, dry cough, difficulty breathing/shortness of breath, or fatigue, while non-COVID illness variable was defined as the number of sick household members in the last 7 days (excluding those with COVID symptoms). The child health index was created using the proportion of children under 5 with fever/cough/diarrhoea in the last 2 weeks. The mental health index is a summary index of scores from answers to questions.
Notes	Cannot find NCT and unclear funders although acknowledgments list a potential load of funders. Probably public.

Delaguerre 2022

Methods	Prospective, open-label, non-inferiority randomised (2:1), controlled trial
Participants	Study included healthy individuals aged 18 to 45 years, with negative RADT test 3 days prior to concert event, with no risk factors and not living with someone with risk factors, and residing in Paris. Study excluded people with positive RADT test within 3 days before the gathering. People with clinical signs suggestive of an infectious respiratory disease, or with risk factor for severe COVID-19, or living with someone with risk factors for severe COVID-19. Persons not covered by French National Health Insurance or who cannot stand for the duration of the experiment (about 5 hours from entry line to exit) were excluded. Person under legal guardianship, pregnant woman or woman orally declaring non-use of effective contraception and breastfeeding woman were also excluded.
Interventions	Participants were randomly assigned to: 1. medical face mask wearing during an indoor concert event, or 2. not attending. Both groups had RADT test 3 days before the event Saliva samples for RT-PCR were collected from both groups on D0 and D7 using self-saliva-collection kits
Outcomes	Primary outcome: 1. the number of SARS-CoV-2-positive RT-PCR tests on self-collected saliva at day 7. Secondary outcomes: 1. the conversion rate of salivary carriage between the day 0 and day 7 visits;

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Delaguerre 2022 *(Continued)*

	2. the percentages of adequately masked (nose and mouth covered) faces over the total 4-hour period gathering.
Notes	1. French Ministry of Health. 2. ITT and PP analysis were used. Several imputation for missing data. 3. It is not clear if participants had COVID-19 in the past (in the table with baseline characteristics it is reported quote: “”declared Covid-19 history”: what does it mean? 4. Surgical masks were worn also by all attendees, regardless of study participation? 5. What is the intervention? Combined screening test + surgical mask?

Loeb 2022

Methods	Multicentre, randomised, non-inferiority trial
Participants	1009 healthcare workers who provided direct care to patients with suspected or confirmed COVID-19. Conducted in 29 healthcare facilities in Canada, Israel, Pakistan, and Egypt from 4 May 2020 to 29 March 2022.
Interventions	Use of medical masks versus fit-tested N95 respirators for 10 weeks, plus universal masking, which was the policy implemented at each site.
Outcomes	The primary outcome was confirmed COVID-19 on reverse transcriptase polymerase chain reaction (RT-PCR) test.
Notes	Financial support was given by the Canadian Institutes of Health Research, World Health Organization, and Juravinski Research Institute. Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M22-1966

Varela 2022

Methods	Open-label non-inferiority randomised controlled trial
Participants	Study was conducted in Colombia Inclusion criteria: people aged ≥ 18 years of both genders and who: (a) lived in a geographic area with active COVID-19 transmission and in areas with medium, medium-high, and high vulnerability index; and (b) worked outside their homes for at least 2 days during the last week. Exclusion criteria: retirement, unemployment, home-based working, history of laboratory-confirmed COVID-19, working in health care, and daily N95 mask or face shield use. In addition, during follow-up if participants reported an occupation change from work outside the home to home-based work, or became unemployed
Interventions	1. Intervention group (IG): instructed to wear closed face shields with surgical face masks 2. Active control group (ACG): instructed to wear only surgical face mask

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Varela 2022 *(Continued)*

	PPE was sent to their home address for each day of participation All participants received a follow-up twice a week by phone All participants received recorded educational intervention via email or phone that provided recommendations about COVID-19 prevention measures, guidance to ensure adherence, and appropriate handling of the assigned PPE. Weekly short questionnaire was performed on days 7, 14, and 21 to evaluate health status SARS-CoV-2 symptoms, PPE use, and adherence.
Outcomes	Primary outcome was the composite result of positive RT-PCR or seroconversion during follow-up Secondary outcomes including PPE use and adherence
Notes	1. Study was nested within an observational study (CoVIDA project). 2. Funding was provided by donors administered by the philanthropy department at the Universidad de Los Andes, external financing from the United Nations Development Programme (UNDP), and donations of diagnostic material from the Engineering Services Laboratory S.A.S. (LABSERVING S.A.S. Colombia). Funders had no input on the study at any stage. 3. Provided analysis as ITT and PP. 4. Missing data were imputed with negative results.

ARI: acute respiratory infection
h: hours
ITT: intention-to-treat
NCT: trial register number
PPE: personal protective equipment
PP: per protocol
RADT: rapid antigen detection test
RT-PCR: reverse-transcriptase polymerase chain reaction

Characteristics of ongoing studies *[ordered by study ID]*

Brass 2021

Study name	Prevention of SARS-CoV-2 (COVID-19) transmission in residential aged care using ultraviolet light (PETRA)
Methods	A multicentre, 2-arm double-cross-over, randomised controlled trial will be conducted to determine the efficacy of GUV devices to reduce respiratory viral transmission in RACF, as an adjunct to existing infection control measures. The study will be conducted in partnership with 3 aged care providers in metropolitan and regional South Australia. RACF will be separated into paired within-site zones, then randomised to intervention order (GUV or control). The initial 6-week period will be followed by a 2-week washout before cross-over to the second 6-week period. After accounting for estimated within-zone and within-facility correlations of infection, and baseline infection rates (10 per 100 person-days), a sample size of n = 8 zones (n = 40 residents/zone) will provide 89% power to detect a 50% reduction in symptomatic infection rate.
Participants	RACF within metropolitan and regional South Australia will be considered for recruitment if they possess the ability to sub-divide communal living areas into discrete areas that enable a concurrent comparison of interventions, with the facility cohorts otherwise subject to the same facility practices (e.g. environmental cleaning, staffing, and social distancing).
Interventions	The intervention will involve the commercially available Laftech GUV appliances: UV-FLOW-C wall- and ceiling-mounted system, UV-FAN-XS wall-mounted air purifier, and UV-FAN M2/95HP air purification device (LAF Technologies, Melbourne, Australia).

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Brass 2021 *(Continued)*

Outcomes	The primary outcome will be the incidence rate ratio of combined symptomatic respiratory infections for intervention versus control. Secondary outcomes include incidence rates of hospitalisation for complications associated with respiratory infection; respiratory virus detection in facility air and fomite samples; rates of laboratory-confirmed respiratory illnesses and genomic characteristics.
Starting date	
Contact information	Andrew P. Shoubridge • The South Australian Health and Medical Research Institute (SAHMRI), Adelaide, SA, Australia • The Microbiome and Host Health Programme, College of Medicine and Public Health, Flinders University, Bedford Park, SA, Australia
Notes	

NCT03454009

Study name	Appropriate time-interval application of alcohol hand gel on reducing influenza-like illness amongst preschool children: a randomised, controlled trial
Methods	This is a comprehensive randomised cluster hand-hygiene improvement intervention to reduce self-reported ARI/ILI and GI illness, absenteeism, presenteeism and related behavioural and attitudinal change over a 90-day trial. The intervention group will receive hand hygiene supplies and a variety of educational materials, including environmental posters in common areas. The control group will perform their usual hygiene activities and will not receive an intervention. Identical weekly surveys will be administered to the intervention and control groups to measure self-reported illness, absenteeism, presenteeism, along with behaviour and attitudes measured at specified intervals during the study. The intervention and control groups were randomised by work floors before the onset of the enrolment period. It is hypothesised that employees in the intervention group will experience reduced self-reported illness, absenteeism, and presenteeism along with improved protective hygiene behaviours and related attitudes, relative to those in the control group over the 90-day trial.
Participants	Inclusion criteria 1. At least 18 years of age or older 2. No known allergies to alcohol or surface disinfecting wipes 3. Works at least 30% of office hours at the study host site 4. Consent to receiving emails from Kent State University Exclusion criteria 1. Under 18 years of age 2. Known allergies to alcohol or surface disinfecting wipes 3. Works less than 30% of office hours at the study host site 4. Does not consent to receiving emails from Kent State University
Interventions	The intervention group will receive hand hygiene supplies and a variety of educational materials, including environmental posters in common areas. The control group will perform their usual hygiene activities and will not receive an intervention.
Outcomes	Self-reported ARI/ILI and GI illness, absenteeism, presenteeism and related behavioural and attitudinal change over a 90-day trial

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NCT03454009 *(Continued)*

Starting date	5 February 2018
Contact information	Maggie Stedman-Smith, PhD, Kent State University College of Public Health
Notes	Recruitment completed. Last update in ClinicalTrials.gov was 1 May 2019. NCT03454009

NCT04267952

Study name	Hand hygiene intervention program on primary school students' health outcomes and absenteeism in school
Methods	Study Type: interventional (clinical trial) Estimated enrolment: 200 participants Allocation: randomised Intervention model: parallel assignment Masking: single (participant) Masking description: participation will not know whether they are in the experimental or control group
Participants	Inclusion criteria: primary school student (especially third- and fourth-class student) Exclusion criteria: people with chronic disease
Interventions	Experimental: first group Hand hygiene intervention programme prepared by using planned behaviour theory will be applied to the students in this group. Active comparator: second group Students in this group will be given classic hand hygiene training.
Outcomes	Primary outcome measure: children with symptoms of infection will be referred to the family physician to have a rapid antigen test and to report the result to the researcher. 10 identified upper respiratory tract symptoms (fever, sore throat, runny nose, etc.) will be recorded weekly by family of children. The researcher will receive symptom information from the family via weekly SMS. The number of days the child does not attend school due to illness and the percentage of absenteeism 1. Group A streptococcal infections in rapid antigen test (time frame: total 20 weeks) 2. Incidence of symptoms of acute upper respiratory tract infection (time frame: total 20 weeks) 3. School absenteeism (time frame: total 20 weeks) Secondary outcome measures: Glogerm gel applied hands will shine areas containing micro-organisms. Contamination rate will be calculated by taking a photo of the hands and performing brightness analysis in Adobe Photoshop program. 1. Pollution rate of hands (time frame: from date of randomisation until the date of first documented progression assessed up to 7 months)
Starting date	9 September 2019

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NCT04267952 *(Continued)*

Contact information	Contact: Uyanık +905068949969; gulcinyelten@hotmail.com
Notes	Recruitment is ongoing. Last update in ClinicalTrials.gov was 13 February 2020. NCT04267952

NCT04471766

Study name	Evaluation of locally produced cloth face mask on COVID-19 and respiratory illnesses prevention at the community level - a cluster-RCT
Methods	Study type: interventional (clinical trial) Estimated enrolment: 66,000 participants Allocation: randomised Intervention model: parallel assignment Masking: single (outcomes assessor) Primary purpose: prevention
Participants	Ages eligible for study: 10 years and older (child, adult, older adult) Sexes eligible for study: all Accepts healthy volunteers: no Criteria Inclusion criteria: 1. Household resident 2. Age 10 years and older Exclusion criteria: 1. Refusal to participate
Interventions	Experimental: certified cloth face mask plus preventive information Active comparator: information on COVID-19 prevention
Outcomes	Self-reported main symptoms of COVID-19 (3 or more of fever, cough, fatigue, shortness of breath, loss of smell/taste) Consultation for COVID-19 like illness or reported positive test, or both Self reported COVID-19 like illness plus hospitalisation or death Any death during the follow-up period: 1. Reported COVID-19 like illness (time frame: 4 months' follow-up) 2. Consultation (time frame: 4 months' follow-up) 3. Severe illness (time frame: 4 months' follow-up) 4. Mortality (time frame: 4 months' follow-up)
Starting date	Estimated study start date: July 2020
Contact information	Amabelia Rodrigues, PhD, 00245966078659; a.rodrigues@bandim.org

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NCT04471766 *(Continued)*

Notes	The number of cases of COVID-19 is still increasing, and transmission of SARS-CoV-2 seems to occur mainly through person-to-person transmission through respiratory droplets, indirect contact with infected people and surfaces. The use of face masks is recommended as a public health measure, but in many settings only domestic cloth made masks are available to the majority of the people. However, masks can be of different quality, and very little is known about the utility of cloth face masks at the community level. In Bandim Health Project's Health and Demographic Surveillance System we evaluated the effect of providing locally produced cloth face masks on the severity of COVID-19 like illness and mortality in an urban population. The locally produced cloth mask is made according to a laboratory-certified model and was provided to the intervention group alongside information of how the risk of transmission can be reduced. The control group received information alone. Follow-up will be implemented through telephone calls and post epidemic home visits.

ARI: acute respiratory tract infections
GUV: germicidal ultraviolet
ILI: influenza-like illness
GI: gastrointestinal
n: number
RACF: residential aged care facilities
RCT: randomised controlled trial
SARS: severe acute respiratory syndrome

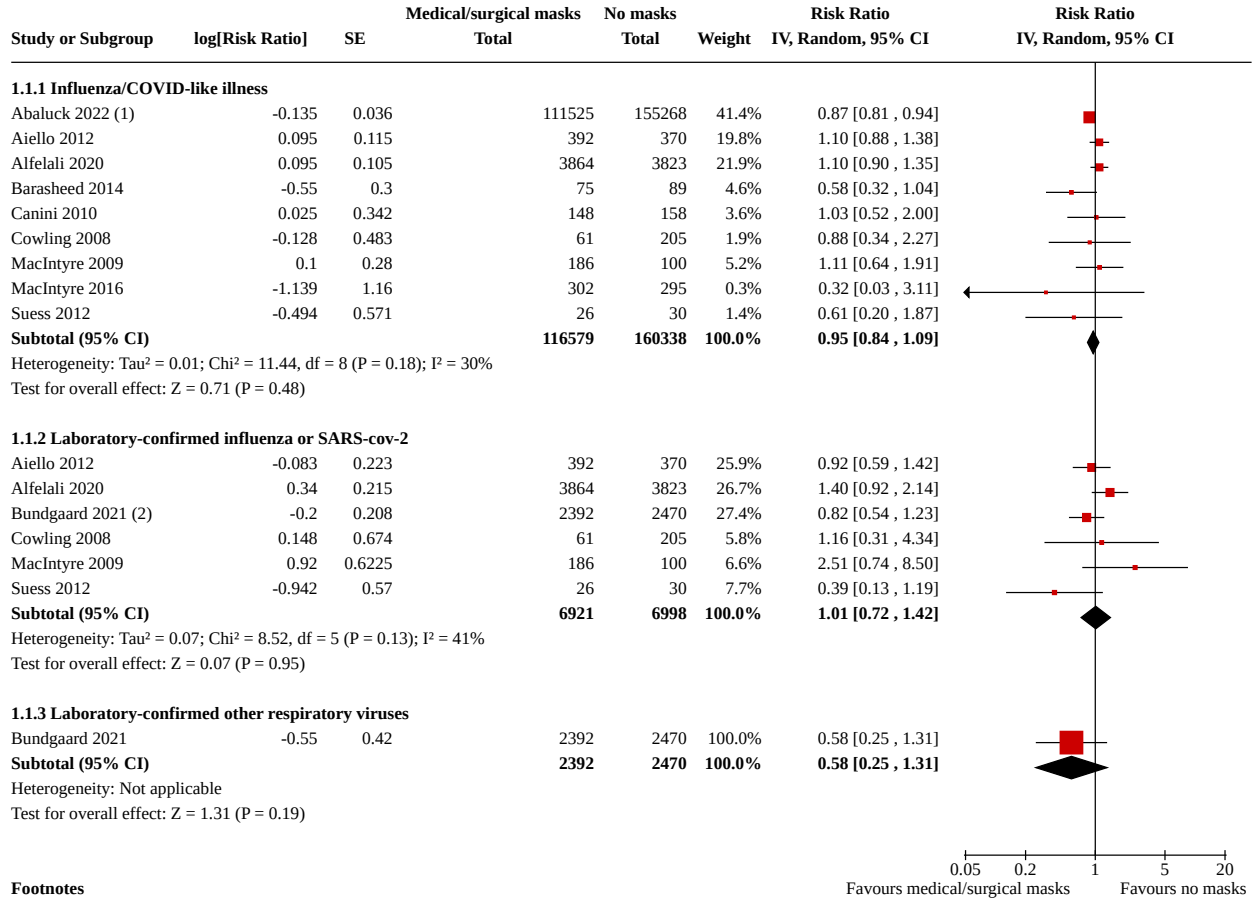
DATA AND ANALYSES

Comparison 1. Randomised trials: medical/surgical masks versus no masks

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Viral illness	10		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.1.1 Influenza/COVID-like illness	9	276917	Risk Ratio (IV, Random, 95% CI)	0.95 [0.84, 1.09]
1.1.2 Laboratory-confirmed influenza or SARS-cov-2	6	13919	Risk Ratio (IV, Random, 95% CI)	1.01 [0.72, 1.42]
1.1.3 Laboratory-confirmed other respiratory viruses	1	4862	Risk Ratio (IV, Random, 95% CI)	0.58 [0.25, 1.31]

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Analysis 1.1. Comparison 1: Randomised trials: medical/surgical masks versus no masks, Outcome 1: Viral illness



Study or Subgroup	log[Risk Ratio]	SE	Medical/surgical masks Total	No masks Total	Weight	Risk Ratio IV, Random, 95% CI
1.1.1 Influenza/COVID-like illness						
Abaluck 2022 (1)	-0.135	0.036	111525	155268	41.4%	0.87 [0.81 , 0.94]
Aiello 2012	0.095	0.115	392	370	19.8%	1.10 [0.88 , 1.38]
Alfelali 2020	0.095	0.105	3864	3823	21.9%	1.10 [0.90 , 1.35]
Barasheed 2014	-0.55	0.3	75	89	4.6%	0.58 [0.32 , 1.04]
Canini 2010	0.025	0.342	148	158	3.6%	1.03 [0.52 , 2.00]
Cowling 2008	-0.128	0.483	61	205	1.9%	0.88 [0.34 , 2.27]
MacIntyre 2009	0.1	0.28	186	100	5.2%	1.11 [0.64 , 1.91]
MacIntyre 2016	-1.139	1.16	302	295	0.3%	0.32 [0.03 , 3.11]
Suess 2012	-0.494	0.571	26	30	1.4%	0.61 [0.20 , 1.87]
Subtotal (95% CI)			**116579**	**160338**	**100.0%**	**0.95 [0.84 , 1.09]**
Heterogeneity: Tau² = 0.01; Chi² = 11.44, df = 8 (P = 0.18); I² = 30%						
Test for overall effect: Z = 0.71 (P = 0.48)						
1.1.2 Laboratory-confirmed influenza or SARS-cov-2						
Aiello 2012	-0.083	0.223	392	370	25.9%	0.92 [0.59 , 1.42]
Alfelali 2020	0.34	0.215	3864	3823	26.7%	1.40 [0.92 , 2.14]
Bundgaard 2021 (2)	-0.2	0.208	2392	2470	27.4%	0.82 [0.54 , 1.23]
Cowling 2008	0.148	0.674	61	205	5.8%	1.16 [0.31 , 4.34]
MacIntyre 2009	0.92	0.6225	186	100	6.6%	2.51 [0.74 , 8.50]
Suess 2012	-0.942	0.57	26	30	7.7%	0.39 [0.13 , 1.19]
Subtotal (95% CI)			**6921**	**6998**	**100.0%**	**1.01 [0.72 , 1.42]**
Heterogeneity: Tau² = 0.07; Chi² = 8.52, df = 5 (P = 0.13); I² = 41%						
Test for overall effect: Z = 0.07 (P = 0.95)						
1.1.3 Laboratory-confirmed other respiratory viruses						
Bundgaard 2021	-0.55	0.42	2392	2470	100.0%	0.58 [0.25 , 1.31]
Subtotal (95% CI)			**2392**	**2470**	**100.0%**	**0.58 [0.25 , 1.31]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.31 (P = 0.19)						

Footnotes
(1) Covid-like-illness
(2) SARS-cov-2

Comparison 2. Randomised trials: N95 respirators compared to medical/surgical masks

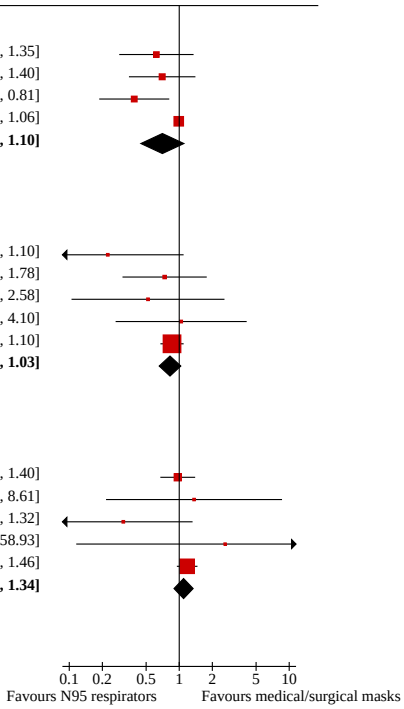
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Viral illness	5		Risk Ratio (IV, Random, 95% CI)	Subtotals only
2.1.1 Clinical respiratory illness	3	7799	Risk Ratio (IV, Random, 95% CI)	0.70 [0.45, 1.10]
2.1.2 Influenza-like illness	5	8407	Risk Ratio (IV, Random, 95% CI)	0.82 [0.66, 1.03]
2.1.3 Laboratory-confirmed influenza	5	8407	Risk Ratio (IV, Random, 95% CI)	1.10 [0.90, 1.34]
2.2 Viral illness in healthcare workers	4		Risk Ratio (IV, Random, 95% CI)	Subtotals only
2.2.1 Clinical respiratory illness	3	7799	Risk Ratio (IV, Random, 95% CI)	0.70 [0.45, 1.10]
2.2.2 Influenza-like illness	4	8221	Risk Ratio (IV, Random, 95% CI)	0.81 [0.59, 1.11]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.2.3 Laboratory-confirmed influenza	4	8221	Risk Ratio (IV, Random, 95% CI)	1.05 [0.79, 1.40]

Analysis 2.1. Comparison 2: Randomised trials: N95 respirators compared to medical/surgical masks, Outcome 1: Viral illness

Study or Subgroup	log[Risk Ratio]	SE	N95 respirators Total	Medical/surgical masks Total	Weight	Risk Ratio IV, Random, 95% CI
2.1.1 Clinical respiratory illness						
MacIntyre 2011	-0.478	0.397	949	492	18.5%	0.62 [0.28 , 1.35]
MacIntyre 2013 (1)	-0.357	0.355	516	286	20.8%	0.70 [0.35 , 1.40]
MacIntyre 2013	-0.942	0.374	581	286	19.7%	0.39 [0.19 , 0.81]
Radonovich 2019	-0.01	0.035	2243	2446	41.0%	0.99 [0.92 , 1.06]
Subtotal (95% CI)			**4289**	**3510**	**100.0%**	**0.70 [0.45 , 1.10]**
Heterogeneity: Tau² = 0.13; Chi² = 8.37, df = 3 (P = 0.04); I² = 64%						
Test for overall effect: Z = 1.54 (P = 0.12)						
2.1.2 Influenza-like illness						
Loeb 2009	-1.496	0.81	210	212	2.0%	0.22 [0.05 , 1.10]
MacIntyre 2009	-0.306	0.45	92	94	6.6%	0.74 [0.30 , 1.78]
MacIntyre 2011	-0.654	0.817	949	492	2.0%	0.52 [0.10 , 2.58]
MacIntyre 2013	0.04	0.7	1097	572	2.7%	1.04 [0.26 , 4.10]
Radonovich 2019	-0.151	0.124	2243	2446	86.7%	0.86 [0.67 , 1.10]
Subtotal (95% CI)			**4591**	**3816**	**100.0%**	**0.82 [0.66 , 1.03]**
Heterogeneity: Tau² = 0.00; Chi² = 3.19, df = 4 (P = 0.53); I² = 0%						
Test for overall effect: Z = 1.68 (P = 0.09)						
2.1.3 Laboratory-confirmed influenza						
Loeb 2009	-0.031	0.186	210	212	27.7%	0.97 [0.67 , 1.40]
MacIntyre 2009 (2)	0.31	0.94	92	94	1.2%	1.36 [0.22 , 8.61]
MacIntyre 2011	-1.171	0.74	949	492	1.9%	0.31 [0.07 , 1.32]
MacIntyre 2013	0.96	1.59	1097	572	0.4%	2.61 [0.12 , 58.93]
Radonovich 2019	0.166	0.11	2243	2446	68.8%	1.18 [0.95 , 1.46]
Subtotal (95% CI)			**4591**	**3816**	**100.0%**	**1.10 [0.90 , 1.34]**
Heterogeneity: Tau² = 0.00; Chi² = 4.15, df = 4 (P = 0.39); I² = 4%						
Test for overall effect: Z = 0.89 (P = 0.37)						



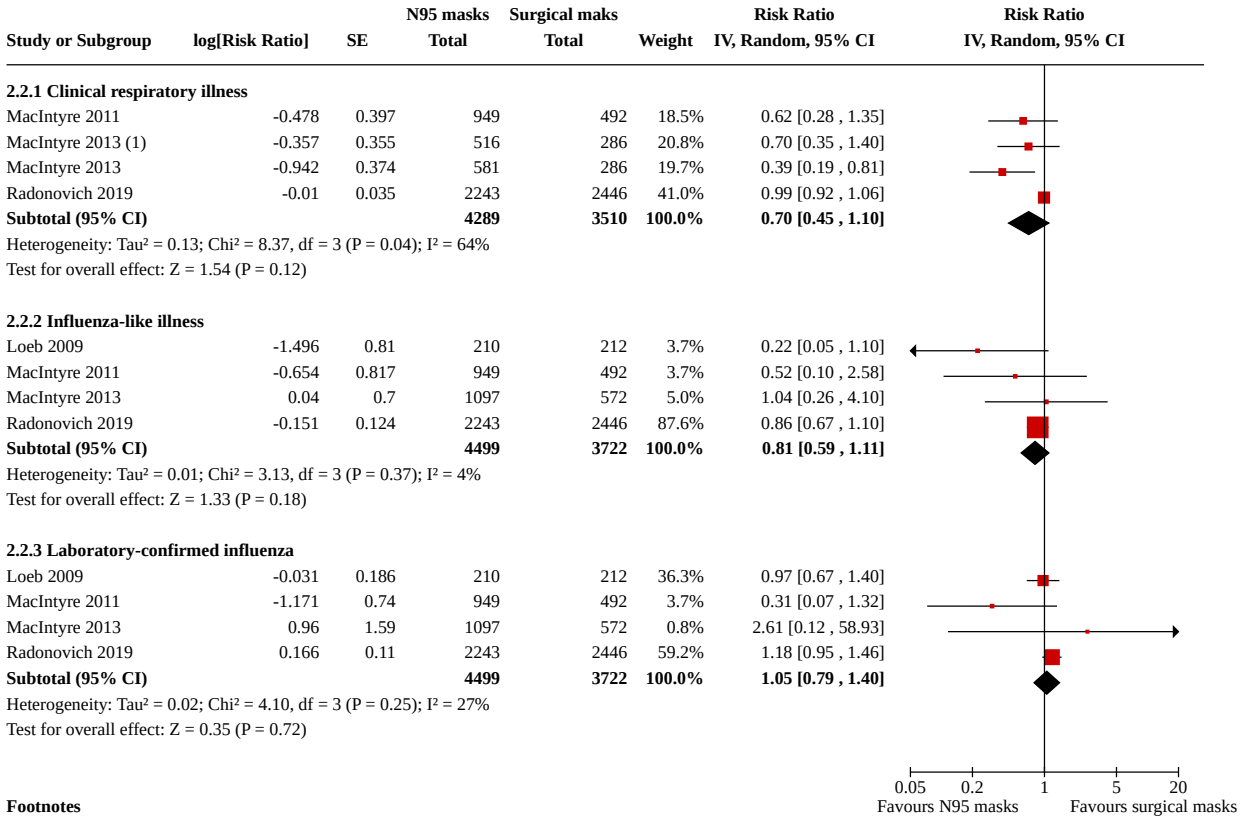
Footnotes

(1) MacIntyre 2013 includes 2 comparisons: N95 vs surgical masks and targeted N95 vs surgical masks

(2) MacIntyre 2009 reported on outcome laboratory confirmed infections

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Analysis 2.2. Comparison 2: Randomised trials: N95 respirators compared to medical/surgical masks, Outcome 2: Viral illness in healthcare workers



Footnotes

(1) MacIntyre 2013 includes 2 comparisons: N95 vs surgical masks and targeted N95 vs surgical masks

Comparison 3. Randomised trials: hand hygiene compared to control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Viral illness	19		Risk Ratio (IV, Random, 95% CI)	Subtotals only
3.1.1 Acute respiratory illness	9	52105	Risk Ratio (IV, Random, 95% CI)	0.86 [0.81, 0.90]
3.1.2 Influenza-like illness	11	34503	Risk Ratio (IV, Random, 95% CI)	0.94 [0.81, 1.09]
3.1.3 Laboratory-confirmed influenza	8	8332	Risk Ratio (IV, Random, 95% CI)	0.91 [0.63, 1.30]
3.2 ARI or ILI or influenza (including outcome with most events from each study)	19	71210	Risk Ratio (IV, Random, 95% CI)	0.89 [0.83, 0.94]
3.3 Influenza or ILI: sensitivity analysis including outcomes with the most precise and unequivocal definitions	12	28205	Risk Ratio (IV, Random, 95% CI)	0.88 [0.77, 1.02]

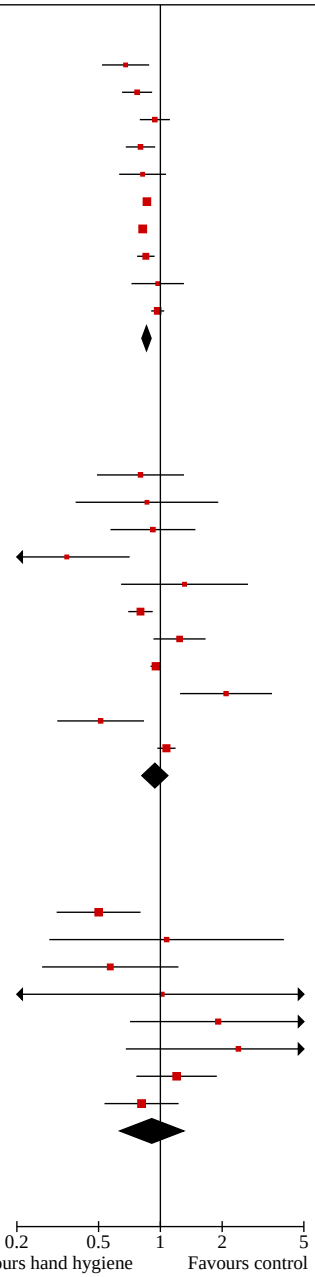
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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.4 ARI or ILI or influenza: subgroup analysis	19	71210	Risk Ratio (IV, Random, 95% CI)	0.89 [0.83, 0.94]
3.4.1 Children	11	29259	Risk Ratio (IV, Random, 95% CI)	0.91 [0.84, 0.98]
3.4.2 Adults	8	41951	Risk Ratio (IV, Random, 95% CI)	0.84 [0.78, 0.91]
3.5 Absenteeism	3	3150	Risk Ratio (IV, Random, 95% CI)	0.64 [0.58, 0.71]

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Analysis 3.1. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 1: Viral illness

Study or Subgroup	log[Risk Ratio]	SE	Hand hygiene Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
3.1.1 Acute respiratory illness						
Ashraf 2020	-0.39	0.135	588	1123	3.3%	0.68 [0.52 , 0.88]
Azor-Martinez 2018 (1)	-0.261	0.086	339	149	6.7%	0.77 [0.65 , 0.91]
Azor-Martinez 2018	-0.062	0.086	274	149	6.7%	0.94 [0.79 , 1.11]
Correa 2012	-0.223	0.084	794	933	6.9%	0.80 [0.68 , 0.94]
Larson 2010	-0.199	0.134	946	904	3.3%	0.82 [0.63 , 1.07]
Little 2015	-0.151	0.02	8241	8667	20.5%	0.86 [0.83 , 0.89]
Millar 2016	-0.198	0.016	10000	10000	21.4%	0.82 [0.80 , 0.85]
Nicholson 2014	-0.163	0.05	847	833	12.6%	0.85 [0.77 , 0.94]
Sandora 2005	-0.03	0.15	602	451	2.7%	0.97 [0.72 , 1.30]
Swarthout 2020	-0.03	0.037	1496	4769	15.9%	0.97 [0.90 , 1.04]
Subtotal (95% CI)			**24127**	**27978**	**100.0%**	**0.86 [0.81 , 0.90]**
Heterogeneity: Tau² = 0.00; Chi² = 24.86, df = 9 (P = 0.003); I² = 64%						
Test for overall effect: Z = 5.93 (P < 0.00001)						
3.1.2 Influenza-like illness						
Biswas 2019	-0.223	0.249	5077	5778	6.2%	0.80 [0.49 , 1.30]
Cowling 2008	-0.151	0.408	84	205	2.8%	0.86 [0.39 , 1.91]
Cowling 2009	-0.083	0.243	257	279	6.4%	0.92 [0.57 , 1.48]
Hubner 2010	-1.05	0.36	64	65	3.5%	0.35 [0.17 , 0.71]
Larson 2010	0.271	0.363	946	904	3.5%	1.31 [0.64 , 2.67]
Little 2015	-0.223	0.07	8241	8667	17.0%	0.80 [0.70 , 0.92]
Ram 2015	0.215	0.149	193	184	11.1%	1.24 [0.93 , 1.66]
Roberts 2000	-0.051	0.03	299	259	19.4%	0.95 [0.90 , 1.01]
Simmerman 2011	0.737	0.263	292	302	5.7%	2.09 [1.25 , 3.50]
Teesing 2021	-0.67	0.248	976	886	6.2%	0.51 [0.31 , 0.83]
Zomer 2015	0.068	0.052	278	267	18.2%	1.07 [0.97 , 1.19]
Subtotal (95% CI)			**16707**	**17796**	**100.0%**	**0.94 [0.81 , 1.09]**
Heterogeneity: Tau² = 0.03; Chi² = 38.62, df = 10 (P < 0.0001); I² = 74%						
Test for overall effect: Z = 0.83 (P = 0.41)						
3.1.3 Laboratory-confirmed influenza						
Biswas 2019	-0.693	0.24	508	689	19.8%	0.50 [0.31 , 0.80]
Cowling 2008	0.07	0.671	84	205	6.0%	1.07 [0.29 , 4.00]
Cowling 2009	-0.562	0.39	257	279	12.7%	0.57 [0.27 , 1.22]
Hubner 2010	0.02	0.834	64	65	4.2%	1.02 [0.20 , 5.23]
Larson 2010	0.648	0.504	946	904	9.2%	1.91 [0.71 , 5.13]
Ram 2015	0.875	0.644	193	184	6.4%	2.40 [0.68 , 8.48]
Simmerman 2011	0.182	0.23	292	302	20.4%	1.20 [0.76 , 1.88]
Stebbins 2011	-0.211	0.212	1695	1665	21.4%	0.81 [0.53 , 1.23]
Subtotal (95% CI)			**4039**	**4293**	**100.0%**	**0.91 [0.63 , 1.30]**
Heterogeneity: Tau² = 0.11; Chi² = 13.58, df = 7 (P = 0.06); I² = 48%						
Test for overall effect: Z = 0.53 (P = 0.60)						



Footnotes

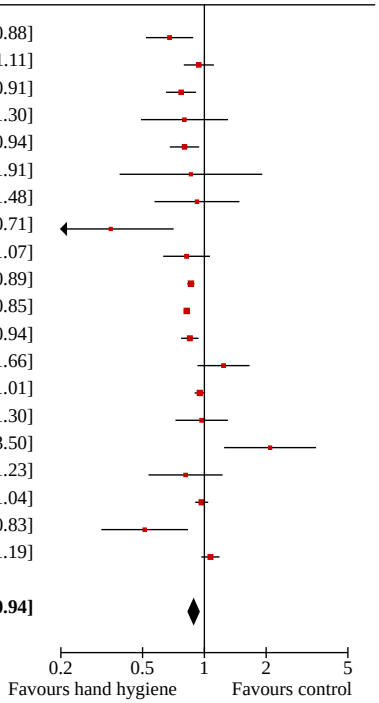
(1) Azor 2018 included 2 hand-washing groups: one using soap and water (RR 0.94) and the other using hand sanitizer (RR 0.77)

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Analysis 3.2. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 2: ARI or ILI or influenza (including outcome with most events from each study)

Study or Subgroup	log[Risk Ratio]	SE	Hand hygiene Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
Ashraf 2020	-0.39	0.135	588	1123	3.7%	0.68 [0.52 , 0.88]
Azor-Martinez 2018 (1)	-0.062	0.086	274	149	6.1%	0.94 [0.79 , 1.11]
Azor-Martinez 2018	-0.261	0.086	339	149	6.1%	0.77 [0.65 , 0.91]
Biswas 2019	-0.223	0.249	5077	5778	1.4%	0.80 [0.49 , 1.30]
Correa 2012	-0.223	0.084	794	933	6.3%	0.80 [0.68 , 0.94]
Cowling 2008	-0.151	0.408	84	205	0.6%	0.86 [0.39 , 1.91]
Cowling 2009	-0.083	0.243	257	279	1.5%	0.92 [0.57 , 1.48]
Hubner 2010	-1.05	0.36	64	65	0.7%	0.35 [0.17 , 0.71]
Larson 2010	-0.199	0.134	946	904	3.7%	0.82 [0.63 , 1.07]
Little 2015	-0.151	0.02	8241	8667	10.8%	0.86 [0.83 , 0.89]
Millar 2016	-0.198	0.016	10000	10000	11.0%	0.82 [0.80 , 0.85]
Nicholson 2014	-0.163	0.05	847	833	8.8%	0.85 [0.77 , 0.94]
Ram 2015	0.215	0.149	193	184	3.2%	1.24 [0.93 , 1.66]
Roberts 2000	-0.051	0.03	299	259	10.2%	0.95 [0.90 , 1.01]
Sandora 2005	-0.03	0.15	602	451	3.2%	0.97 [0.72 , 1.30]
Simmerman 2011	0.737	0.263	292	302	1.3%	2.09 [1.25 , 3.50]
Stebbins 2011	-0.211	0.212	1695	1665	1.8%	0.81 [0.53 , 1.23]
Swarthout 2020	-0.03	0.037	1496	4769	9.8%	0.97 [0.90 , 1.04]
Teesing 2021	-0.67	0.248	976	886	1.4%	0.51 [0.31 , 0.83]
Zomer 2015	0.068	0.052	278	267	8.6%	1.07 [0.97 , 1.19]
Total (95% CI)			**33342**	**37868**	**100.0%**	**0.89 [0.83 , 0.94]**

Heterogeneity: Tau² = 0.01; Chi² = 83.20, df = 19 (P < 0.00001); I² = 77%
Test for overall effect: Z = 3.83 (P = 0.0001)
Test for subgroup differences: Not applicable

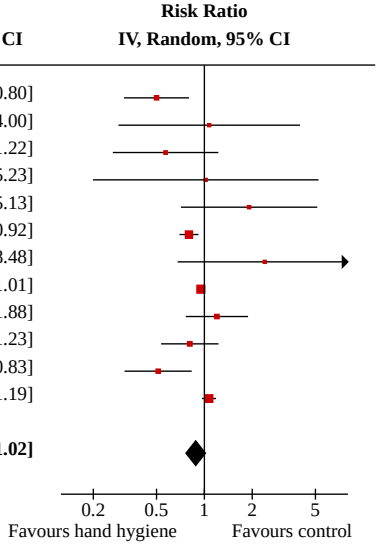


Footnotes
(1) Azor 2018 included 2 treatment groups: soap and water (RR 0.94); and hand sanitizer (RR 0.77)

Analysis 3.3. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 3: Influenza or ILI: sensitivity analysis including outcomes with the most precise and unequivocal definitions

Study or Subgroup	log[Risk Ratio]	SE	Hand hygiene Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
Biswas 2019	-0.693	0.24	508	689	6.6%	0.50 [0.31 , 0.80]
Cowling 2008	0.07	0.671	84	205	1.1%	1.07 [0.29 , 4.00]
Cowling 2009	-0.562	0.39	257	279	3.0%	0.57 [0.27 , 1.22]
Hubner 2010	0.02	0.834	64	65	0.7%	1.02 [0.20 , 5.23]
Larson 2010	0.648	0.504	946	904	1.9%	1.91 [0.71 , 5.13]
Little 2015	-0.223	0.07	8241	8667	19.7%	0.80 [0.70 , 0.92]
Ram 2015	0.875	0.644	193	184	1.2%	2.40 [0.68 , 8.48]
Roberts 2000	-0.051	0.03	299	259	23.3%	0.95 [0.90 , 1.01]
Simmerman 2011	0.182	0.23	292	302	7.0%	1.20 [0.76 , 1.88]
Stebbins 2011	-0.211	0.212	1695	1665	7.8%	0.81 [0.53 , 1.23]
Teesing 2021	-0.67	0.248	976	886	6.3%	0.51 [0.31 , 0.83]
Zomer 2015	0.068	0.052	278	267	21.5%	1.07 [0.97 , 1.19]
Total (95% CI)			**13833**	**14372**	**100.0%**	**0.88 [0.77 , 1.02]**

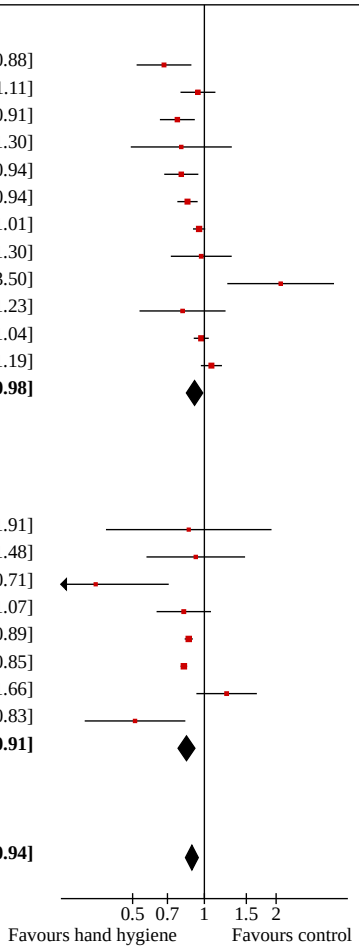
Heterogeneity: Tau² = 0.02; Chi² = 31.95, df = 11 (P = 0.0008); I² = 66%
Test for overall effect: Z = 1.75 (P = 0.08)
Test for subgroup differences: Not applicable



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Analysis 3.4. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 4: ARI or ILI or influenza: subgroup analysis

Study or Subgroup	log[Risk Ratio]	SE	Hand hygiene Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
3.4.1 Children						
Ashraf 2020	-0.39	0.135	588	1123	3.7%	0.68 [0.52 , 0.88]
Azor-Martinez 2018	-0.062	0.086	274	149	6.1%	0.94 [0.79 , 1.11]
Azor-Martinez 2018 (1)	-0.261	0.086	339	149	6.1%	0.77 [0.65 , 0.91]
Biswas 2019	-0.223	0.249	5077	5778	1.4%	0.80 [0.49 , 1.30]
Correa 2012	-0.223	0.084	794	933	6.3%	0.80 [0.68 , 0.94]
Nicholson 2014	-0.163	0.05	847	833	8.8%	0.85 [0.77 , 0.94]
Roberts 2000	-0.051	0.03	299	259	10.2%	0.95 [0.90 , 1.01]
Sandora 2005	-0.03	0.15	602	451	3.2%	0.97 [0.72 , 1.30]
Simmerman 2011	0.737	0.263	292	302	1.3%	2.09 [1.25 , 3.50]
Stebbins 2011	-0.211	0.212	1695	1665	1.8%	0.81 [0.53 , 1.23]
Swarthout 2020	-0.03	0.037	1496	4769	9.8%	0.97 [0.90 , 1.04]
Zomer 2015	0.068	0.052	278	267	8.6%	1.07 [0.97 , 1.19]
Subtotal (95% CI)			**12581**	**16678**	**67.2%**	**0.91 [0.84 , 0.98]**
Heterogeneity: Tau² = 0.01; Chi² = 36.24, df = 11 (P = 0.0002); I² = 70%						
Test for overall effect: Z = 2.36 (P = 0.02)						
3.4.2 Adults						
Cowling 2008	-0.151	0.408	84	205	0.6%	0.86 [0.39 , 1.91]
Cowling 2009	-0.083	0.243	257	279	1.5%	0.92 [0.57 , 1.48]
Hubner 2010	-1.05	0.36	64	65	0.7%	0.35 [0.17 , 0.71]
Larson 2010	-0.199	0.134	946	904	3.7%	0.82 [0.63 , 1.07]
Little 2015	-0.151	0.02	8241	8667	10.8%	0.86 [0.83 , 0.89]
Millar 2016	-0.198	0.016	10000	10000	11.0%	0.82 [0.80 , 0.85]
Ram 2015	0.215	0.149	193	184	3.2%	1.24 [0.93 , 1.66]
Teesing 2021	-0.67	0.248	976	886	1.4%	0.51 [0.31 , 0.83]
Subtotal (95% CI)			**20761**	**21190**	**32.8%**	**0.84 [0.78 , 0.91]**
Heterogeneity: Tau² = 0.00; Chi² = 20.32, df = 7 (P = 0.005); I² = 66%						
Test for overall effect: Z = 4.17 (P < 0.0001)						
Total (95% CI)			**33342**	**37868**	**100.0%**	**0.89 [0.83 , 0.94]**
Heterogeneity: Tau² = 0.01; Chi² = 83.20, df = 19 (P < 0.00001); I² = 77%						
Test for overall effect: Z = 3.83 (P = 0.0001)						
Test for subgroup differences: Chi² = 1.83, df = 1 (P = 0.18), I² = 45.2%						

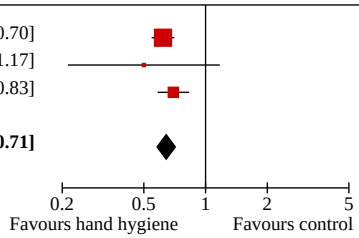


Footnotes

(1) Azor 2018 includes 2 intervnetion groups: soap and water (RR 0.94) and hand sanitizer (RR 0.77)

Analysis 3.5. Comparison 3: Randomised trials: hand hygiene compared to control, Outcome 5: Absenteeism

Study or Subgroup	log[Risk Ratio]	SE	Hand Hygiene Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
Azor-Martinez 2016	-0.478	0.065	621	720	64.8%	0.62 [0.55 , 0.70]
Hubner 2010	-0.693	0.435	64	65	1.4%	0.50 [0.21 , 1.17]
Nicholson 2014	-0.362	0.09	847	833	33.8%	0.70 [0.58 , 0.83]
Total (95% CI)			**1532**	**1618**	**100.0%**	**0.64 [0.58 , 0.71]**
Heterogeneity: Tau² = 0.00; Chi² = 1.43, df = 2 (P = 0.49); I² = 0%						
Test for overall effect: Z = 8.45 (P < 0.00001)						
Test for subgroup differences: Not applicable						

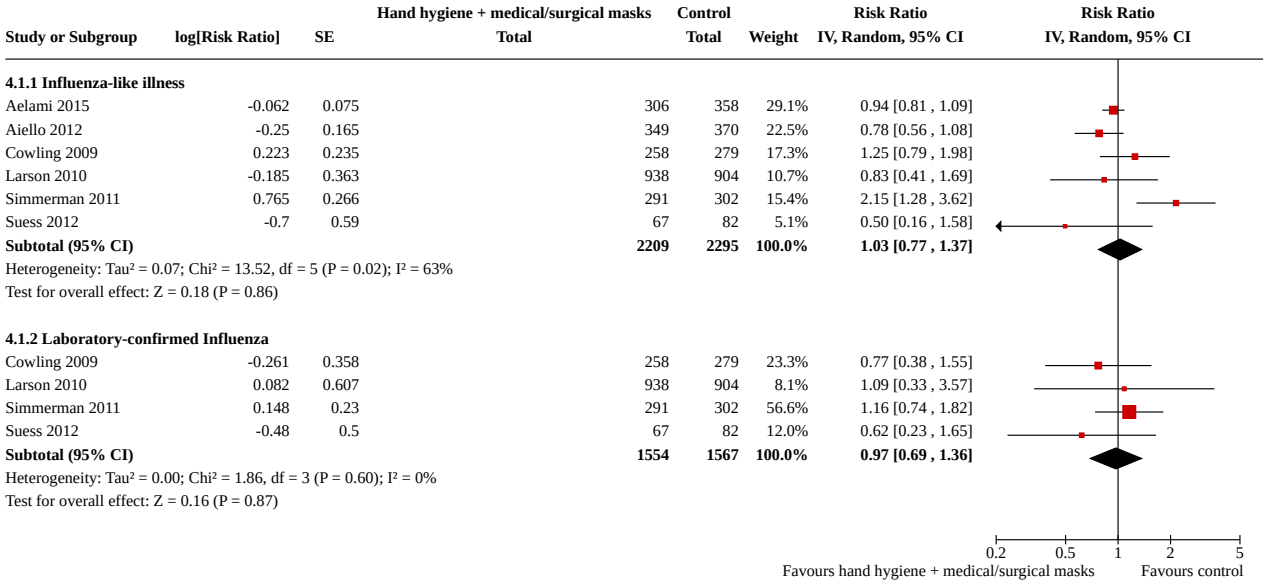


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Comparison 4. Randomised trials: hand hygiene + medical/surgical masks compared to control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Viral illness	6		Risk Ratio (IV, Random, 95% CI)	Subtotals only
4.1.1 Influenza-like illness	6	4504	Risk Ratio (IV, Random, 95% CI)	1.03 [0.77, 1.37]
4.1.2 Laboratory-confirmed Influenza	4	3121	Risk Ratio (IV, Random, 95% CI)	0.97 [0.69, 1.36]

Analysis 4.1. Comparison 4: Randomised trials: hand hygiene + medical/surgical masks compared to control, Outcome 1: Viral illness

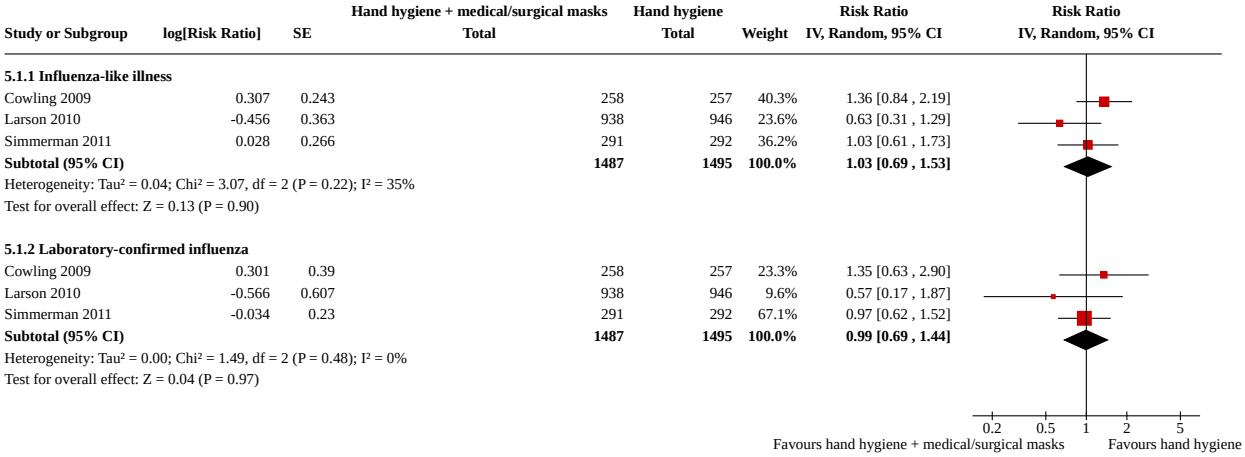


Comparison 5. Randomised trials: hand hygiene + medical/surgical masks compared to hand hygiene

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Viral illness	3		Risk Ratio (IV, Random, 95% CI)	Subtotals only
5.1.1 Influenza-like illness	3	2982	Risk Ratio (IV, Random, 95% CI)	1.03 [0.69, 1.53]
5.1.2 Laboratory-confirmed influenza	3	2982	Risk Ratio (IV, Random, 95% CI)	0.99 [0.69, 1.44]

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Analysis 5.1. Comparison 5: Randomised trials: hand hygiene + medical/surgical masks compared to hand hygiene, Outcome 1: Viral illness

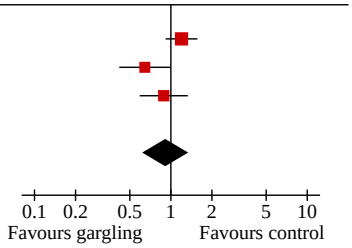


Study or Subgroup	log[Risk Ratio]	SE	Hand hygiene + medical/surgical masks Total	Hand hygiene Total	Weight	Risk Ratio IV, Random, 95% CI
5.1.1 Influenza-like illness						
Cowling 2009	0.307	0.243	258	257	40.3%	1.36 [0.84 , 2.19]
Larson 2010	-0.456	0.363	938	946	23.6%	0.63 [0.31 , 1.29]
Simmerman 2011	0.028	0.266	291	292	36.2%	1.03 [0.61 , 1.73]
Subtotal (95% CI)			**1487**	**1495**	**100.0%**	**1.03 [0.69 , 1.53]**
Heterogeneity: Tau² = 0.04; Chi² = 3.07, df = 2 (P = 0.22); I² = 35%						
Test for overall effect: Z = 0.13 (P = 0.90)						
5.1.2 Laboratory-confirmed influenza						
Cowling 2009	0.301	0.39	258	257	23.3%	1.35 [0.63 , 2.90]
Larson 2010	-0.566	0.607	938	946	9.6%	0.57 [0.17 , 1.87]
Simmerman 2011	-0.034	0.23	291	292	67.1%	0.97 [0.62 , 1.52]
Subtotal (95% CI)			**1487**	**1495**	**100.0%**	**0.99 [0.69 , 1.44]**
Heterogeneity: Tau² = 0.00; Chi² = 1.49, df = 2 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.04 (P = 0.97)						

Comparison 6. Randomised trials: gargling compared to control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Viral illness	2	830	Risk Ratio (IV, Random, 95% CI)	0.91 [0.63, 1.31]
6.2 SARS-CoV-2	2	394	Risk Ratio (IV, Random, 95% CI)	0.07 [0.02, 0.23]

Analysis 6.1. Comparison 6: Randomised trials: gargling compared to control, Outcome 1: Viral illness



Study or Subgroup	log[Risk Ratio]	SE	Gargling Total	Control Total	Weight	Risk Ratio IV, Random, 95% CI
Goodall 2014	0.18	0.137	256	236	39.5%	1.20 [0.92 , 1.57]
Satomura 2005 (1)	-0.44	0.22	104	57	29.5%	0.64 [0.42 , 0.99]
Satomura 2005	-0.12	0.207	119	58	31.0%	0.89 [0.59 , 1.33]
Total (95% CI)			**479**	**351**	**100.0%**	**0.91 [0.63 , 1.31]**
Heterogeneity: Tau² = 0.07; Chi² = 6.01, df = 2 (P = 0.05); I² = 67%						
Test for overall effect: Z = 0.52 (P = 0.61)						
Test for subgroup differences: Not applicable						

Footnotes

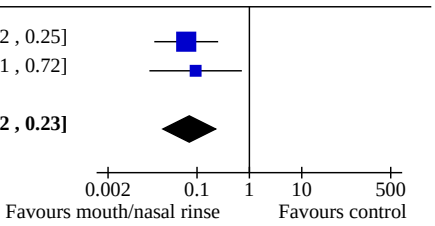
(1) Satomura 2005 included 2 intervention groups

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Analysis 6.2. Comparison 6: Randomised trials: gargling compared to control, Outcome 2: SARS-CoV-2

Study or Subgroup	Mouth/nose rinse Events	Total	Control Events	Total	Weight	Risk Ratio IV, Random, 95% CI
Almanza-Reyes 2021	2	114	33	117	67.7%	0.06 [0.02 , 0.25]
Gutiérrez-García 2022	1	84	10	79	32.3%	0.09 [0.01 , 0.72]
Total (95% CI)		**198**		**196**	**100.0%**	**0.07 [0.02 , 0.23]**
Total events:	3		43			

Heterogeneity: Tau² = 0.00; Chi² = 0.11, df = 1 (P = 0.74); I² = 0%
Test for overall effect: Z = 4.49 (P < 0.00001)
Test for subgroup differences: Not applicable



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ADDITIONAL TABLES

Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist

Author, year	Brief name	Recipient	Why	What (materials)	What (procedures)	Who provided	How	Where	When and how much	Tailoring	Modification of intervention throughout trial	Strategies to improve or maintain intervention fidelity	Extent of intervention fidelity
Masks compared to either no masks or different mask types													
Abaluck 2022 (additional sources: Abaluck 2021a, Abaluck 2021b, Kwong 2021)	Community-level mask promotion and distribution of free masks. A. Cloth masks or B. Surgical masks with possible additional village level elements: i) incentive	Leaders and adult householders of rural and peri-urban villages	Increase large-scale adoption and proper wearing of face masks to slow the spread of COVID-19 and save lives informed by research in public health, psychology, eco-	Masks colour-coded by households, either: A. cloth masks: an exterior layer of 100% non-woven polypropylene (70 grams/m^2 [gsm]), 2 interior layers of 60% cotton/40% polyester interlocking knit (190 gsm), an elastic loop that goes around the head above and below the ears, and a nose bridge; filtration efficiency: 37%[1] B. 3 layers of 100% non woven polypropy-	All villages: 1. household distribution of surgical or cloth masks and showing of mask-wearing video; 2. distribution and promotion of masks at village markets; 3. mask distribution at mosques; 4. mask promotion in public spaces; 5. role modelling and advocacy by local leaders, including Imams during Friday prayers using a scripted speech. Periodic monitoring of passers-by and reminding people to put on masks	Local NGO staff and volunteers (Bangladesh NGO Green-Voice)[5] and Innovations for Poverty Action (IPA) Village Imams and police officers No "spe-	Masks and promotion delivered face to face in households, markets, mosques and streets of villages both as groups and individually Text messages delivered by	Households, markets, mosques and streets of 572 villages (in rural Bangladesh)	8 weeks per village rolled out over a 6 week period (November 2020 to January 2021) 1 day of training per village Once off mask distribution and promotion at households (4 days / village)	Periodic monitoring and then additional training of staff provided as needed Different locations and timing of observation across different days	In the first 5 weeks of the study staff found low engagement in some villages with local mask use, so mask promotion staff were retrained by researcher partway through the in-	Numbers of masks distributed was noted Promoters periodically monitored passers-by and reminded people to put on masks Direct surveillance of mask wearing, correct mask-	Numbers of masks distributed: A. 370,643 B. 924,849 Mask-wearing: IGs: 42.3% CG: 13.3% Increase was largest in mosques (37% points) and 25% to 29% points in

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	ii) signage iii) text message reminder and household elements: i) altruism or self-protection messages ii) amount of households receiving texts iii) commitment to mask-wearing	nomics, marketing, and other social sciences on product promotion and dissemination strategies	lene[2], elastic ear loops, and a nose bridge; filtration efficiency: 95%. Sticker that had a logo of a mask with an outline of the Bangladeshi flag and a phrase in Bengali that noted the mask could be washed and reused[3]; filtration efficiency of 76% Initial 3 masks per household Video of notable public figures[4] discussing why, how, and when to wear a mask Brochure based on WHO materials depicting proper mask-wearing Scripted speeches for	Some villages: village police accompanying mask promoters, providing monetary rewards or certificates to villages if mask-wearing rate improves. Some villages: public signalling of mask-wearing via signage, text message reminders, messaging emphasizing either altruistic or self-protection motives for mask-wearing, and extracting verbal commitments from households. Modelling of safe mask wearing by study staff Detailed procedures outlined in online protocol supplement osf.io/23mws/	cialized skills" needed as intervention designed to be easily adopted by other NGOs or agencies Training of staff provided by researchers for mask promotion	phone and individually	Mask distribution 3 to 6 days / week at markets and on 3 Fridays at mosques during the first 4 weeks Weekly or biweekly mask promotion Role-modelling and leader advocacy at Friday prayers Periodic monitoring: 1/ week on weeks 1, 2, 4, 6, 8, and 10;	tervention "to work more closely with local leaders and set specific milestones for that partnership" After 5 weeks, monitoring of mask-wearing was limited to those who appeared to be 18 years or older.	wearing (wearing either a project mask or an alternative face-covering over the mouth and nose) and physical distancing (if s/he was at least one arm's length away from the nearest person)[6] Monetary rewards or certificates to villages if mask-wearing rate improved Additional training	other locations Proper mask-wearing increased by 29.0% Physical distancing increased from 24.1% in CG villages to 29.2% in IG villages No difference between IGs and CGs in number of people observed in public areas, as an indication of social distancing.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	use by role models and local leaders at Friday prayers		daily schedule provided in Protocol – 1 hour per site for 9 sites 8am to 5pm		for mask promotion staff	
	Scripted text messages				Recording of activities undertaken by intervention staff including the degree to which leaders or imams understood the script, sites observed etc (see p.9 of Protocol osf.io/23mws/) "consistent with the WHO guideline that defines physical distancing as one meter of separation."
	Monetary rewards (USD 190) or non-monetary reward (certificate) for villages		Each village observed on 2 alternating days of the week.			
	Signage for household doors declaring they are a mask-wearing household		Observations occurred 7 days of the week (9 am to 7 pm)			
	Smart phone for delivery and receipt of text message reminders		Detailed schedules provided in online protocol supplement via osf.io/23mws/			
	Loudspeaker for announcements in markets by research staff					

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

						Masks woven by and procured from local Bangladeshi garment factories within 6 weeks after ordering: $0.50 per cloth mask and $0.13 per surgical mask	www.who.int/western-pacific/emergencies/covid-19/information/physical-distancing (accessed 13 June 2022).
						Masks and hand sanitiser for staff delivering intervention Costs: Cloth masks: $275.10/village Surgical masks: $88.90/village PPE for staff: $70/village Media costs: $100/village Transport and other costs: $30/village	
						Handouts and written and some audio scripts for role	

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

				models, leaders, surveillance officers and texts etc provided by the research team and in online protocol supplement via osf.io/23mws/									
Alfelali 2020	Face masks	Hajj pilgrims aged ≥ 18 years	Prevent and control viral respiratory infections at mass gatherings	50 surgical face masks per participant (3M™ Standard Tie-On surgical mask, Cat No: 1816) Written instructions for mask use (See S1 Appendix)	Provide masks and verbal and printed instructions, rules for mask use and demonstration of appropriate mask usage provided (See S1 Appendix) Rules for mask use: • "Try to avoid touching the front of the mask. • Change your mask if it is damp, wet or dirty. • Always clean your hands before and after changing the masks. • Put used masks in a plastic bag and throw it into a rubbish bin. You will find bins somewhere close to your tent in Mina."	464 volunteer trained research team members approached pilgrims in their tents Training included how to approach pilgrims and explanation and demonstration of	Individually and face to face to groups of pilgrims in tents	Tents of pilgrims for Hajj in Makkah (Saudi Arabia) 50 to 150 pilgrims per large tent, sleeping head-to-head and sharing meals and rites	Mask wearing for 24 hours if possible, over days of Hajj season inside and outside assigned tents 3 consecutive Hajj seasons (5 to 6 days, October 2013 to 2015)	Written information provided in preferred language (Arabic or English) Pilgrims who used at least 1 mask each day were considered to have used the mask during that day (i.e.	None described	4 day diaries of mask use: number of masks used and hours worn each day (see S1 Appendix)	Mask use: IG: Daily: 24.7% Intermittently: 47.7% None: 20.9% CG: Daily: 14.3% Intermittently: 34.9% None: 43.7% Mask use of at least 4 hours consistently greater

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

					mask use				could be < 24 hours)			in IG than CG
Barasheed 2014	Supervised mask use	Religious pilgrims ≥ 15 years	Prevent respiratory virus infections at mass gatherings through mask use	Plain surgical face masks (3M Standard Tie-On Surgical Mask, Cat No: 1816) manufactured by 3M company, USA; 5 masks per day Written instructions on face mask use Special polythene bags for disposal	Masks provided to index case and their contacts with advice on mask use (before prayers, in seminars, and after meals). Written instructions provided on face mask use, need to change them, and disposal.	Not described, presumably the medical researchers	Face-to-face provision of masks, instructions, and reminders	Tents of pilgrimage site (Mina Valley, Saudi Arabia)	Advice on mask use given throughout pilgrimage stay (5 days)	None reported.	None reported.	The medical researchers followed pilgrims each day to remind participants about recording their mask usage in health diary.	Face mask use: mask group: 56/75 (76%), control group: 11/89 (12%) (P < 0.001) 76% of intervention tents wore masks. 10 of 75 (13%) pilgrims in 'mask' tents wore face masks during sleep.
Bundgaard 2021 (additional source- Bundgaard 2020)	Face masks (surgical)	Community-dwelling adults aged 18 years or older with inter-	Reduce wearers' risk for SARS-CoV-2 infection out-	Per participant: 50 x 3-layer, disposable, surgical face masks with ear loops (TYPE II EN 14683 (Abena, Denmark); filtration rate,	Supply of masks sent to home address by courier Provision of written instructions sent by courier about how and when to wear masks including	Researchers provided the masks (funded by Salling Group), in-	Individually by mail, email, online and telephone	Mask wearing: when outside the home - and in the	Mask wearing: whenever outside the home or when guests in the home,	Changing of mask if worn for more than 8 hours	None described	Face mask adherence: Self-report (Yes / Partial / No) (Suppl 4)	Face mask adherence: % Adhere: 46% Partial: 47% No: 7%

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	net access	side the home through protection of the nose and mouth from droplets or aerosols or contaminated fingers and hands	98%; made in China) 1 badge (saying: "I am testing face masks – for you and me") Written instructions and instructional videos for proper use of masks (See supplement 8) of published paper including link to video for proper face mask use [in Danish] vimeo.com/406952695	links to instructional video for face mask use Instruction to follow advice of local health authorities (in Denmark) Provision of follow-up support by email and a phone help-line for questions	structions and follow-up support Background and training of researcher not described Hotline provided medical expertise and guidance, (qualification and training needed for this support not specified)	home when they had guests (in Denmark) Instructions and support at home and online	up to 8 hours for 1 mask, for 1 month (April to May 2020) 1 off instructions for mask use and again as needed Weekly follow-up emails Hotline available at all times during study period	If guests in the home, wear mask Individualised support as needed via email or telephone	Average mask use per day Self-assessed adherence with health authority guideline on social distancing and hygiene (Suppl)	Mean face masks used: Weekdays: 1.7 Weekends: 1.3 Health authority guidance adherence not reported

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

Canini 2010	Surgical face masks	Householders (over 5 years)	Limit transmission of influenza transmission by large droplets produced during coughing in households	Initial supply of 30 masks: for adults and children > 10: surgery masks with ear loops, 3 plys, anti fog (AEROKYN, LCH medical products, Paris, France) Children 5 to 10: face mask KC47127, (Kimberly-Clark, Dallas, TX, USA) Closed plastic bags for disposal	Masks given immediately on home visit by attending general practitioner with demonstration of proper use and instruction to be worn for 5 days in presence of another household member or in confined space (e.g. car) and to change every 3 hours or if damaged.	General practitioners	Face-to-face individually	Households in France	One-off provision of masks worn for 5 days	None described.	None described.	Not described, but reported mask usage was measured	34/51 (66%) wore masks > 80% of the duration. Reported mask-wearing: 11 ± 7.2 masks during 4.0 ± 1.6 days with an average use of 2.5 ± 1.3 masks per day and duration of use of 3.7 ± 2.7 hours/day
Jacobs 2009	Face masks	Hospital healthcare providers (nurses, doctors, and co-medical personnel)	Decrease risk of infection through limiting droplet spread through masks	Hospital-standard disposable surgical Mask MA-3 (Ozu Sangyo, Tokyo, Japan); quantity not specified	Provision of masks and instructions for use	Not described, presumably research team	Face-to-face	Tertiary care hospital in Tokyo, Japan Face masks worn whilst on hospital property.	77 days	None described.	None described.	Self-reported adherence	Self-reported adherence for both groups reported as good, with full adherence by 84.3% and remainder complying

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

													79.2% to 98.7%.
Loeb 2009	2 active interventions A. surgical masks B. N95 respirators	Healthcare workers (nurses)	Reduce transmission of influenza in healthcare settings through coughing or sneezing with protective masks	A. Surgical masks B. N95 respirators	Provision of masks or N95 respirators Instruction in use and proper placement of devices Fit-testing and demonstration of positioning of N95 using standard protocol and procedure (details provided) Qualitative fit-testing using saccharin or Bitrex protocol[7]	Provided by research team (not further described) Fit-testing by technician for N95	In-person face-to-face	Tertiary hospitals in Ontario, Canada	1 influenza season (12 weeks) Use of mask as required[8] when providing care to or within 1 m of patient with febrile respiratory illness, ≥ 38 °C, and new or worsening cough or shortness of breath Nurses to wear N95 when caring for patients with "febrile respira-	Fit-testing of nurses not already fit-tested	Ceased before end of season	Adherence audits during peak of season by trained auditor who stood short distance from patient isolation room	18 episodes: N95: 6/7 participants (85.7%) wearing assigned device versus 100% for masks

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

									tory illness"				
MacIntyre 2009	2 active interventions in addition to infection control guidelines A. Surgical masks (SM) B. P2 masks (P2)	Householders with a child with fever and respiratory symptoms	Prevent or reduce respiratory virus transmission in the community through non-pharmaceutical interventions	A. 3M surgical mask, catalogue no. 1820; St Paul, MN, USA for adults B. P2 masks (3M flat-fold P2 mask, catalogue no. 9320; Bracknell, Berkshire, UK) A and B: health guidelines and pamphlets about infection control	Provision of masks and pamphlets and education about infection prevention and mask use Telephone calls and exit interviews to record adherence to mask use All groups: health guidelines, pamphlets about infection control were provided	Not described, presumably research team	Face-to-face and by telephone	Households in Sydney, Australia	2 winter seasons (3 months and 6 months) 2 weeks of follow-up Masks to be worn at all times when in same room as index child, regardless of distance from child	None described.	None described.	Daily telephone calls to record mask use throughout day Exit interviews about adherence	Reported mask use: Day 1 SM: 36/94 (38%) P2: 42/92 (46%) stated wearing "most or all" of the time. Other participants were wearing face masks rarely or never. Day 5: SM: 29/94 (31%) P2: 23/92 (25%)
MacIntyre 2011	3 active interventions A. Medical masks	Healthcare workers	Protect HCWs by preventing transmis-	Daily supply of A. 3 medical masks (3M medical mask, catalogue number 1820, St Paul, MN, USA)	Supply of masks or respirators. Instruction in when to wear it, correct fitting, and storage (in paper bag in personal locker)	Masks provided to hospitals. Training of	Masks and training provided face-	Emergency departments and respi-	Entire work shift for 4 weeks	Taken off for toilet and meal breaks and at	None described.	Mask/respirator use monitored by: (i) observed	Adherence for usage was high for all and not

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	B. N95 respirators fit-tested C. N95 respirators non-fit-tested		sion of influenza and other respiratory viruses from patients through mask wearing	2 respirators: B. N95 fit-tested mask (3M flat-fold N95 respirator, catalogue number 9132) fit-tested with 3M FT-30 Bitrex Fit Test kit according to manufacturer's instructions (3M, St Paul, MN, USA) C. N95 non-fit-tested mask (3M flat-fold N95 respirator, catalogue number 9132) Diary cards for usage recording	Instruction in importance of hand hygiene before and after removal For fit-tested group: fit-testing procedure	staff provided by 1 member of research team.	to-face, not described if training was individually or in groups.	ratory wards in hospitals in Beijing, China		end of shift		adherence by head ward nurse recorded daily; (ii) self-report diary cards carried during day recording; (i) no. hours; (ii) usage. Exit interviews	significantly different amongst arms. Medical mask: 76%, 5 hours N95 fit-tested: 74%, 5.2 hours N95 non-fit-tested: 68%, 4.9 hours
MacIntyre 2013	3 active interventions A. N95 respirators at all times B. N95 respirators targeted use C. Medical masks	Healthcare workers (nurses and doctors)	Protect HCWs from respiratory infections from patients through mask use	Daily supply of: A. and B. 2 respirators (3M Health Care N95 Particulate Respirator; catalogue number 1860) 3M FT-30 Bitrex Fit Test Kit C. 3 masks 3 masks (3M Standard Tie-On Surgical Mask catalogue number mask 1817; 3M, St Paul, MN, USA) Pocket-sized diary card with	Supply of respirators Instructions in use including times and fit Fit-testing procedure according to the manufacturer's instructions (3M) For targeted N95: checklist of defined high-risk procedures, including common aerosol-generating procedures	3M supplied respirators and masks. Provider of instructions not specified.	Masks and training provided face-to-face, not described if training was individually or in groups.	Emergency departments and respiratory wards of tertiary hospitals in Beijing, China	For 4 weeks, A and B worn at all times on shift; B. targeted (intermittent) use of N95 respirators only whilst performing high-risk procedures or barrier.	None described.	None described.	Self-reported daily record of number of hours worked, mask or respirator use, number of high-risk procedures undertaken collected by study staff.	Adherence highest for targeted N95 (82%; 422/516) versus N95 (57%; 333/581) versus medical mask (66%; 380/572).

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

				tick boxes for mask use									
MacIntyre 2015	2 active interventions A. Cloth masks B. Medical masks	Hospital healthcare workers	Prevent respiratory infections in HCWs from patients through mask-wearing	A. 5 cloth masks for study duration (2- layer, cotton) B. 2 medical masks daily for each 8-hour shift for study duration (3 layers, non-woven material) All masks locally manufactured. Written instructions on cleaning cloth masks	Cloth or medical masks to be worn at all times on shift. Cloth masks to be washed with soap and water daily after shifts, and the process of cleaning to be documented. Provision of written instructions for cloth mask cleaning	Researchers arranged supply of masks and instructions and any training of staff assisting the delivery.	Masks and written instructions provided face-to-face.	Hospital wards in Vietnam	4 weeks (25 days) of face mask use	Masks not worn while in the toilet or during tea or lunch breaks.	None described.	Monitored adherence with mask use by self-report diary card and exit survey and interviews with a subsample (ACTRN12610000887077)	Mask-wearing adherence: cloth mask: 56.8% medical mask: 56.6% Reported cloth mask washing: 23/25 days (92%)
MacIntyre 2016	Medical mask use	Sick householders with ILI (index cases) and their well contacts of the same household	Protect well people in the community from transmission of respiratory pathogens by contacts with ILI through mask use	21 medical masks (3M 1817 surgical mask) Diary cards for mask use	Supply of masks Instructions for mask wearing and handwashing protocol Provision of diary cards	Study staff member provided masks and instructions in use.	Masks and instructions provided face-to-face and individually.	Fever clinics of major hospitals in Beijing, China	3 masks/day for 21 days Mask wearing: whenever in the same room as a household member or a visitor to the household Handwashing: before	Allowed to remove their masks during mealtimes and whilst asleep and to cease wearing once symptoms	None reported.	Self-reported daily record of mask use using diary card	Mask use: mask group: 4.4 hours; control group: 1.4 hours

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

									putting on and after taking off	resolved		
Radonovich 2019	2 active interventions A. N95 respirators (N95) B. Medical masks (MM)	Healthcare personnel of outpatient sites within medical centres	Prevent HCP from acquiring workplace viral respiratory infections and transmitting them to others by effective respiratory protection by N95 respirators which reduce aerosol exposure and inhalation of small airborne	A. N95 respirators: 3M Corporation 1860, 1860S, and 1870 (St Paul, MN, USA) or Kimberly Clark Technol Fluidshield PFR95-270, PFR95-274 (Dallas, TX, USA) B. Medical mask Precept 15320 (Arden, NC, USA) or Kimberly Clark Technol Fluidshield 47107 (Dallas, TX, USA). Reminder signs posted at each site A portable computer equipped with data recording software (HandyAudit; Toronto, Canada) to document adherence	Participants instructed to wear assigned protective devices whenever they were positioned within 6 feet (1.83 m) of patients with suspected or confirmed respiratory illness and to don a new N95/MM with each patient interaction. Hand hygiene recommended to all participants in accordance with Centers for Disease Control and Prevention guidelines. Infection prevention policies were followed at each study site. Reminder signs posted at sites and emails sent. Annual fit-testing conducted for all participants.	Centres provided device supplied by study to HCP. Study personnel posted reminder signs and emails and conducted adherence observations.	Face-to-face individual provision of devices and adherence observations Onsite posting of signs Other reminders by email	Outpatient sites within medical centres in USA	As instructed, for each new patient interaction during 12-week period of peak viral respiratory illness each year for 4 years (total of 48 weeks)	Fitting of N95 masks	None described.	Reminder signage posted at study sites, and emails sent by study personnel. Self-reported daily device wearing of “always”, “sometimes”, “never”, or “did not recall" Observation of device-wearing behaviours as participants entered and exited care rooms conducted	Device wearing: N95: 89.4% reported “always” or “sometimes” versus MM: 90.2% “Never” N95: 10.2% MM: 9.5%

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

			particles, meet filtration requirements, and fit tightly	(Radonovich 2016)	Filtration testing performed on the device models in the study. Further details in protocol (Radonovich 2016).						during unannounced, inconspicuous visits to randomly selected sites documented on portable computer	
Hand hygiene												
Alzaher 2018	Hand hygiene workshop	Primary school girls	Targeted school children to improve hand hygiene to reduce school absences due to upper respiratory infection and spread of infection in	6-minute video-clip of 2 siblings that attended school-based health education about hand hygiene Short interactive lecture about: common infections in schools, methods of transmission, hand-washing procedure using soap and water including when to wash hands	Delivery of workshop and distribution of supporting materials (games and posters) to school and students	Study investigator delivered workshop.	Delivered face-to-face in group format for the workshop	2 primary girls' schools in Saudi Arabia	1-hour once-off workshop; posters and games provided to school	Not described	Not described	Posters in restrooms as reminders of hand-washing hygiene during 5-week follow-up period after workshop	Not reported

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

			schools and to families	Puzzle games related to hand hygiene Posters with cartoon princesses' picture promoting hand-washing									
Arbogast 2016	Multimodal hand hygiene intervention programme in addition to control of brief video	Office buildings and the employees of health insurance company	Reduce hand-to-mouth germ transmission from shared workspaces and workplace facilities and thereby healthcare claims and absenteeism through improved workplace hand	Alcohol-based hand sanitiser (PURELL Advanced, GOJO Industries Inc, Akron, OH, USA) installed as wall-mounted dispensers, stands, or free-standing bottles One 8-ounce bottle of hand sanitiser (PURELL Advanced) per cubicle One 100-count canister of hand wipes (PURELL Wipes) per cubicle	Hand hygiene supplies installed in offices. Replenishment product was made easily available to individual employees upon request via a simple process. Monitoring of product shipments into sites Physical collection and full replacement of soap, sanitiser, and wipes Intervention and control group: educational video embedded at end of baseline online knowledge survey	Not described, presumably study investigators arranged installations	Hand hygiene supplies provided in office environments and individually at staff cubicles/offices. Video provided individually via email.	High-traffic common areas of 2 US health insurance company offices (e.g. near elevators, at entrances) and appropriate public spaces (e.g. coffee area, break rooms, conference rooms, training	13.5 months overall One-off email video 11 days before study hand hygiene supplies installed. 13 months of provision of supplies 2 times evening collection and	Sanitiser installed in high-use areas of the offices.	Not described	Employee survey at 4 months included questions about hand hygiene practice adherence. Monitoring of product shipments into the sites and physical collection of the soap, sanitiser, and wipes products 2 times	Intervention group employees: reported 40% more cleaning of work area regularly; significantly more likely to keep the hand sanitiser with them and use it throughout the day; significant increases in hand sanitiser use for at-risk

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	hygiene	Replenishment products stored in supply room (in addition to existing foam hand wash (GOJO Green Certified Foam Handwash) and an alcohol-based hand sanitiser foam wall-mounted dispenser (PURELL, GOJO Industries) already provided near the restroom exits prior to intervention) Identical soap in all restrooms Intervention and control group: brief (< 1-minute educational video) about proper hand hygiene technique, for both washing and sanitising hands	rooms, lobbies, reception areas); individual staff cubicles of mostly open plan offices (average 309 square feet). Office restrooms	full replacement of products	in the study; collected samples were measured and usage rates were estimated	activities[9] Estimated use by average employee from sample collection: sanitiser 1.8 to 3.0 times/day, soap 2.1 to 4.4 times/day, wipes at their desk 1.4 to 1.5 times/week

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

				''Wash Your Hands'', signage promoting hand hygiene adherence, was already posted next to restroom exits at both the control and intervention sites.									
Azor-Martinez 2016	Handwashing programme	Primary school children and their parents and teachers	Prevent transmission of upper respiratory infections in schools and to families through non-pharmaceutical intervention of handwashing programme in schools	Brochure about hand-washing awareness and habits Workshop content materials Stories, songs, and classroom posters about hand hygiene and infection transmission Hand sanitiser (ALCO ALOE GEL hand sanitiser by Americo Govantes Burguete, S.L. Madrid, Spain containing 0.2% chlorhexidine digluconate, 1% phenoxyethanol,	Brochure sent to parents by mail with study information sheet. Workshop provided for pupils and teachers: frequent infections in schools, transmission and prevention, instructions on correct hand-washing (water and soap, soaping > 20 s, drying hands), use of hand sanitisers and possible side effects Classroom activities linked to hand hygiene and infection transmission	Brochure sent by school administration. Workshop and verbal and written information presumably provided by the study research assistant. Classroom	Brochure sent by mail to individual parents. Workshops and classroom activities delivered in groups face-to-face. Teacher reinforcement of hand hy-	Primary school classes in Spain (details not provided)	8 months overall One-off brochure and installation of hand sanitiser dispensers 2-hour workshop held 1 month before study commencement Fortnightly class-	Supervision and administration of hand sanitiser as needed by teachers, especially for younger children	Not described	Daily reinforcement by teachers of hand hygiene Fortnightly support by research assistant promoting handwashing Self-reported correct handwashing procedure (water and soap, soaping	Self-reported correct handwashing included in analysis but not separately reported.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

				0.1% benzalkonium chloride, 5% aloe barbadensis, 70% denat ethyl alcohol, excipients quantity sufficient for 100 mL alcohol 70%, pH 7.0 to 7.5) Informational poster about when and how to wash hands Written and verbal guidance to teachers, parents, and students on properties, possible side effects, and precautionary measures for gel use and storage	Reinforcement of hand hygiene by teachers Hand sanitiser dispensers fixed to walls with an informational poster about hand-washing Supervision of younger children when using hand sanitiser and administration of sanitiser if needed Instruction of children in hand-washing procedures after toilet and when dirty and correct hand sanitiser use[10]	activities provided by research assistant and teachers. Supervision and administration of hand sanitiser for younger children by teachers	giene provided to class face-to-face. Hand sanitiser use supervision was provided individually and face-to-face.		room activities As required, teacher supervision and administration of hand sanitiser Daily reinforcement of hand hygiene by teachers			> than 20 s, drying hands)	
Azor-Martinez 2018	Educational and hand hygiene programme 2 active in-	Day care centres and their attending children, their parents,	Prevent transmission of respiratory infections by improved hand	A. Liquid soap (no specific antibacterial components (pH = 5.5)) OR B. Hand sanitiser (70% ethyl alcohol (pH = 7.0 to 7.5)) for home use and	Installation of liquid soap or hand sanitiser dispensers in classrooms Supervision and administration of hand sanitiser if required	Workshop delivered by researchers. Research assistant	Workshops delivered face-to-face in groups to parents and staff.	Classroom of DCCs (in Spain) for child interventions	8 months overall Initial 1-hour workshop 1 month before study	Administration of hand sanitiser in the case of young children	Not described	Not described Reported that no monitoring of adherence	Families or DCC staff, or both, used 1660 L of hand sanitiser, estimated use by each child of

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	terventions: A. soap and water B. hand sanitiser	and DCC staff	hygiene of children, parents, and staff through handwashing practices and use of hand sanitiser due to its bactericide and virucide properties	in dispensers for school classroom Workshop content handout Stories, songs, and posters about hand hygiene and infection transmission	3 hand hygiene workshops for parents and DCC staff: 1. Hand-washing practices, hand sanitiser use, possible side effects and precautionary measures (HSG only) 2. RIs and their treatments 3. Fever Instructions to children, parents, and DCC staff on usual hand-washing practices and protocol[11] Classroom activities (stories and songs) about hand hygiene and infection transmission	provided hand hygiene materials to DCCs and parents. Parents and staff supervised and administered sanitiser where indicated.	Workshop content emailed to attendees individually. Individual face-to-face supervision of hand sanitiser use, as indicated	Workshops provided at DCCs.	commencement 3 further identical sessions/DCC provided again 1 month apart Fortnightly classrooms and DCC activities One-off installation of dispensers As-needed supervision of hand sanitiser use Dose of sanitiser: 1 to 2	DCC staff could attend training at other DCC if unable to attend at own DCC.	through continuous observation of hand hygiene behaviours was done, but amount of hand sanitiser was measured	dose 6 to 8 times/ day.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

									mL/disinfection				
Biswas 2019	Hand sanitiser and respiratory hygiene education	Primary schools and their students and staff	Reduce community-wide influenza virus transmission by improving handwashing and respiratory hygiene and use of sanitiser in schoolchildren as contributors to community-wide virus transmission	Hand sanitiser (63% ethyl alcohol) in colourless, transparent 1.5-litre local plastic bottles (manufactured by a local pharmaceutical company and was available commercially in Bangladesh (price: USD 5.75/L)) Video clip on respiratory hygiene practices Behavioural change materials – 3 colour posters (see Appendix of paper) Curriculum materials for hygiene classes	Installation of hand sanitiser in wall dispensers in all classrooms and outside all toilets, refilled by field staff as needed Encouragement of use of sanitiser at 5 key times during the day[12] Hand and respiratory hygiene education provided.[13] Integration of hygiene messages into school's hygiene curriculum Delivery of video clip on respiratory hygiene practice Behaviour change materials distributed and placed around schools.	Selected teachers responsible for dissemination of intervention messages throughout were trained over 2 days in these messages, behaviour change communication, sanitiser use, and practices for preventing spread of respiratory	Hand sanitiser and education materials provided to schools. Education provided in classrooms in groups and face-to-face.	Primary schools (in Bangladesh) Sanitiser in each classroom and outside toilets Education in classroom	10 weeks Intervention messages conveyed in classrooms 3 times/week.	Refills provided as needed.	Not described	Structured field observation by 2 field staff of 5 hours/school observing handwashing and respiratory hygiene behaviours of children at 2 different locations in a classroom or outside Every other day, field staff measured the level of hand sanitiser in the morning and in the af-	Handwashing observed opportunities: IG 604/921 (66%) versus CG 171/802 (21%) Hand sanitiser used in 91% of observed handwashing events in intervention schools. Average consumption of hand sanitiser/child/day: 4.3 mL

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					Use of sanitiser by classroom teachers after training Training of selected teachers in consultation with head of school and management committee in key messages Communication of key messages by the selected teachers to other teachers	secretions. Classroom teachers conveyed intervention messages during regular hygiene classes. Field staff replaced supplies as needed.						ternoon to calculate amount of hand sanitiser used/day/school and enrolled children.	Observation of proper cough or sneeze etiquette: IG: 33% versus CG: 2%
Correa 2012	Alcohol-based hand rubs	Child-care centres and their staff and children	Reduce incidence and transmission of infection in chil-	Dispensers of alcohol-based hand rubs with ethanol 62.0% (PURELL, GOJO Industries, Akron, OH, USA) Workshop materials[14]	ABH and training on proper use to staff and children Pre-trial ABH use workshop to teachers that followed recommended HH teaching tech-	Local representative of GOJO Industries Inc.	Face-to-face training and provision of materials; group training	Child-care centres in Colombia (centres or community homes)	8 months overall 1 ABH dispenser per centre with	Refilled ABH as needed	Not described	Visual reminders and monthly refresher training Monitoring	Teachers at 7 intervention centres reported almost complete substi-

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dren by improved hand hygiene where water is scarce including provision of ABH and training in hand hygiene teaching techniques	Visual reminders on ABH techniques in bathrooms and next to dispensers	niques and instructed teachers to add ABH to routine HH and give preference to hand-washing with soap and water if hands visibly soiled Continuous refilling of ABH ABH technique refresher workshops (8/centre) Monitoring of safety, proper use of ABH, amount of ABH used	provided dispensers and dispenser installations free of charge. Fieldwork team delivered other components.	ABH in centres, classrooms, and common areas depending on size Visual reminders in bathrooms and next to dispensers Workshops and training presumably provided in centres.	< 14 children; 1 per classroom in larger centres; 1 per classroom + 1 for common areas in centres with > 28 children 1 workshop pre-trial to staff Monthly 30-minute ABH technique refresher training (8 per centre) Biweekly monitoring	of safety, proper use of ABH, amount of ABH used Semi-structured survey on completion of teachers' perceptions about changes in HH practices and use of HSW and ABH. Measurement of consumption of resources and costs related to ABH use and HSW	tution of HSW with ABH, and HSW decreased from 3 times per day to 1 per day, and ABH rose to 6 per day. Teachers at remaining 14 centres reported partial substitution of HSW with ABH. Controls reported HSW 3 times per day. Median number of ABH applications per child rose from 3.5

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

										to 4.5 in preschools and 3.5 to 5.5 in community centres.			
DiVita 2011	Household handwashing promotion	Householders with index patient with ILI	Prevent influenza transmission in households in resource-poor settings through provision of handwashing facilities and use of them at critical times for pathogen transmission	Hand-washing stations with soap	Provision of hand-washing stations Hand-washing motivation to wash at critical times for pathogen transmission (e.g. after coughing or sneezing)	Not specifically described, presumably the researchers	Face-to-face provision of facilities in households "Motivation" not described	Household in Bangladesh	Over 2 influenza seasons One-off provision of handwashing facilities Frequency of "motivation" not described	Not described	Not described	Not described	Not described
Feldman 2016	2 active interventions	Naval ships and	Reduced infection	Septadine solution (Floris, Misgav, Israel) 70% alcohol	Installation of CHG disinfection devices on ships alongside	Provision of CHG pre-	CHG sent to ships	Navy fast missile boats	4 months	CHG replenished	Not described	Total amount of CHG dis-	Mean volume CHG:

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	A. Hand disinfection with chlorhexidine gluconate + hygiene education B. Hygiene education	their sailors	transmission and improved hand hygiene in sailors who are at increased risk due to closed environments, contact with shared surfaces, and poor HH culture	and 0.5% CHG; inactive materials: purified water, glycerin, propylene glycol, and methylene blue	regular soap and water Supply and replenishment of CHG (sent to ships regardless of replenishment demands) Hygiene instruction by a naval physician (to both intervention groups and study control group)	sumably by study team and funds Hygiene instruction by naval physician	directly. Mode of hygiene instruction not described.	and patrol boats of naval base in Israel Dispensers installed in key locations on-board (adjacent to heads (toilets), mess decks (dining rooms), common areas).	Unlimited supply of CHG replenished on demand for 4 to 5 months. Automatic amount dispensed: 3 mL	on demand.		pensed was tallied.	8.2 mL per sailor per day (projected yearly cost USD 45 per sailor)
Gwaltney 1980	A. Virucidal hand preparation B. Placebo (no control)	Healthy young adults	Reduce infection rates by interrupting viral spread by hand	A. Virucidal hand preparation: aqueous iodine (2% iodine and 4% potassium iodide)	Immersion of each finger and thumb of both hands to proximal interphalangeal joint (interphalangeal joint of thumb) into designated preparation for 5 seconds then air-dried for 5 to 6 min	Researchers	Face-to-face and individually	US university	Exposure to donors on 3 consecutive days (days 2, 3, and 4) after initial exposure	Not described	Not described	Reported knowledge of hand preparation use as active, placebo, or don't know	Active (n = 24): 6 active 2 placebo 16 don't know Placebo (n = 22):

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			or self-inoculation route	B. Placebo: aqueous solution of food colours (Kroger; Kroger Co., Cincinnati, OH, USA) mixed to resemble the colour of iodine with 0.01% iodine and 0.02% potassium iodide to give an odour of iodine Masks	Exposure of recipients to donors either immediately after treatment or after 2-hour delay by hand contact with donor stroking fingers for 10 s Masks worn by donors and recipients during procedure. Recipients placed in single isolation rooms after second exposure till end of experiment.								6 active 7 placebo 9 don't know
Hubner 2010	Alcoholic hand disinfection	Employees (administrative officers)	Reduce absenteeism and spread of infection in administration employees with frequent customer	2 alcohol-based hand rubs (500 mL bottles) for desktop use to ensure minimal effort for use: 1. Amphisept E (Bode Chemie, Hamburg, Germany) ethanol (80% w/w) based formula with antibacterial, antifungal, and limited virus inactivating activity.	Provision of hand rub and instruction on use as needed at work only and in accordance with prevailing standard[15]: at least 5 times per day, especially after toileting, blowing nose, before eating, and after contact with ill colleagues, customers, and archive material	Presumably provided or arranged by study team	In person to staff	Administration offices in Germany Hand rubs used at desk or work (not outside of work).	12 months overall Hand rub used as much needed for complete wetting of the hands (at least 3 mL or a palmful)[16] at least	Hand rub use especially after toileting, blowing nose, before eating, and after contact with ill colleagues,	Not described	Self-reported adherence with hand hygiene measures	Reported mean hand disinfection frequency times per day: > 5: 19% 3 to 5: 59.8% 1 to 2: 20.5% < 1: 0.7%

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

			con-tact and work with paper docu-ments through im-proved hand hy-giene	2. For partici-pants with skin problems: Sterillium (Bode Chemie, Hamburg, Germany) 2-propanol (45% w/w), 1-propanol (30% w/w), and mecetro-nium etilsul-fate (0.2% w/w), with a refatting effect and has activity against bacteria, fungi and enveloped viruses. Hand cream: Baktolan balm, water-in-oil emulsion with no non-antibac-terial properties (Bode Chemie, Hamburg, Ger-many)				5 times per day.	cus-tomers, and archive mater-ial			
Lade-gaard 1999 (trans-lated from Dan-ish)	Hand hy-giene pro-gramme	Day-care centres and their staff, chil-dren, and par-ents	Re-duce risk of infec-tion in child care through in-creased hy-	Personnel guide on rec-ommendations for: hygiene, ventilation, out-of-stay care, stricter hygien-ic regulations in cases with se-lected diseases	Staff meeting in each DCC and training in microbiological cause of infection spread guided by National Board of Health and Hygiene	Re-search team pre-sum-ably pro-vided train-ing.	Face-to-face with train-ing and activi-ties by group with staff and	On-site in DCCs	2-month interven-tion peri-od 1-hour training of chil-dren	None de-scribed.	None de-scribed.	None de-scribed.	None re-ported.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	of children	genic education of daycare professionals, motivation of daycare facilities for regular hand hygiene, and informing parents about hand hygiene	Fairy tale and poster "The Princess Who Won't Wash Hands" Colouring in drawings "Wash hands" song and rhymes T-shirt for children with the inscription "Clean hands - yes thank you" Diploma for children and book "The Princess Who Won't Wash Hands" to also be used by parents with their child Informational leaflet for parents in envelope	Education of children in hand-washing (about bacteria and why and when to wash hands) Practical hand-washing classes with 4 to 5 children at a time Provision of t-shirt, book, and diploma to children Provision of leaflet for parents	children Information sent home to parents via children.

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Little 2015	Web-based hand-washing intervention	Householders (over 18) who were general practice patients	Prevent transmission of respiratory tract infections through improved hand hygiene to reduce spread via close contact (via droplets) and hand-to-face contact	Website-based programme: provided information about the importance of influenza and role of hand-washing; developed a plan to maximise intention formation for hand-washing; reinforced helpful attitudes and norms; addressed negative beliefs (URL provided for demonstration version no longer active; see www.lifeguideonline.org)	Provision of link to website for direct log in Automated emails prompted participants to use sessions and complete monthly questionnaires and maintain hand-washing.	Researchers delivered web-based programme and emails.	Online individually	Households in England	4 months overall 4 weekly web-based sessions Monthly email questions to maintain hand-washing over 4 months	Tailored feedback provided within web programme	None described.	Emailed questions monthly to maintain hand-washing	None reported.
Luby 2005	Hand-washing promotion at neighbourhood level with 2 interven-	Neighbourhoods and their households	Improve hand-washing and bathing with soap in settings where commu-	Slide shows, videotapes, and pamphlets illustrating health problems from contaminated hands and specific hand-washing instructions	Hand-washing promotion to neighbourhoods: Neighbourhood meetings of 10 to 15 householders (mothers) from nearby homes and monthly meetings for men Soap to households	Research team in collaboration with Health Oriented Preventive Edu-	Face-to-face in small groups and individually	Neighbourhoods and homes in Karachi, Pakistan	1-year weekly household visits 30- to 45-minute neighbour-	Soap replaced regularly.	None described.	None described, though soap use measured.	Households' mean use of study soap per week: 3.3 bars Average use per resident

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	tions at household level A. Antibacterial soap B. Plain soap	nicable diseases are leading causes of childhood morbidity and mortality	Soaps: 90-gram white bars without brand names or symbols, same smell with identical generic white wrappers with serial numbers matched to households A. Households: 2 to 4 white bars of 90-gram antibacterial soap containing 1.2% triclocarban (Safeguard Bar Soap: Procter & Gamble Company (Cincinnati, OH, USA) B. Households: plain soap (no triclocarban) Soap packets	Fieldworker home visits: discussed importance of and correct hand-washing (wet hands, lather them completely with soap, rub them together for 45 seconds, and rinse off completely) technique and promote regular hand-washing habits[17] Encouragement of daily bathing with soap and water	cation (HOPE)[18] Fieldworkers were trained in interviewing and handwashing promotion.	hood meetings 2 to 3 times/week first 2 months then weekly for months 2 to 9, then monthly Monthly men's meetings first 3 months Weekly household visits					per day: 4.4 g
Millar 2016 additional details from Ellis 2010	Skin and soft-tissue infection prevention	Military trainees	Improve personal hygiene practices	A. Enhanced standard: supplemental materials (a pocket card and posters in the barracks)	Provision of education and hygiene-based measures in addition to standard SSTI prevention brief upon entry:	Not described, presumably the researchers	Face-to-face and individually for body wash and	US military training base	One-off education on entry to training	None described.	None described.	None described.	None described.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	tion intervention in addition to SSTI brief on entry also provided to control A. Enhanced standard B. Chlorhexidine		to prevent infection, especially acute respiratory infection in military trainees who are at increased risk	B. CHG: CHG-based body wash (Hibiclens, Mölnlycke Heath Care, Norcross, GA, USA)	Enhanced standard: supplemental materials CHG: as for enhanced standard group, plus a CHG-based body wash and instructions for use		pocket card Mode of education not described.		CHG: use of wash 1 per week for entire training period (14 weeks)				
Morton 2004	Healthy hands (alcohol gel as handwashing adjunct)	Elementary schools and their children and staff	Prevent infections in elementary school-age children who are particularly vulnerable through adjunct use of alcohol gel and	Alcohol gel and dispensers: AlcoSCRUB (60% ethyl alcohol) supplied by Erie Scientific Company, Portsmouth, NH, USA "Healthy Hands Rules" protocol[19] (Figure 3 in paper) Healthy Hand Resource Man-	Healthy hands protocol introduced after "Germ unit" education in classes Daily reminders to children on public address system (in first week) then weekly reminders Review of protocol in each classroom after vacation by school nurse 2 classroom visits from school nurse	Gel provided by suppliers. Research team provided educational aspects. Classroom teach-	Face-to-face training in classes and individual information giving and monitoring	Elementary schools in USA Wall-mounted near door entrance of each classroom at age-appropriate height	46 days 0.5 mL dispensed per application. Use of "special soap" according to "Healthy Hands Protocol" (Fig-	Reinforcement teaching provided if gel usage indicated that it was needed. Germ unit education tailored	1 student was concerned gel was making her sick, so school nurse provided additional classroom visit to allay concerns.	Usage of gel calculated.	5 gel applications per day 1 dispenser lasted 1 month.

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			edu-cation based on Health Belief Model (HBM) (Kirscht 1974)	ual for school nurse, available for parents Monthly newsletters to parents ''Healthy Hands'' refrig-erator magnet for families (see Figure 2 in pa-per) Information-al letter to lo-cal primary care providers, paediatricians, family practi-tioners, and ad-vanced practice nurses "Germ Unit" curriculum and materials in-cluding Germ models and Glo Germ	"Healthy Hands" magnet provid-ed to parents and guardians. "Hand Checks on Wednesdays" to identify adverse ef-fects of gel	ers re-spon-sible for en-cour-aging use of gel and rein-forcing proto-col School nurse assist-ed in mon-itor-ing and hand checks for ad-verse effects.			ure 3 in paper)	for each grade level.			
Nichol-son 2014	Hand-wash-ing with soap	House-holds with 5-year-olds and	Target-ed 5-year-old chil-dren	Initial supply of 5 bars of free soap (90-gram Lifebuoy bars) replenished on submission of	Provision of soap and social marketing programme (Sidibe 2009) (Lifebuoy branding) to edu-cate, motivate, and	Dedi-cated team of "pro-mot-	Face-to-face in groups	"Class-rooms" held in com-munity	41 weeks Weekly "class-rooms"	Moth-ers were asked to pro-vide	Tech-nical diffi-culties with "soap	Regis-ters for "class-rooms" and home	Soap con-sump-tion:

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	their mothers	and their mothers as change agents to reduce incidence of respiratory infections (and diarrhoeal disease) through handwashing using behaviour change principles (Claessen 2008), including social norms for child and mother (Perkins 2003), using fear of contamination	empty wrappers. Environmental cue reminders (wall hangers, danglers) Rewards (e.g. stickers, coins, toy animals)	reward children for HWWS at key times Weeks 1 to 17: handwashing occasions, germ education, soap's importance in germ removal Week 18 onward: encouragement of HWWS on 5 key occasions supported by environmental cues "Classrooms" for children Home visits for mothers Parents' evenings to boost morale, build networks, and run competition for adherence, assignment completion, and folder decoration Establishment of a "Good Mums" club for sharing HWWS tips	ers" delivered education and home visits. Mothers provided supplied rewards.	Individually by mother to child	buildings Home visits of households in Mumbai, India	after school and home visits HWWS encouraged 5 key occasions: after defecation, before each of 3 meals, and during bathing. Week 18 onward: handwashing on 5 occasions for 10 consecutive days 6 weekly parents' meetings	and share handwashing tips with other mothers, competitions held for mothers.	acceleration sensors" to measure HWWS behaviours prevented successful use.	visits where 3-week gaps in attendance triggered supervisors to ask participants to resume or be withdrawn Monitoring of soap resale on open market by use of unique identifiers on soap wrappers and twice weekly checks in local shops Collection of used soap wrappers as	IG versus CG: 235 g versus 45 g

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	B. Every 120 min C. Once before lunch		contact transmission; and are of increasingly younger ages through hand gel as a single strategy of convenient and effective disinfection	Leaflet describing risk factors for ILI for each family		by researchers. Leaflets distributed through school. Monitoring of use by 2 research assistants	Leaflets given to each family.		C. once only before lunch, the school standard for hand hygiene	mained in their classrooms and continued to follow the school standard for hand hygiene.	sign after each disinfection round.	
Priest 2014	Hand sanitiser provision (in addition to hand hygiene education session also provided to control group)	Primary schools and their students, teachers, and administrative staff	Reduce person-to-person community transmission of infectious disease by targeting improved	''No touch'' dispensers (> 60% ethanol) for each classroom that dispensed dose when hands were placed under an infrared sensor Supply of top-up sanitiser as needed	Dispensers installed into each classroom. Teachers asked to ensure that the children used sanitiser at particular times and to oversee general use (McKenzie 2010). Weekly classroom visits to top-up of	School liaison research assistants topped-up sanitiser. Teachers	Installation of dispensers to classrooms Supervision of children by teachers delivered	City schools in New Zealand	20 weeks (2 school terms) Sanitiser to be used by students at least after coughing/sneezing, blowing their nose,	Children were able to use the sanitiser at any time they wished as well as at key times (McKenzie 2010).	Change of sanitiser after week 10 to flavourless type of the same % ethanol in 41 of 396 classrooms	Weekly classroom visits by school liaison research assistants who recorded quantity of sanitiser used	100% dispensing 45 mL per child Average hand sanitiser dispensed/child for 34 schools: 94 mL

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			and additional hand hygiene of school children through supervised hand sanitiser provision as an alternative to improving and maintaining bathroom facilities		sanitiser and measure quantity used 30-minute in-class hand hygiene education session provided (also to control group) plus instruction in hand sanitiser use.		face-to-face individually and as a class.	and as they leave for morning break and for lunch break. Approximately 0.45 mL of sanitiser dispensed per wash. Weekly top-up of sanitiser		(10%) (in 9 of 34 schools) due to children tasting it when eating, affecting use.	Total amount of sanitiser per classroom was measured. adherence defined as dispensing a volume equivalent to at least 45 mL per child of hand sanitiser solution over the trial period.	Median classroom difference in sanitiser usage between first 10 weeks and second 10 weeks amongst classes that switched products was 220 mL.
Ram 2015	Soap and intensive handwashing promotion	Household compounds and its householders (adults and children) that	Reduce household transmission of ILI and influenza by promoting hand-	Hand-washing station in central location of each compound using: large water container with a tap; plastic case for soap;	Hand-washing station in each compound Didactic and interactive group-level education and skills training describing influenza symptoms, transmission, and prevention, promot-	Intervention staff arranged provision of handwashing station and pre-	All elements delivered face-to-face but at compound (facilities), group (ed-	Household compounds in a rural area of Bangladesh consisting of several house-	Initiation of intervention within 18 hours of study enrolment, then daily visits until 10 days follow-	Daily surveillance included observation of individual handwashing rein-	None described.	Daily surveillance of facilities and reinforcement and modelling of handwashing be-	Soap present for at least 7 days in all compounds and on all 10 days in 133 compounds (74%).

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	had a householder with ILI	washing in households with householder with ILI as other householders who are well are at highest risk of exposure due to crowded and poorly ventilated homes. Followed constructs of Social Cognitive Theory and the Health Belief Model (Glanz 2008)	bar of soap. Cue cards depicting critical times for hand-washing: after coughing or sneezing; after cleaning one's nose or child's nose, after defecation; after clearing a child who has defecated; before food preparation or serving; before eating.	ing health and non-health benefits of hand-washing with soap and identification of barriers and proposed solutions to hand-washing with soap Daily surveillance including weighing of soap and replacing if ≥ 20 g and resupply of water in container if needed Posting of cue cards Asking householders to demonstrate hand-washing with soap technique	sumably provided education. Intervention staff conducted daily surveillance and reinforcement visits.	ucation), and individual levels (reinforcement).	holds with common courtyard, shared latrine, water source, and cooking facilities	ing resolution of index case patient's symptoms Day 1 set up of hand-washing station	forcement and modelling as needed.	haviours including observed hand-washing Cue cards in common areas of courtyard Presence or absence of soap during each of first 10 days of surveillance from 180 household compounds Patterns and amount of soap use measured.[20]	Soap and water together were present 7 or more of first 10 days in 99% of compounds, with water and soap observed together on all 10 days in 99 compounds (55%) Soap consumption per capita: median: 2.3 g maximal: 5 g (on Day 7)

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

			and behaviour change communication using social marketing concepts										
Roberts 2000	Education about infection control measures, handwashing, and aseptic nose wiping	Childcare centres and their staff and children	Reduce transmission of respiratory infections in childcare centres through improved infection control procedures	GloGerm (GloGerm, Moab, UT, USA) Newsletters to staff Songs and rhymes on hand-washing Plastic bags (sandwich bags available at supermarkets) to cover hand for nose wiping	Staff training in good health (developed by Kendrick 1994) and practical exercise of hand-washing with GloGerm Fortnightly visits and newsletter to reinforce training and to communicate techniques Recommended hand-washing technique as per guidelines of the time[21] and after toileting, before eating, after changing diaper (staff and child), and after wiping nose unless barrier used Teaching of technique to children and	Training and reinforcement activities provided by 1 of the researchers. Teachers delivered training to children based on their training.	Face-to-face in groups for training and classes and individually as needed to children or staff	Childcare centres in Canberra, Australia	8 months overall 3-hour training in evening or 1-hour during lunch for new staff after study start Duration of hand-washing: "count to 10" to wash and "count to 10" to rinse	Training for new staff provided as needed.	None described.	6-weekly adherence measured by recorded observation of recommended practice for 3 hours in the morning in each centre, graded by quantiles of frequency of recommended hand-washing by children.	Adherence was reported only in relation to analysis of outcomes. High adherence reported for nose wiping and child hand-washing.

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					wash hands for infants								
Sandora 2005	Healthy Hands Healthy Families	Families with an index child in out-of-home childcare	Reduce illness transmission in the home through multifactorial campaign centred on hand hygiene education and hand sanitiser	Alcohol-based hand sanitiser: active ingredient: 62% ethyl alcohol (PURELL Instant Hand Sanitiser; GOJO Industries, Inc, Akron, OH, USA) Hand hygiene educational materials at home (fact sheets, toys, games)	Supply of hand sanitiser and hand hygiene materials Biweekly telephone calls Biweekly educational materials	Study investigator	Not stated whether materials mailed or delivered in person	Homes in USA Sanitiser use in home	5 months overall Biweekly educational materials Sanitiser dispensed 1 mL each pump.	None described.	None described.	Recorded amount of hand sanitiser used (as reported by the primary caregiver)	Median frequency of reported times of hand sanitiser use: 5.2 per day 38% used > 2 ounces of hand sanitiser per fortnight = 4 to 5 uses per day
Savolainen-Kopra 2012 further details from Savolainen-Kopra 2010	STOPFLU Enhanced hygiene 2 active interventions IR1. Soap and	Office workers of office work units	Prevent transmission of respiratory infections in workplaces through enhanced hand hy-	IR1: Liquid hand soap ("Erisan Nonsid" by Farmos Inc., Turku, Finland) IR2: in addition: Alcohol-based hand rub, 80% ethanol ("LV" by Berner Inc.,	Toilets equipped with liquid hand soap (all groups) or alcohol-based hand rub (IR2). Guidance on other ways to limit transmission of infections, e.g. frequent handwashing in office and at home, coughing, sneezing into disposable handkerchief	In collaboration with occupational health clinics servicing the corporation	In-person provision of soap or hand rub Guidance and written instructions	Office work units in corporations in Helsinki, Finland	15 to 16 months overall Monthly visits by nurse throughout	Nurses assisted with any practical problems with intervention as they arose.	None described.	Adherence assessed by an electronic self-report survey of transmission-limiting habits 3 times (more	Avoiding handshaking became more common and remained high in both groups. Recorded use for per-

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	water wash IR2. Alcohol-based hand rub	giene with behavioural recommendations to reduce transmission by droplets during coughing or sneezing	Helsinki, Finland) Bottles of hand hygiene product (free of charge) to be used at home and in the office (IR2). Written instructions on hygiene for further reference	or sleeve, avoiding hand-shaking Visits to work clusters and monitoring of materials availability Monthly electronic "information spot" about viral diseases for motivation to maintain hygiene habits Adherence activities	Specially trained research nurse provided guidance and visited worker clusters throughout intervention period.	given personally. Face-to-face visits by study nurse				New employees received guidance on hand hygiene and habits.		details in protocol). Use of soap (IR1) and alcohol-based disinfectant (IR2) for personal use was recorded. Study nurse checked availability of soap and alcohol rub.	sonal use smaller than predicted use based on hand hygiene instructions. Soap or disinfectant usage per participant: IR1: 6.1 IR2: 6.9
Stebbins 2011	"WHACK the Flu" (hand sanitiser and training in hand and respirato-	Elementary schools and their students and homeroom teachers	Targeted school-aged children as important sources of influenza transmission	Hand sanitiser dispensers with 62% alcohol-based hand sanitiser from PURELL (GOJO Industries, Inc, Akron, OH, USA) automatically dispensing 1 dose	Delivery of grade-specific presentations on "WHACK the Flu" concepts and proper hand-washing technique and sanitiser use: (W)ash or sanitise your hands often; (H)ome is where you stay when you are sick; (A)void touching your eyes, nose	Project staff provided education. Home room teachers rein-	Face-to-face at schools, presumably as a group in classes	Elementary schools (Pittsburgh, USA) Dispensers installed	Whole intervention over 1 influenza season One-off installation of hand	Encouraged to wash hands or use additional doses of hand sanitiser, or	None reported.	Monthly teacher surveys of observed NPI-related behaviour in their students before, during, and after influen-	Teacher surveys of observed classroom NPI behaviour indicated successful adoption and mainte-

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	ry hygiene)		through improved cough etiquette and hand hygiene in schools including sanitiser as potential inexpensive non-pharmaceutical interventions		and mouth; (C)over your coughs and sneezes; and (Keep your distance from sick people (provided URL no longer active) Desired frequency of hand wash use taught to student (see When and how much) Installation of hand sanitiser dispensers Refresher training at each school Reinforcement of message and monitoring of sanitiser	forced message and monitored proper use of sanitiser.		in each classroom and all major common areas.	sanitiser dispensers One-off 45-minute education presentation and one-off refresher training at onset of influenza season Goal of use of 1 dose (0.6 mL) of sanitiser 4 times per day[22]	both, as needed		za season Measurement of hand sanitiser use at 2-week intervals throughout the intervention period	nance of behaviours throughout influenza season. Average sanitiser use: 2.4 times per day
Talaat 2011	Intensive hand hygiene campaign	Schools and their students, teachers, and parents	Reduce or prevent transmission of influenza viruses amongst children	Soap supplied as needed. Grade-specific student booklets each including a set of 12 games and fun activities that promoted hand-washing	Establishment of a hand hygiene team in each school Provision of hand hygiene activities: weekly exercises (e.g. games, aerobics, songs, experiments); school activities, (e.g. obliga-	Hand hygiene team (3 teachers from social studies, arts, and	Delivered face-to-face in groups and individually	Elementary schools (grades 1 to 3) in Cairo, Egypt In school	12 weeks overall Weekly hand hygiene campaign activities	Soap and hand-drying material provided by school administration if chil-	None described.	Observation by social workers of hand hygiene activities, availability of soap and drying material,	About 93% of the students had soap and drying material available.

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	through intensive hand hygiene intervention campaign	Hand hygiene activities materials including: games (e.g. how to escape from the germs); puzzles; soap activities (e.g. soap drawing); song specially developed to promote hand hygiene Teachers' guidebook including detailed description of the students' activities and methods to encourage students to practice these activities. Posters with messages to wash hands with soap and water upon arriving at school, before and after meals, after using the bath-	tory hand-washing under supervision, morning broadcast, parent meetings, students-parents information transfer); specific school initiatives: (e.g. competitions and awards, hand-washing committee, school trips to soap factory and water purification plant) More details in Table 1 of paper Song played regularly. Social worker weekly visits Distribution of flyers to parents	sports and the school nurse) ensured that all pre-designed activities for the hand hygiene campaign were implemented. 6 independent social workers visited the schools.	environment and classrooms Poster near sinks in classrooms and on playground	Weekly visits by social workers Twice-daily obligatory supervised hand-washing required by students for about 45 seconds, followed by proper rinsing and drying with a clean cloth towel.	dren did not bring their own as was the custom or families could not afford it. Schools could create own motivating activities such as selecting a weekly hand hygiene champion, developing theatre plays, and launching school contests for	and students' hand-washing during the day Schools created own activities to improve adherence.	All but 2 intervention schools "had a rigorous system of ensuring that school-children were washing their hands at least twice daily".

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

				room, and after coughing or sneezing. Informational flyers for parents reinforcing the messages delivered at the schools.						drawings and songs.			
Teesing 2021 (additional sources: Teesing 2020a and Teesing 2020b)	HANDSOME multimodal nursing home HH adherence intervention	HH management staff and nurses and nursing students (with or of 3 or 4-year nursing degree) and residents	Change hygiene policy and individual HH behaviour of nurses through multimodal intervention designed specifically for nursing homes based on literature, interviews at nurs-	Materials for lessons about WHO-defined 5 moments for HH[23] using HANDSOME novel method: 'Room In' (moment 1), 'Room Out' (moments 4 and 5 combined), 'Before Clean' (moment 2), and 'After Dirty' (moment 3)[24] Nurse's watches and certificates earned on completion of e-learning Paint for washing hands exercise	See Table 1 of Teesing 2020a and Teesing 2020b for more details 1. Policy change: - management meeting (with senior nursing home manager, infection prevention specialist, and facilities manager), - personal hygiene rules - HH materials audit 2. Nursing staff interventions (The New Way of Working) i) 3 live lessons: a. introduction of HANDSOME/WHO HH moments; teaching and discussion re HH when handling medication, food,	Meeting and materials provided by researcher Study team member delivered 3 live lessons with involvement of senior NH manager Senior NH man-	Face to face in groups (management and nursing staff) Lessons in groups of maximums of 18/ session Online individual e-learning	In residents' rooms or other areas of 2 units each of 33 Dutch nursing homes with ≥ 3 nurses providing intense psychogeriatric and/ or somatic care to geriatric residents	4 months (Jan to Apr 2017) Management meeting (45 to 60 min) Personal hygiene policy presentation (10 min) Live lessons: 1 (20 min) 2 (30 min)	Persuasive communication used to encourage continuing when NH wanted to stop When < 3 nurses working at the unit, either the observers continued obser-	None described, except that the process was iterative in response to feedback from individual nursing homes	Unobtrusive HH direct observation disguised as registering of frequency of health care activities recorded on computer tablet (see Figure 2 in Teesing 2020a and Table 3 of Teesing 2020b) Compliance registered if	HH compliance (12 m f/ u) IG: 36% CG: 21% (OR 2.28, CI 1.67 to 3.11) HH compliance increased more for IG than CG for each WHO-defined moment, except for moment 2

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	ing homes and intervention mapping principles, the principle of repetition and informal discussions with members of over 20 nursing home organisations in an iterative process See protocol for more details of intervention mapping process using	28 stickers representing barriers to HH in 4 themes (facilities, forgetting, choosing not to do HH, and the telephone) E-learning materials including videos modelling knowledge, guided practice and promotion of active learning 10 posters (multiple copies, new one each month) Prize for photo competition NH certificate of good HH Small bottle of hand sanitiser for lesson participants	laundry; when to use hand sanitiser/soap/gloves. Team HH goal-setting; b. make inventory and solutions for barriers to HH adherence; and c. exercise washing hands with paint to see where missed; teaching how to disinfect hands ii) e-learning: introduction and 7 lessons showing: - correct/incorrect HH behaviour - common HH actions - when to use gloves - food and medication preparation Quizzes: iii) reminder posters hung throughout NH showing large picture of hands and text: “Did you remember to wash your hands?” (in Dutch’) iv) photo competition: prize for best photo of hands	agers involved in delivery of aspects, including a lesson on NH personal hygiene policy between lessons 1 and 2 Nurses and doctors in training provided adherence observation and assessment	Meetings on-site Lessons on-site and online Posters throughout NH	3 (40 min) given multiple times on 1 day E-learning: 5 to 10 min each Adherence observer training: 2 to 3 days Adherence observation: during observation hours (8 am to 1.30 pm, weekdays)	vations at an additional ward (who also received the intervention) or they stopped observing HH needed to happen in the same room as action occurred, except if a nurse brought a resident to another room, they carried something soiled or no door	HH occurred immediately before (moments 1 and 2) or after (moments 3, 4 and 5) a HH opportunity without touching another object (e.g. door handle) and only if hand sanitiser or soap, water and paper towel used Hand-related personal hygiene[28] for each nurse according to Dutch guidelines[29]1 / every	Estimated attendance at lessons: varied per unit: 23% had < 50% attending at least 1 lesson, 18% had 50% to 74% attendance at at least 1 lesson and 59% had > 75% attendance at least 1 lesson (n = 22).

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	determinants and methods to develop strategies for intervention components	See website (www.zorgvoorbeter.nl/hygiene/hand-hygiene-verbeteren-verpleeghuis) for materials (in Dutch) used for intervention:[25] - Manual (84p) - E-learning module - PowerPoint presentation and script - Assignments - Awareness activities - Audit materials - Policy materials - Posters Adherence recording application and computer table Adherence observer training materials using method adapt-	3. Arts and craft project for residents involving hands that NH displays Adherence recording procedures Provision of hand sanitiser to lesson participants Provision of good HH certificate to NH if higher than average adherence Provision of nurse's watch on completion of e-learning Provision of adherence observers training		needed to be opened before leaving the room; for these instances, HH should take place at the end of action	nurse / day Attendance at live lessons and e-learning was recorded Participants asked if HH policy information received and if posters seen

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									ed from a study in Dutch hospital[26]: videos and case studies and examination using videos from Hand Hygiene Australia[27]
									[1] World Health Organization. (2012). Hand hygiene in outpatient and home-based care and long-term care facilities: a guide to the application of the WHO multimodal hand hygiene improvement strategy and the "My Five Moments For Hand Hygiene" approach. World Health Organization. apps.who.int/iris/handle/10665/78060 (accessed 15 June 2022)
									[2] Moment 1 (before touching a resident) = Room In; Moment 4 (after touching a resident) and Mo-

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

Temime 2018	Multifaceted hand hygiene programme (including alcohol-based hand rub)	Nursing home staff, residents, visitors, and outside care providers	Nursing homes and their residents, staff, and visitors and external providers have an increased risk of person-to-person transmission of pathogens, and HH is a simple and cost-effective tool for infection control; however, compliance with HH is poor in nurs-	Dispensers and pocket-sized containers of hand rub solution Posters promoting hand hygiene Developed local HH guidelines eLearning module on infection control and HH training with online quizzes requiring sufficient performance	Facilitated access to hand rub solution Campaign to promote HH with posters and event organisation Formation of local work groups in each NH Development of local HH guidelines Staff education using eLearning Monitoring of quantity of hand rub solution used	Same nurse provided HH training for all NHs. Provision of hand rub by NH Local work group developed guideline. eLearning module and posters presumably developed by research team.	Provision of materials face-to-face Education and quizzes via eLearning	Nursing homes in France	1 year overall One-off provision of hand rub One-off eLearning repeated if unsatisfactory performance.	If staff did not score sufficiently on online quiz, they were invited to repeat the eLearning.	None described.	Estimated mean amount of hand rub solution used per resident per day assessed as proxy for HH frequency, based on quantity of hand rub solution bought by NH (which was routinely monitored in all the NHs).	Hand rub solution used: baseline quantity of consumed hand rub solution was 4.5 mL per resident per day. Over the 1 year, mean quantity consumed was significantly higher in intervention NH (7.9 mL per resident per day) than control (5.7 per resident per day).

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			ing homes.										
Turner 2004a Clinical trial 1	3 active interventions (no control) Product: A. Ethanol B. Salicylic acid C. Salicylic acid with pyroglutamic acid	Healthy volunteers	Assess the residual virucidal activity of organic acids used in currently available over-the-counter skin products for the prevention of experimental rhinovirus colds	1.7 mL of hand products: A. 62% ethanol, 1% ammonium lauryl sulphate, and 1% Klucel) B. 3.5% salicylic acid, or vehicle containing C. 1% salicylic acid and 3.5% pyroglutamic acid	Disinfection of hands then application of test product then allowed to dry. 15 min later, fingertips of each hand contaminated with 155 $TCID_{50}$ of rhinovirus type 39 in a volume of 100 µL. Hands air-dried for 10 min. Intentional attempted inoculation with virus by contact with fingers, conjunctiva, and nasal mucosa with fingers of right hand. Left hand eluted in 2 mL of virus-collecting broth.	Researchers	Face-to-face individually	Communities in Manitoba, Canada	1.7 mL of product applied. See What for timing	Not described	Not described	Not described	Not described
Turner 2004b Clinical trial 2	2 active interventions (no control)	Healthy volunteers	Assess the residual virucidal activity of organic acids	Skin cleanser wipe containing: A. 4% pyroglutamic acid formulated with 0.1% benzalkonium chloride B. 62% ethanol	Application of product to hands with towelette then allowed to dry. 15 min later, fingertips of each hand contaminated with 106 $TCID_{50}$	Researchers	Face-to-face individually	Communities in Manitoba, Canada	Dose not reported; see What for timing Additional group	Not described	Not described	Not described	Not described

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	Skin cleaner wipe product: A. Pyroglutamic acid B. Ethanol	used in currently available over-the-counter skin products for the prevention of experimental rhinovirus colds	of rhinovirus type 39 in a volume of 100 µL. Intentional attempted inoculation with virus by contact with fingers, conjunctiva, and nasal mucosa with fingers of right hand. Left hand eluted in 2 mL of virus-collecting broth.						chal-lenged 1 h after application; final group challenged 3 h after application (remained at study site and not allowed to use or wash hands between).			
Turner 2012	Antiviral hand lotion	Healthy adults	Reduce rhinovirus infection and illness through hand disinfection with ethanol and organic acid sanitiser	Lotion containing 62% ethanol, 2% citric acid, and 2% malic acid Daily diary	Provision of lotion and instructions for use Meetings with participants to check compliance	Staff of study site presumably supplied lotion. Study site staff met with participants.	Face-to-face and presumably individually, but not specified	Study site at university community in the USA	9 weeks Every 3 hours whilst awake and after handwashing for 9 weeks Compliance meetings	None reported.	None reported.	Self-reported daily diary of time of each product application Twice weekly for 5 weeks then weekly meetings with	"All subjects … applied at least 90% of the expected amount of hand treatment" (p. 1424)

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									twice weekly for first 5 weeks then weekly meetings with participants			participants to reinforce compliance with treatment	
Yeung 2011	Multifaceted hand hygiene programme (including alcohol-based hand rub)	Long-term care facilities and their healthcare workers	Promote use of alcohol-based hand rub by staff in LTCFs as an effective, timely, and low-irritant method of hand hygiene in a high-risk environment	Free supply of pocket-sized containers of alcohol-based antiseptic hand rub (either WHO formulation I (80% ethanol) or II (80% propanol) carried by each HCW (supplier: Vickmans Laboratories) Replacement hand rub as required Hand hygiene seminar content Reminder materials (3 to 5 posters and specially designed ballpoint pens)	Provision of materials Provision of hand hygiene seminars to HCWs covering: indications, proper method, and importance of antiseptic hand rubbing and washing according to WHO 2006a) guidelines Provision of feedback session Direct, unobtrusive observation of hand hygiene adherence Training of observation staff	Study team delivered the materials, seminars, and observer training. Administrative staff of LTCF provided replacement hand rub and communicated with HCWs.	Delivered face-to-face and individually for hand rub and pens; not described if education was individually or by group, but seminar implies as a group	LTCFs in Hong Kong Posters posted in common areas. Adherence observations occurred in common rooms and resident rooms but not bathing or toi-	7 months overall Initial 2-week intervention period, then 7 months of hand rub provision and reminders 3 identical seminars at start of intervention; each staff member to attend once	Replacement of hand rub as required	As adherence dropped off in the middle months, the feedback session was delivered.	Direct observation of HCW adherence to handwashing and antiseptic hand rubbing (recorded separately and anonymously) during bedside procedures or physical contact with residents 3300 hand hygiene opportunities during	90% attendance of seminars Hand rubbing with gel increased significantly from 1.5% to 15.9%. Handwashing decreased significantly from 24.3% to 17.4%. Control: 30%

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						6 registered nurses conducted direct observation of adherence after 2-hour training (100% inter-rater reliability).		let areas.	Feedback session 3 months after start of intervention 2-hour training of observers Adherence observations either 9 am to 12 pm or 3 pm to 6 pm, 1 LTCF at a time			248.5 hours of observation on 92 days	Overall handwashing adherence increased from 25.8% to 33.3%.
Zomer 2015	Hand hygiene products and training	Day-care centres and their caregivers (staff)	Reduce infections in children attending DCCs through improved access	HH products: dispensers for paper towels, soap, alcohol-based hand sanitiser, and hand cream, with refills for 6 months	Provision of free HH products sponsored by SCA Hygiene Products, Sweden. Provision of posters and stickers for children and staff	Study team arranged supply of HH products and presumably provided	Products provided to DCCs in person for staff use. Mode of	DCCs in regions of the Netherlands	6 months overall Initial one-off supply of products	Replacement hand hygiene provided as required.	None described.	6-month follow-up observation of whether intervention dispensers and posters/stickers in use	2 DCCs did not use any HH products. Sanitiser products used in at least 1 of 2 groups

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	to HH materials (Zomer 2013a) and compliance of their DCC caregivers to hand hygiene guidelines based on socio-cognitive and environmental determinants of caregivers' HH behaviour[30] (Zomer 2013b)	Reminder posters and stickers for children and DCC caregivers Training materials including booklet	Provision of training about RIVM 2011 for mandatory HH[31] Distribution of training booklet Team training sessions aimed at goal-setting and formulating HH improvement activities (Erasmus 2011; Huis 2013)	training.	training not specified.	3 training sessions with 1-month interval 2 team training sessions	Survey of DCC caregivers HH guidelines compliance observed at 1, 3, and 6 months' follow-up: no. of HH actions/no. of opportunities	in 94%, 89%, 86%, and 45% of intervention DCCs. Posters used in 86%, stickers in 74%. DCC survey results: 79% attended at least 1 training session; 77% received HH guidelines booklet. HH compliance at 6 months: IG: 59% vs CG: 44% (Zomer TP, et al,

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													unpublished data) All intervention DCCs received guidelines training; all but 2 received at least 1 team training.
Hand hygiene and masks													
Aelami 2015	Hygienic education and package	Religious pilgrims	Prevent influenza-like illness by reduced infection transmission through personal hygiene measures	Hygiene package of: alcohol-based hand rub (gel or spray) surgical masks soap paper handkerchiefs user instructions	Not clearly described, but it appears that packages may have been distributed by trained physicians before departure to or on site of country of pilgrimage	Not specifically described	Not described, but it appears that packages were distributed face-to-face and individually	Not described if before departure (from Iran) or on site (in Saudi Arabia)	One-off during Hajj season	Not described	Not described	Not described	None described
Aiello 2010	2 active in-	Students living	Reduce the	7 face masks (standard medical procedure	Weekly supply of masks through student mailboxes	Not described, except	Education via email	University resi-	One-off education, 6	Mask wearing	University spring	Weekly web-based	Average mask use

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terventions: A. Face mask (FM) B. Face mask and hand hygiene (FM + HH)	in university residences	incidence of and mitigate ILI by use of non-pharmaceutical interventions of personal protection measures	masks with ear loops TECNOL procedure masks; Kimberly-Clark) 7 re-sealable plastic bags for mask storage when not in use (e.g. eating) and for disposal Alcohol-based hand sanitiser (62% ethyl alcohol in a gel base, portable 2-ounce squeeze bottle, 8-ounce pump) Hand hygiene education (proper hand hygiene practices and cough etiquette) via emailed video, study website, written materials detailing appropriate hand sanitiser and mask use	Provision of basic hand hygiene education through an email video link, the study website, and written materials; instruction to wear mask as much as possible; education in correct mask use, change of masks daily, use of provided re-sealable bags for mask storage and disposal Provision of replacement supplies which students signed for upon receipt	education provided via study website (URL not provided) "Trained staff" for compliance monitoring Study-affiliated residence hall staff provided replacement supplies.	and study website; provision of masks and sanitiser in person to residences	dence halls in the USA	weeks (excluding spring break) of face mask and/or hand hygiene measures which commenced at "the beginning of the influenza season just after identification of the first case of influenza on campus" (p.496). Replacement supplies provided as needed.	during sleep optional and encouraged outside of residence.	break occurred during weeks 4 and 5 of the study, with most students leaving campus and travelling; they were not required to continue protective measures at that time.	student survey included: self-reported average number of times hands washed/day and average duration of handwashing to obtain composite "optimal handwashing" score (at least 20 s ≥ 5/day); average no. of mask hours/day/week; average hand sanitiser use/day/week and amount used. Trained staff	hours/day: FM + HH 2.99 versus FM 3.92 Average handwashing times/day: FM + HH 6.11 versus FM 8.18 vs control group 8.75 Daily washing seconds/day: FM + HH 20.65 versus FM 23.15 vs control 22.35 Hand sanitiser use times/day:

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

											in residence hall common areas observed silently and anonymously improper mask use, instances of hand sanitiser use.	FM + HH: 5.2 versus FM 2.31 vs control 2.02 No. of proper mask wearing participants/hour of observation: FM + HH 2.26 versus FM 1.94
Aiello 2012	2 interventions: A. Face mask (FM) B. Face mask and hand sanitiser (FM + HH)	Students living in university residences	Prevent ILI and laboratory-confirmed influenza by use of non-pharmaceutical interventions of personal protection	Packets of 7 standard medical procedure masks with ear loops (TECNOL procedure masks, Kimberly-Clark, Roswell, GA, USA) and plastic bags for storage during interruptions in mask use (e.g. whilst eating, sleeping) and for daily disposal	Intervention materials and educational video provided. Supply of masks and instructions on wearing Provision of replacement masks or sanitisers as needed on site	Trained study staff available at tables in each residence hall for surplus masks and sanitiser and for observing compliance	Hygiene packs delivered to student mailboxes; face-to-face supply also available	University residence halls in the USA	One-off educational video at start Weekly supply of hygiene packs Masks to be worn at least 6 hours/day	Students encouraged but not obliged to wear masks outside of residence hall.	1-week university spring break during the study when majority of students left campus	Weekly student survey including compliance (e.g. masks hours/day, frequency and amount of sanitiser use, number of hand washes/day, duration of hand-	Self-reported mask wearing: no significant difference Sanitiser use: significantly more in FM + HH than FM or control groups

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			measures (e.g. face masks and hand hygiene)	Hand sanitiser (2-ounce squeeze bottle, 8-ounce pump bottle with 62% ethyl alcohol in a gel base) Replacement face masks and hand sanitiser Educational video: proper hand hygiene and use of standard medical procedure face masks					Study staff available onsite with replacement supplies as needed for duration of intervention (6 weeks, excluding spring break)			washing (seconds) Observed compliance completed by trained study staff who daily and anonymously observed mask wearing in public areas of residences.	More results in S1 of paper. Staff observed an average of 0.0007 participants properly wearing a mask for each hour of observation.
Cowling 2009	2 active interventions in addition to control of lifestyle education: A. Enhanced hand hy-	Householders with index patient with influenza	Reduce transmission of influenza in households through personal protective measures	A. and B. Liquid soap for each kitchen and bathroom: 221 mL Ivory liquid hand soap (Proctor & Gamble, Cincinnati, OH, USA) Alcohol hand rub in individual small bottles (100 mL) WHO recom-	Home visits Provision of soap, hand rub, and masks as applicable and when to use them HH: education about efficacy of hand hygiene Demonstration of proper hand-wash-	Trained study nurse provided interventions.	Face-to-face to householders	Households in Hong Kong	Initial home visit scheduled within 2 days (ideally 12 h) of index case identification. Further home	Not described	Not described	Monitoring of adherence during home visits Evaluation of adherence on final visit by interview or self-	Most initial visits completed within 12 h. Intervention groups "reported higher adherence … than the

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	giene (HH) B. Face masks and enhanced hygiene (FM + HH)	mended formulation I, 80% ethanol, 1.45% glycerol, and 0.125% hydrogen peroxide (Vickmans Laboratories, Hong Kong, China) B. Adults: box of 50 surgical face masks (Tecnol–The Lite One (Kimberly-Clark, Roswell, GA, USA) to each household member or C. Children 3 to 7: box of 75 paediatric masks	ing and antisepsis techniques + FM: education about efficacy of surgical face masks in reducing disease spread to household contacts if all parties wear masks Demonstration of proper wearing and hygienic disposal All groups: provision of education about the importance of a healthy diet and lifestyle, both in terms of illness prevention (for household contacts) and symptom alleviation (for the index case)	visits day 3 and 6, 7-day follow-up HH: use of liquid soap after every washroom visit, sneezing or coughing, when their hands were soiled. Use rub when first returning home and immediately after touching any potentially contaminated surfaces FM: masks worn as often as	reported practices and counting of amount of soap and rub left in bottles and remaining masks for FM group	control group. Self-reported data were consistent with measurements of amount of soap, alcohol hand rub, and face masks used" (p.443) (see Table 6 in paper). "Adherence to the hand hygiene intervention was slightly higher in the hand hygiene group than the face mask plus hand hygiene group."	

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									possible at home (except eating or sleeping) and when the index patient was with the household members outside of the household				Median masks used: Index: 9 Contact: 4 More details in paper and Appendices
Larson 2010	2 active interventions in addition to control of URI education: A. Alcohol-based hand sanitiser (HS) B. Face masks and hand	Hispanic householders with at least 1 preschool or elementary school child	Reduce incidence and secondary transmission of URIs and influenza through non-pharmaceutical household level inter-	A. and B. 2-month supply of hand sanitiser in 8-, 4-, and 1-ounce containers: PURELL (Johnson & Johnson, Morris Plains, NJ, USA) B. 2-month supply of masks: Procedure Face Masks for adults and children (Kimberly-Clark,	Provision of materials and instructions for when to use including demonstration of use and observation of return demonstration by householder A. Mask worn when householder had: "temperature of ≥37.8°C and cough and/or sore throat in the absence of a known cause other than influenza" (CDC definition of influenza-like illness at the time).	4 trained bilingual research assistants (RAs) with minimum baccalaureate degree and experience in community-based research;	Face-to-face to householders	Households in New York, USA	19-month follow-up Initial home visit, then at least every 2 months Sanitiser for use at home, work, and school	Change masks between interactions with person with ILL Householders' questions and misconceptions addressed	None described.	RA home visits for adherence with random accompaniment by project manager, who also made random calls to householders Telephone calls to reinforce	Sanitiser use (mean ounces/month) HH: 12.1 FM + HH: 11.6 Mask compliance was "poor": 22/44 (50%) used within 48 hours of onset.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	sanitiser (FM + HS)		ventions	Roswell, GA, USA) Replacement supplies at least once every 2 months Disposable thermometers Educational materials about URI prevention, treatment, and vaccination (written in Spanish or English language)	Home visits to reinforce adherence, replenish supplies and record use, answer questions B. Telephone calls to reinforce mask use All groups received URI educational materials.	procedures were practised with each other until demonstrated proficiency			B. Telephone calls days 1, 3, 6 Masks worn for 7 days when within 3 feet of person with ILL or no symptoms.	on home visits.		mask use Used bottles or face masks, or both, monitored for usage.	Mask users reported mean mask use of 2.
Simmerman 2011	2 active interventions: A. Handwashing education and handwashing kit (HW)	Households with a febrile, influenza-positive child	Decrease influenza virus transmission in household with a febrile influenza-positive child through promoted	A. and B. Hand-washing kit per household including graduated dispenser with standard unscented liquid hand soap (Teepol brand. Active ingredients: linear alkyl benzene sulfonate, potassium salt, and sodium lauryl ether sulphate)	A. and B. Provision of intensive hand-washing education on initial home visit to household members with 5 approaches: discussion, individual hand-washing training, self-monitoring diary, provision of soap, and provision of written materials (Kaewchana 2012) Individual hand-washing training	Study nurse conducted home visits, provided education and monitoring activities.	Education provided face-to-face as a group to household member and individually for hand-washing	In homes (in Bangkok, Thailand)	One-off provision of kits at initial home visit conducted within 24 hours of enrolment Subsequent home visits on	B. No face masks whilst eating or sleeping as impractical and could hinder breathing in ill child	None described.	Self-monitoring diary recording hand-washing frequency > 20 s and face mask use for that group Reinforcement	Reported average hand-washing episodes/day: HW: 4.7 HW + FM: 4.9 Parents had highest frequency (5.7), others (4.8),

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	B. Handwashing education, handwashing kit, and face masks (HW + FM)	use of handwashing or handwashing with face mask use	Replacement soap as needed Written materials from education including pamphlets and posters attached near sinks in household. B. Box of 50 standard paper surgical face masks and 20 paediatric face masks (Med-con company, Thailand #14IN-20AM-B-30IN)	("why to wash", "when to wash", and "how to wash" in 7 hand-washing steps described in Thailand Ministry of Public Health guidelines) B. Provision of education of benefits of and appropriate face mask wearing Soap replaced as needed. More details (Kaewchana 2012)	training.	days 3, 7, and 21 90-day supply of handwashing supplies 30-minute education provided at initial home visit	Impromptu education and training provided by nurses as questions arose.	of messages by nurses on subsequent home visits Amount of household liquid soap and number of face masks used	siblings (4.3), index cases (4.1). Average soap used/week: HW: 54 mL/person HW + FM: 58.1 mL/person B. Mask use: 12/person/week Mask wearing median minutes/day: 211 Parents 153, other relations 59, index patients 35, siblings 17

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Suess 2012	2 active interventions in addition to written information: A. Mask/hygiene (MH) B. Mask (M)	Households with an influenza-positive index case in the absence of further respiratory illness within the preceding 14 days	Prevent influenza transmission in households through easily applicable and accessible non-pharmaceutical interventions such as face masks or hand hygiene measures	A. Alcohol-based hand rub (Sterilium, Bode Chemie, Germany) A. and B. Surgical face masks in 2 different sizes: children < 14 years (Child's Face Mask, Kimberly-Clark, USA) and adults (Aérokyn Masques, LCH Medical Products, France) Written information provided on correct use of intervention and on infection prevention (Suess 2011) (tips and information on the new flu A/H1N1) (URL provided is no longer active) Digital tympanic thermometer	A. Provision of hand rub and masks A. and B. Provision of masks only Provision of thermometer and how to use it Mask fit assessed (at first household visit) Information provided by telephone and written instructions at home visit on proper use of interventions and recommendations to sleep in a different room than the index patient, not to take meals with the index patient, etc. (Suess 2011) In-person demonstration of interventions at first home visit All participating households received general written infor-	Study personnel arranged provision of materials, rang the participants, visited the homes, demonstrated and assessed fit of masks.	Provision of materials in person to households Initial telephone delivery of information Face-to-face home visits	Households in Berlin, Germany	Over 2 consecutive flu seasons Day 1 households received all necessary material instructions. Household visits no later than 2 days after symptom onset of the index case, then days 2, 3, 4, 6, 8 (5 times) or on days 3, 4, 6, 8 (4 times) depending on the day of recruitment	Adult masks worn if masks for under 14-year-olds did not fit properly. If other household members developed fever (> 38.0 °C), cough, or sore throat, they were asked to adopt the same preventive behaviour as the index patient.	In the season 2010/11 participants also recorded number of masks used per day.	Self-reported daily adherence with face masks, i.e. if they wore masks "always", "mostly", "sometimes", or "never" as instructed. Participants of the MH households additionally noted the number of hand disinfections per day. Exit questionnaire about (preventive) behaviour during	Face mask use (median/individual): MH: 12.6 M: 12.9 Daily adherence was good, reaching a plateau of over 50% in nearly all groups from the third day on. MH hand rub use (median): 87 mL (Suess 2011) MH mean frequency of daily hand

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		mation on infection prevention.					
	General written information on infection prevention		Hand rub use: after direct contact with the index patient (or other symptomatic household members), after at-risk activities or contact[31]	the past 8 days, general attitudes towards NPI, the actual amount of used intervention materials, and, if applicable, problems with wearing face masks.	disinfection: 7.6 (SD 6.4) times per day	See paper and Suess 2011 for more results.	
			Mask use: at all times when index patient and/or any other household member with respiratory symptoms were together in 1 room	Used intervention material per household member was calculated by dividing the amount used per household by the number of household members.			

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									Regular change of face masks, not worn during the night or outside the household			See paper and Suess 2011 for more details.	
Hand hygiene and surface/object disinfection													
Ban 2015	Hand hygiene and surface cleaning or disinfection	Kindergartens and the families of their students	Reduce transmission of infection in young children from contaminated surfaces or hands through hand hygiene and surface cleaning or disinfection	Antibacterial products for hand hygiene and surface cleaning or disinfection: liquid antimicrobial soap for hand-washing (0.2% to 0.3% parachlorometaxylenol). Instant hand sanitiser for hand disinfecting (72% to 75% ethanol), antiseptic germicide (4.5% to 5.5% parachlorometaxylenol diluting before use). Bleach (4.5% to 5.0% sodium hypochlorite, diluting before	Provision of products to kindergartens and families Instruction of parents or guardians and teachers in hand hygiene techniques and use of antibacterial products Daily cleaning of kindergartens with products At least twice/week cleaning of homes and weekly cleaning or disinfecting of items such as children's toys, house furnishings, frequently touched objects (doorknobs,	Research team provided products and instructions and monitoring.	Materials provided to kindergartens and families in person and presumably instructions in person to families and staff.	In kindergartens (hard surfaces) and families' homes (Xiantao, China)	1 year overall Daily handwashing with soap before eating, after using bathroom, nose blowing, and outdoor activities Hand sanitiser carried daily.	Families and teachers could contact study management at any time as needed. Exchange of empty bottles for new ones at any time	Not described	Close contact with teachers and families for monitoring, e.g. unscheduled parents' meetings, quarterly home visits, phone interviews, and monthly cell phone messages	Consumption of products by person (mL/person/day). Liquid soap: 7.7 Sanitiser: 1.4 Bleach: 25.0 Antiseptic-germicide: 12.5

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				use) for surface disinfecting. Produced by Whealthfields Lohmann (Guangzhou) Company Ltd.	tables or desks), kitchen surfaces (utensils, cutlery, countertops, chopping boards, sinks, floors, etc.), bathroom surfaces (toilet, sink, floor, etc.) Monitoring activities				Kindergarten cleaning daily Home cleaning at least twice/week			Monthly survey of consumption of products by volume, total usage, person usage	
Carabin 1999	Hygiene programme	Daycare centres and their staff and children	Reduce infections in at-risk children (under 3 years old) in DCCs with inexpensive, easily implementable and practical interventions	Hygiene materials and documents, e.g. colouring books, hand-washing posters, hygiene videotapes Materials for training Reimbursement of equivalent of 1 full-time educator's salary Bleach (diluted 1:10) for toy and play area cleaning	Provision of comprehensive hygiene training session to entire DCC staff, especially the educators of participating classrooms Training in recommendations for hygiene practices: i. toy cleaning ii. hand-washing technique and schedule iii. use of creative reminder cues for hand-washing iv. open window for daily period v. sandbox and play area cleaning	Training appears to have been provided by study team.	Appears staff trained as a group, i.e. "entire DCC staff"	Daycare centres in Canada Location of training not described, except may have been off-site from DCCs since 1 DCC did not "send" staff to training.	15-month trial One-off 1-day training Toy cleaning at least every 2 days Handwashing at least after DCC arrival, after outside play, after bathroom, before lunch	Teachers to use creative reminder cues for handwashing with children	Not described	Follow-up telephone questionnaire for DCC directors about following training recommendations	Use of materials: colouring book: 22/24 poster: 23/24 videotapes: 18/24 staff meetings: 19/24 Increased frequency of toy cleaning: 6/24 Use of rake and shovel for

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					Payment of salary of educator for the day to encourage participation DCC meetings to discuss training session with all staff				Open windows at least 30 min/day Biweekly cleaning of sandbox/play area				sandpit: 17/24 Frequency of cleaning sandbox: 14/24
Kotch 1994	Hygiene	Caregivers at child day-care centres (CDCCs)	Develop feasible, multicomponent hygienic intervention to reduce infections in children at CDCCs who are at increased risk	Hygiene curriculum for caregivers Availability of soap, running water, and disposable towels Waterless disinfectant scrub (Cal Stat) used only if alternative was not washing at all. Handouts posted in CDCC.	Delivery of hygiene curriculum to caregivers through initial training session which required demonstration of participants' handwashing and diapering skills Local procedures: Hand-washing of children and staff Disinfection of toilet and diapering areas Physical separation of diapering areas from food preparation and serving areas Hygienic diaper disposal Daily washing and disinfection of toys,	Research team delivered training. Scrub donated by Calgon Vetal Laboratories.	Face-to-face training and follow-up group and individually	Classrooms of child day-care centres in the USA	8 months overall 3-hour initial training session Cleaning schedules as described in column What (procedures) On-site follow-up training	Follow-up sessions addressed questions and local adaptations to procedures. As-required induction training	During intervention, research team encouraged directors to address physical barrier to hygiene practice, such as distance between sink and diaper-	Follow-up sessions reinforced training. Meeting with directors 5 weekly unobtrusive recorded observation by training staff	Rate of compliance to barrier modification was better in younger centres, which were more likely to have written guidelines.

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					sinks, kitchen and bathroom floors Daily laundering of blankets, sheets, dress-up clothes Hygienic preparation, serving, and clean up of food Separate training of food handlers As-required induction training for new staff Onsite follow-up training reinforcing adaptations, demonstrations and discussion of hygiene techniques, responding to questions, and review of handouts Monthly meeting with centre directors to encourage leadership and support				1 week and 5 weeks later		ing areas and sink access in rooms.		
McConeghy 2017	Multifaceted handwashing and sur-	Nursing homes and their staff	Reduce exposure to pathogens	Education and launch materials	Pre-intervention: NH administrators required to:	Study personnel equipped staff with knowl-	Face-to-face interaction with staff for	Nursing homes in the USA	6 months overall: training period: 3 months	Sites could use existing comparable	2 sites retrained due to low training	Cloud-based audit and feedback system via	Online training participation rates:

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face-cleaning intervention	and person-person transmission in high-risk facility of close environment and potentially contaminated surfaces through multifaceted intervention equipping staff to protect residents from infection within the "culture" of care	Online module for certified nursing assistants about: infection prevention, product, and monitoring "Essential bundle" of hygiene products supplied at no cost: - hand sanitiser gel and foam - antiviral facial tissues - disinfecting spray - hand and face wipes Plus additional: - 4 skin cream and wipe products iPads for compliance audits Newsletters for support during intervention	- identify a "Heroes In Prevention" champion and team - allow all staff participation in education - iPad use for staff in each floor or community - ask staff to incorporate intervention into workflow Delivery of 3 components: - education - cleaning products - compliance audit and feedback Education: Launch event for all staff to publicise programme and explain roles Intensive training of "hygiene monitors" for data collection and compliance audit and feedback tool Training of site champion Training of select group of certified	edge and tools and support. NH staff (e.g. champion, hygiene monitors, nursing assistants) delivered aspects of interventions after specific training.	planning and some aspects and delivery of products Some aspects delivered online (e.g. nursing modules, compliance auditing)	Onsite and at unit/team levels Online training	1-hour launch event 1 or 2 hygiene monitors/site 1 champion/site 1-hour online module for selected nursing assistants iPads for each community or floor Weekly teleconferences initially de-	products from another vendor and fill in any gaps with study products. New staff provided with education, as needed and came onboard. Retraining of sites with low training participation rates	participation rate.	secure login to web browsers on NHs' existing computers or via iPads included weekly product consumption to get measure: weekly count of product units consumed x no. of hand hygiene occasions	> 90% for 3/5 sites, 13% and 23% for 2/5 Administrators demonstrated high fidelity in reporting measures of handwashing (> 80% of time). Handwashing rates in Figure 1B in paper reported as "relatively constant" and "not ideal in the first few months", but improved

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					nursing assistants (online module) Audit and feedback activities Ongoing support during intervention: - newsletter with best practices - teleconferences with each NH - "onboarding" education of new staff				creased in frequency over time. Weekly measurement of product consumption				significantly over time.
Sandora 2008	Multifactorial intervention, including alcohol-based hand sanitiser and surface disinfection	Elementary school and its students	Reduce transmission of infections in school-children through improved hand hygiene and environmental disinfection	1 container of disinfecting wipes (Clorox Disinfecting Wipes (The Clorox Company, Oakland, CA, USA); active ingredient, 0.29% quaternary ammonium chloride compound) Pre-labeled 1.7-ounce containers of alcohol-based hand sanitiser (AeroFirst non-aerosol alcohol-based	Sanitiser and wipes provided to classroom/teacher with instructions for use. Teachers disinfected desks once daily. Hand sanitiser to be used: before and after lunch, after use of the restroom (on return to the classroom; hand hygiene with soap and water occurred in the restroom, because sanitisers were not placed there), after	Research team arranged supply of materials and instructed teachers on use. Teachers instructed in use of materials and in col-	Products provided to schools. Instruction provided face-to-face to teachers and children.	Elementary schools and their classrooms in the USA	8-week period Desks disinfected once a day.	Products replenished as needed.	None described.	Individually labelled containers collected every 3 weeks from the classroom to assess adherence.	Product usage: average wipes used/ week: 897 (128 wipes/ classroom/week) Average bottles of hand sanitiser used per week: 8.75 (1.25 bottles/classroom/week)

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				foaming hand sanitiser (DEB SBS Inc, Stanley, NC, USA, for The Clorox Company); active ingredient, 70% ethyl alcohol) Receptacle in classrooms for empty containers	any contact with potentially infectious secretions (e.g. after exposure to other ill children or shared toys that had been mouthed)	lecting empty containers and distributing new product.							
Quarantine/Physical distancing													
Helsingen 2021	Rapid-Cycle Re-Implementation of TRAining Facilities in Norway (TRAiN) hygiene and physical distancing measures	Members of health and fitness training facilities aged 18 to 64 years not at increased risk for severe COVID-19	Enable safe reopening of fitness training facilities to maintain health and fitness by reducing the risk of SARS-CoV2 transmission	Infection mitigation measures described by "Norwegian guidelines for Hygiene and Social Distancing in Training Facilities during the COVID-19 Pandemic" (in Norwegian t-i.no/wp-content/uploads/2020/04/Bransjestandard-for-sentre.pdf) See Supplementary Appendix for "Standard for COVID-19 infection preven-	Implementation of the following during regular floor training facilities and group classes: - avoidance of body contact - 1 metre distance between individuals, - 2 metre distance for high intensity activities Provision of disinfectants at all workstations Requirement of HW and cleaning of all equipment by mem-	Facility employees controlled access and enforced implementation of guidelines and procedures at all times Staff present dur-	Face-to-face individually and as a group	5 health and fitness training facilities in Oslo, Norway	3 weeks May 22nd to June 15th, 2020 Hours of access not reported; presumably the participants had unlimited access to training facility within the procedures	Masks not required, so were optional Change rooms available Access controlled to avoid overcrowding	None described	Staff monitored access and distancing No apparent measures of fidelity	None described

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tion measures in fitness centers during the TRAiN-study"	bers before and after use with utensils provided	ing all opening hours	for distancing	Staff monitored that distance measures were ensured
	No physical contact between participants or participants and instructors			
Disinfectant readily available at workstations and strategic places (reception, booking station, changing rooms, toilets, water taps used for drinking or refilling bottles)	Regular cleaning of facilities by facility employees	Not reported if training needed for facility staff		
	Create lists of what should be cleaned and how often			Number of people attending depended on size of gym and associated changing rooms, showers and toilets. Facility to calculate the maximum number who could train at the
Rubbish cans without lids				
	Disinfection of instructor microphones			
Washbasin with soap or hand disinfection				
	Extra cleaning of frequently touched surfaces (e.g. door handles, card readers, washbasin batteries)			
Personal microphones for instructors (i.e. not shared)				
	Frequent refilling at all hygiene stations			
Infection preventive measures reminders online and via posters in facilities				
	Avoid queuing by making sure group classes do not start and stop at same			

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	time and keep 15 min minimum between group classes		same time while maintaining 1 to 2 m distance, as well as toilet, shower and change room capacity
	Access control by facility employees		
	Closure of showers and sauna but changing rooms open		
	Staff presence during all opening hours		
	Removal of lids on trash cans		
	Reminders of infection preventive measures		
	Communication to members about changes to training for social distancing		
	Advice to members to stay home if any COVID-19 related symptoms		

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					Advice to members to avoid touching eyes, nose and mouth Closure of childcare facilities								
Miyaki 2011	Quarantine from work (stay-at-home order)	Employees	Prevent spread of influenza in workplaces by quarantining workers who had a cohabiting family member with an ILI	Full wages to employee	Non-compulsory asking of workers whose family members developed an ILI to stay at home voluntarily on full wages. Daily measuring of temperature before leaving work. Where symptoms were doubtful, industrial physician made judgement. Company doctors provided input on cancelling of stay-at-home orders as required.	Health management department oversaw the procedures and decisions.	Mode of advice to employees not described.	Car industries in Japan	Stay-at-home order for 5 days after resolution of ILI symptoms or 2 days after alleviation of fever over 7.5 months	Strict standard for cancelling of stay-at-home orders described.	None described.	Recording of compliance with stay-at-home request	100% compliance to stay at home reported.
Young 2021 (additional source: Denford 2022)	Daily contact testing (DCT) with Lateral Flow Device (LFD)	Students and staff from secondary schools and further	Provide a quicker, more convenient and alternative	SARS-CoV-2 Lateral Flow Device (LFD) (Orient Gene, Huzhou, China)[47]	In addition to twice weekly asymptomatic testing with LFD according to national policy: students and staff who were close contacts[48] of students or staff members	A study worker was funded at each school but role not	Individually and face to face	172 secondary government funded, residential,	March to May 2021 Daily contact testing was performed at arrival	When testing could not start immediately following iden-	None reported	Daily participation rates in IG measured per day and per participant	Testing did not occur on 15.8% of person-school-days due to school or public health

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for contacts of COVID-19 cases	education colleges	testing option and policy for COVID-19 close contact testing in schools, as an alternative to self-isolation	who had a positive LFD or PCR were identified and offered daily LFD testing on arrival at school or college each morning (if asymptomatic and no household member isolating due to testing positive for COVID-19) Participants swabbed own nose (anterior nares), supervised by trained staff. Swabs tested by school staff using LFC Contacts with negative LFC attended education but were asked to self-isolate at home after school and on weekends/holidays Contacts with 5 negative tests (tests done over 7 consecutive days) including one on or after the 7th day of testing were released from self-isolation Contacts with positive test were required to self-isolate for 10 days, along with their contacts. Their school-based contacts were identified and process repeated	specified School staff tested the swabs that were taken by students Study staff trained according to national NHS Test and Trace standard process supervised LFD testing	special and independent day schools and further education colleges in England	at school each morning Day 1 of testing began the day after a case was identified Testing was done over 7 consecutive days (allowing for no testing on weekends) Schools actively participate between 19 April 2021 to 27 June 2021 (considered periods of low to moderate COVID-19 incidence)	tification of a case (e.g. due to a weekend), testing could start within 3 days of case identification	Compliance was calculated / school / week, and participant type, (= sum of all study school days of individuals eligible for DCT returning a test result or already having completed follow up each day, divided by the sum of individuals eligible for DCT. Qualitative interviews conducted to understand reasons for participation and	agency directives IG participation rate: 42.4% with marked variation between schools (range 0% to 100%). See Figure 2 for non-participation reasons breakdown (e.g. testing kit unavailable, whole cohort moved to isolation). Staff more likely to participate than students.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

								not (reported separately in Denford 2022)	See Figure 2 for participation by school type breakdown "Although contacts at government-funded schools with students 11–16 years old with a low proportion of free school meals were most likely to participate, other school types were similar, such that differences in participation related to fac-

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													tors other than school type." (p. 1227) Qualitative analysis of interviews indicated daily testing may be feasible and acceptable but needs improved communication to students and parents about rationale, test interpretation and actions (Denford 2022)
Other (miscellaneous/multimodal) interventions													
Ashraf 2020 (additional	6 active interventions of Wa-	Residents of households	Improve environmental	Free technologies and supplies:	Provision and delivery of supplies or installations as described in Materials column according to	540 CHW or 'promoters'	Mostly face to face in groups and in-	Households and compounds	2 years from May 2012	CHWs identified and ad-	S: latrine pits adapted	Measured by a separate trained	CHWs visited more than planned

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

sources: Arnold 2013, Luby 2018, Parvez 2018, Rahman 2018, Unicomb 2018)	ter, sanitation, hygiene (WASH) and nutrition components: A. Water (W) B. Sanitation (S) C. Handwashing (H) D. Water + sanitation + handwashing (WSH) E. Nutrition F. Nutrition + WSH (WSHN	of village compounds and for some interventions, particularly pregnant women and their infants and children < 5 years	conditions to interrupt transmission of respiratory pathogens and improve child malnutrition thereby reducing childhood respiratory illness and improving childhood morbidity based on the Integrated Behavioural Model for Water Sanitation and Hy-	W: chlorine (sodium dichloroisocyanurate) tablets (Aquatabs, Medentech, Wexford, Ireland) - 10 L insulated safe storage vessel (Lion Star Plastics, Sri Lanka) with a lid and tap for drinking water per household S: Dual-pit pour flush latrines with water seals for all compound households. Each pit had 5 concrete rings 0.3 m high; - Potties[34] (RFL, Bangladesh) - Sanisco ops[35] (locally developed hand-tool made for the trial for removal of faeces from compound) for households with index children	intervention type or combination. Interventions deployed so that they were in place before index children were born In combined intervention arms, the sanitation measures were delivered first, followed by handwashing, then water treatment. Household visits and community discussions based on behaviour change strategy by CHWs (paid a monthly stipend), including interactive sessions for developing solutions to improve practice. Key recommendations per IG: W: children drink treated, safely stored water from vessel (filled vessel with added 1 33 mg tablet, wait 30 min before drinking)	who were local women and residents of study villages recruited through transparent merit-based selection methods and consultation with community leaders CHWs had completed minimum of 8 years formal education, lived within	dividually with some activities by phone	(n = 5551) of rural villages in Gazipur, Kishoreganj, Mymensingh and Tangail Districts in Bangladesh Households spread across 0.2 to 2.2 km radius	6 to 8 households / CHW 1:12 supervisor to CHW ratio CHWs visited households 1 / week for first 6 months, then at least 1 / fortnight Promoter training: Initial: W, S, HW: 4 days; N, WSH: 5 days; WSHN: 9 days	dressed any barriers that arose through ongoing dialogue with caregivers CHWs met with supervisors monthly to adapt technology and behaviour-change approaches to meet evolving conditions CHW supervisors available	when insufficient space (2% of cases) Functional water seals count was low (< 80% benchmark) in initial months which triggered a rapid response which improved uptake (Rahman 2018); households were using own latrines with broken water seals in	team (university graduates) at regular intervals using a priori benchmarks: a) surveys and spot checks in 30 to 35 households / IG / per month, over 20-month period; b) 5-hours of structured observations in 324 IG and 108 control households, approximately 15 months after interventions	(5 to 7 / month) which researchers suggest may have affected uptake Reported “high adherence to all interventions” with “marked differences in promoted behaviors from the control group at both year 1 and year 2,” with over 75% adherence in the single IG and combined IGs.

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giene[33] and 2 years of iterative testing and revision. Intervention specific behavioural objectives: W: drink treated and safely stored water S: safe faeces disposal H: HW with soap at key times N: age-appropriate nutrition birth	H: 2 HW stations, 1 water reservoir near kitchen (16 L) and 1 near latrine (40 L), each with basins for rinsing with a soapy water bottle (RFL, Bangladesh) and detergent sachets for index households[36] N: supply of lipid-based nutrient supplements (LNS, Nutriset; Malaunay, France) (for 6 to 24 months olds) 2 10g sachets per day per child; (118 kcal, 9.6g fat, 2.6g protein, 12 vitamins and 10 minerals) Cost: USD 0.08/day 18-month shelf life Stipends for CHWs (USD 20/month for 24	S: family use double pit latrines, potty train children and how to safely dispose of faeces and clean and maintain latrines H: family wash hands with soap after defecation, after cleaning a child who has defecated, before eating or before feeding a child, and before food preparation N: recommendations for exclusive breastfeeding up to 180 days and maternal and infant nutrition to mothers and index children; introduce diverse complementary food at 6 months; feed LNS from 6 to 24 months, mixed into the child's food (not intended as a replacement for breastfeeding or complementary foods). Messages adapted from the Alive & Thrive programme[37]	walking distance of IG cluster and passed a written and oral examination. They attended multiple training sessions and quarterly refreshers. Training covered active listening, strategies for developing collaborative solutions and techni-	Refresher training: 1 day each 21 day training of adherence team Monthly CHW supervisor meetings	by cell phone as needed Training of promoter varied in content and length depending on intervention type Potties provided if children < 3 years	parallel with trial latrines so pre-existing latrines were closed, visits by CHWs were increased and water-seal removal or breakage was discouraged Initial professional trainer for CHW training did not engage trainees enough so replaced with inter-	commenced. Measured: W: Presence of stored drinking water with detectable free chlorine (> 0.1 mg/L) S: a latrine with functional water seal, sani-scoop accessibility H: presence of soap at primary HW stations N: reported consumption of LNS sachets	Similar adherence in single W, S, H and N IGs compared with WSH and WSHN S: observed use of latrines: 94% to 97%; child sanitation practices (37% to 54%) H: HW with soap in IG more common after toilet use (67% to 74%) versus 18% to 40% in non-IGs and after cleaning child's anus (61% to 72%) but

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	to 24 months	months) delivered through mobile phone network to ensure timely payments Promoter's guide for visits for each relevant intervention including: - visit objective, - target audience - steps and materials to be used CHW ID badges Cell phones for CHW supervisors Training Plan and Manual for CHW supervisors covering: i) basic training - introduction of project, CHW roles and responsibilities, introduc-	On household visits, following a structured plan, CHWs greeted targeted household members, checked presence and functionality of relevant hardware and signs of use, observed recommended practice using a guide. CHWs used discussions, video dramas, storytelling, games and songs and provided training on hardware maintenance, where applicable Adherence observed and measured by separate team Supervision meetings of CHWs and periodic internal monitoring of their performance Intervention Delivery Team managed delivery through regular team phone calls, field meetings, field reports and liaison with relevant government and other stakeholders. It co-	cal aspects of interventions (see Table 1 of Luby 2018 for more details) CHWs were trained by 47 CHW supervisors who received direct training on intervention delivery Hardware installation team (n = 18)	nal training resource group Due to observation of intervention fatigue reported by CHWs and suboptimal practices observed, new behaviour change activities were developed (e.g. further technology use, increasing self-efficacy and	See Rahman 2018 for more details (Table 1) Continuous oversight and periodic monitoring of CHWs performance (CHW replaced within 1 month of attrition or critically low performance	low before food handling W: > 65% mothers and children observed drinking chlorine-treated water from safe container N: LNS feeding > 80% 33 low performing CHWs discontinued See Luby 2018, Parvez 2018, Arnold 2013, Unicomb 2018 for more details	

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	tion to behaviour-change principles based on the IBM-WASH theoretical framework and interpersonal and counselling communication skills. ii) Intervention-specific training iii) classroom practice / role playing	ensure rapid identification of issues with delivery. Including a dedicated training officer, it also trained the CHW supervisors who then trained the CHWs under their supervision ("train the trainer" approach)	9 field research officers The Intervention Delivery Team[38] co-ordinated delivery including CHWs, overseen by Principal Investigators with consultation from Technical Advisory Group (see Unicomb, 2018) Dedicated			roles for men)

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						Training Officer and Communication Development officer Adherence observed by separate team who received formal 21 day training							
Farr 1988a trial 1	2 active interventions in addition to control of no tissues: A. Virucidal	Families	Reduce transmission of viruses from hand contamination via hand-to-hand contact or	3-ply tissues with: A. 5.1 mg/inch^2 (2.54 cm^2) of the virucidal mixture (58.8% citric acid, 29.4% malic acid, 11.8% sodium lauryl sulphate) B. 3 mg/inch^2 (2.54 cm^2) of saccharin ap-	Family visits to distribute tissues Weekly contact of mother Families instructed to only use supplied tissues.	Nurse epidemiologist visited families.	Face-to-face visits to families and individuals in families (especially mothers)	Communities in the USA	6 months overall Monthly family visits Weekly contact with mother	Not described	Not described	Family visits and weekly contact with mother to encourage compliance	Not described

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	nasal tissues B. Placebo tissues		large-particle aerosol through tissues for nose blowing and coughs and sneezes	plied uniformly to all 3 plies of the tissue Tissues prepared by Kimberly-Clark Corporation, Neenah, WI, USA.								
Farr 1988b trial 2	2 active interventions (no control): A. Virucidal nasal tissues B. Placebo tissues	Families	Reduce transmission of viruses from hand contamination via hand-to-hand contact or large-particle aerosol through tissues for nose blowing and coughs and sneezes	2-ply tissues containing: A. 4.0 mg/inch^2 (2.54 cm^2) of antiviral mixture (53.3% citric acid, 26.7% malic acid, 20% sodium lauryl sulphate) B. 3 mg/inch^2 (2.54 cm^2) of succinic acid, malic acid, sodium hydroxide, and polyethylene glycol Tissues prepared by Kimberly-Clark Corporation, Neenah, WI, USA.	Family visits to distribute tissues and encourage compliance Weekly contact of mother Families instructed to only use supplied tissues.	Nurse epidemiologist visited families monthly. Study monitor visited bimonthly.	Face-to-face visits to families and individuals in families (especially mothers)	Communities in the USA	6 months overall Monthly family visits Weekly contact with mother Bimonthly study monitor visit	None described.	None described.	Bimonthly study monitor visits to encourage compliance as well as monthly and weekly contact by nurse	In 124/222 families, 1 or more family members reported not using the tissues regularly and/or reported having side effects from the tissues.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

Fretheim 2022a (additional source: Fretheim 2022b (protocol)	GLASSY (GLasses Against tha tranmission of SARS-CoV-2 in the communitY	Adult members of the public who did not regularly wear glasses and who owned or could borrow glasses to use (e.g. sunglasses)	Provide a simple, readily available, environmentally friendly, safe and sustainable means of personal protection from infection with respiratory viruses including SARS-CoV-2	Instructions via online portal Regular eyewear, e.g. sunglasses owned by participant or that could be borrowed by participant	Request to wear sunglasses or other types of glasses when outside home and close to others in public spaces for 14 days	Research team	Individually Instructions provided via email and online portal (Nettskjema-platform)accessed via webpage hosted by the Norwegian Institute of Public Health	Outside the home, e.g. on public transport, in shopping malls (in Norway)	14 days when outside and close to others in public spaces Over 11 to 12 week period (February – April 2022)	Could borrow glasses if did not own any	None reported.	No contact was made with participants between enrolment and data collection.	Reported use of glasses often, almost always, or always: IG: 71% CG: 11% Negative experiences (especially fogging with mask use): IG: 21/76
Longini 1988	2 active interventions (no control):	Households and their families	Prevent intrafamilial transmission of viral agents in a com-	Treated tissues of 3-ply material identified with no specific identifiers (Kimberly-Clark Corporation) with inside layer containing:	Tissues delivered to households with specific instructions on use (all purposes, when blowing nose, coughing or sneezing) and to discard after use and to help young children use tissues if develop a cold.	Tissues assigned by study sponsor (Kimberly-Clark	Supply of tissues throughout 5-month trial period	Households in the USA	5 months' overall supply	Resupply of tissues as required	None described.	Reported use of tissues "not at all, some of the time, most of the time, or	Reported use "all of the time": A. versus B. 82% versus 71%

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	A. Virucidal nasal tissues B. Placebo tissues		munity setting	A. citric and malic acid plus sodium lauryl sulphate; B. succinic acid.		Corporation).						all of the time"	
Chard 2019 (additional details from- Chard 2018)	Water, Sanitation, and Hygiene for Health and Education in Laotian Primary Schools (WASH HELPS)	Primary schools and their students	Prevent the spread of pathogens within schools through improved water supply and hygiene facilities and improved WASH habits in children at home and throughout the life course	For each school: Water supply for school compound: (borehole, protected dug well with pump, or gravity-fed system) Water tank to supply toilet and hand-washing station School sanitation facilities (3 toilet compartments) Hand-washing facilities: 2 sinks with tapped water and supply of soap available	Provision of school: Water supply, sanitation facilities, hand-washing facilities (individual and group), drinking water filters Behaviour change education and promotion including daily group hygiene activities Daily hand-washing and cleaning schedules	UNICEF paid for materials. School and teachers conducted daily hand-washing activities with children. Students participated in daily group cleaning activities.	Facilities provided within schools. Children participated in group hand-washing and cleaning.	Primary schools and their classrooms (in Laos)	One-off provision of water and hygiene facilities Daily hand-washing activities and cleaning for 1 school year Cleaning schedules posted in at least 1 classroom near toilet.	Water supply tailored to the school requirements/environment. Sanitation facilities provided as needed and designated for boys, girls, and students with disabilities.	Rain water tank provision affected by rain water supply, so changed to tanks with motorised hand pumps or gravity-fed water supply systems. Theft and animal consump-	Unannounced visits every 6 to 8 weeks for structured observations to measure fidelity and adherence Fidelity Index score (0 to 20): for hardware provided see Table 1 in paper and protocol Adherence in-	Fidelity: 30.9% across all schools and visits Adherence: 29.4% Hardware provision: 87.8% of schools School-level adherence: 61.4% Group compound cleaning: 94.8%, toilet use: 75.5%, group toilet

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				(1 bar of soap/ pupil) 3 group hand-washing tables with soap and water At least 1 drinking water filter per classroom Schedules of daily group hand-washing, compound and toilet cleaning Cost per school: USD 13,000 to 17,500							tion of supplied soap reduced supply.	dex: student report of behavioural outcomes index score (0 to 4)	cleaning: 68.3%, group hand-washing: 48.7%, individual hand-washing with soap after toilet use: 23.9%. Further details (Chard 2018)
Hartinger 2016	Integrated environmental home-based intervention package (IHIP)	Households and their household-ers including children	Reduce infections and improve child growth in households in rural communities	Per household: "OPTIMA-improved stove": improved ventilated solid-fuel stove Kitchen sink with in-kitchen water connection providing piped water	Community engagement with local and regional stakeholders in design and development Provision of stoves, kitchen sinks, and plastic bottles for solar water treatment, and hygiene education	Health promoters hired local elementary school teachers and implemented and promoted	Face-to-face and to individual households; mode of delivery of training as individual or	Households in rural communities in Peru	Stoves and sinks installed over initial 3 months. Monthly reinforcement over 12 months of	Tailored to particular household facilities and environments as needed and to local	Not described	Weekly spot-check observations of household hygiene and environmental health conditions (e.g. presence	SODIS use: 60% initially and 10% at end of study Self-reported use by mothers: 90% with

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	with limited facilities through a multi component, low-cost environmental intervention to improve drinking water, sanitation, personal hygiene, and household air quality developed in pilot (Hartinger 2011; Hartinger 2012) using a participatory approach	Point-of-use water quality intervention applying solar disinfection to drinking water	Training of mothers/caretakers in: - solar drinking-water disinfection (SODIS)[39] according to standard procedures - hand hygiene (washing own and children's hands with soap at critical times[40]) - advice to separate animals and their excreta from the kitchen environment Project-initiated repairs	the interventions. 4 teams of field staff conducted spot-check observations.	group not described	SODIS, child and kitchen hygiene Weekly spot checks of compliance Repairs after 9 months Environmental samples test middle and end of 12-month surveillance.	beliefs and cultural customs Repairs to stoves as needed and checked at 9 months	of SODIS bottles on the roof or kitchen) using a checklist Monthly self-report by mothers of stove and sink use	slight decrease at end Self-reported stove use: 90% daily Sink use: 66% daily 35% of stoves needed minor repairs, 1% needed major repairs. Best-functioning stoves achieved mean 45% and 27% reduction of $PM_{2.5}$ and CO, respectively, in

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			that addressed local beliefs and cultural views										mothers' personal exposure.
Huda 2012	Sanitation Hygiene Education and Water Supply in Bangladesh (SHEWA-B)	Villages and their households with a child < 5 years old	Reduce illness in children < 5 years by improving hygiene practices, sanitation and water supply and treatment in their household	Materials for training of community hygiene promoters and promotion activities including flip charts and flash cards with messages alerting participants to presence of unobservable "germs" and practices to minimise germs See Box 1 in paper for 11 key messages.[41]	Engaging local residents under guidance of local NGOs to develop community action plans addressing: Latrine coverage and usage Access to and use of arsenic-free water Improved hygiene practices, especially hand-washing with soap Recruitment and appointment of community hygiene promoters Household visits, courtyard meetings, and social mobilisation activities (e.g. water, sanitation and hygiene fairs, village theatre, group discussions in tea stalls (the social meet-	Community hygiene promoters (local residents with at least 10 years' schooling trained for 10 days on behaviour change communication in water, sanitation, and hygiene)	Face-to-face delivery to groups (villages and households) and individuals	Villages and households in districts of Bangladesh Community activities held in villages. Meetings held in courtyards of groups of households.	18 months overall Expected household visit and courtyard meeting every 2 months Handwashing opportunities: after own or child's defecation, prior to preparing and serving food, prior to eat-	Community action plans developed for and by local residents.	Not described	Structured observation of handwashing and child faeces disposal behaviour in households and spot checks of type of household water and sanitation facilities	HW: Food-related: No significant difference from baseline to 18 months; IG versus CG After anus cleaning: 36% versus 27% Defecation: 30% versus 23% No access to latrine decreased from

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					ing point for village men)) by community promoters Structured observation in households			House-hold visits	ing and feeding a child				10.3% to 6.8%. No significant improvement in access to improved latrines, solid waste disposal, drainage systems, and covered containers for water storage
Ibfelt 2015	Disinfection of toys	Day-care nurseries	Reduce transmission of pathogens via shared toys in day-care environment through regular disinfection	Disinfectants: Turbo Oxysan (Ecolab, Valby, Denmark) for washing machines Sirafan M, Ecolab (1% to 3% benzalkonium chloride, 1% to 3% didecyldimethylammonium chloride, and 5% to 7% alcohol ethoxylates) for immersion or wiping	Collection and commercial cleaning of toys from nurseries: - linen and toys suitable for washing machines were washed at 46 °C and subsequently disinfected - toys not suitable for washing machines immersed in disinfectant or wiped with microfibre cloth	Commercial cleaning company: Berendsen A/S, Søborg, Denmark	Cleaning companies collected the toys and linen and cleaned them offsite, then returned them.	Day-care nurseries in Denmark Commercial industrial cleaning facility	2 to 3 months overall Cleaning every 2 weeks	Staggered cleaning to ensure children had toys to play with whilst others were being cleaned	None described.	None described.	None described.

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			treatment										
Najnin 2019 (see also- Qadri 2015 for further details)	2 active interventions: A. Combined cholera vaccine and 'behaviour change communication' intervention B. Cholera vaccine-alone group	Low-income households and compounds	Prevent or reduce transmission of respiratory illness based on the Integrated Behavioural Model for Water Sanitation and Hygiene (IBM-WASH) theoretical framework (Dreibelbis 2013; Hulland 2013)	A. and B. Cholera vaccine ShanChol™ (Shantha Biotechnics-Sanofi, India) A. Following hardware per compound: a. Hand-washing hardware: (i) Bucket with a tap (provided free of charge) (ii) Soapy water bottle (mixture of a commercially available sachet of powdered detergent (~USD 0.03) with 1.5 L of water in a plastic bottle with a hole punched in the cap) supplied by participating compounds	A. and B. Provision of cholera vaccine (2 doses at least 14 days apart) Provision of hand-washing hardware and behaviour change communication activities Encouragement of hand-washing after defecation, after cleaning child's anus, and before preparing food Encouragement to add chlorine to own water vessels Benefits were again explained. Follow-up visits by health promoters	Dushtha Shasthya Kendra (DSK), an NGO, delivered the hardware and behavioural intervention (through community health promoters). Separate data collectors observed soap availability.	Handwashing and water treatment hardware mostly delivered at the compound level in person. Behaviour change communication messages were delivered both at compound and household levels.	Households and compounds (where several households share a common water source, kitchen, and toilets) in Bangladesh	Behaviour change communication messages delivered first (within 3 months of cholera vaccination). Point-of-use water hardware provided 3 months later. Follow-up health promoter visits 3 times in 2 months after hardware installation,	Hardware-related problems (breakage/leakage) were addressed on health promoter follow-up visits.	None described.	Unannounced home visits by data collectors who observed presence of soap/ soapy water and water in most convenient place for handwashing (either reserved in a container or available at the tap) Residual chlorine was measured indicating uptake of chlorine dispenser.	Presence of soap / soapy water and water: A. Handwashing group compounds: 45% (1729 / 3886); B. Vaccine-only group compound: 22% (438 / 1965); C. Control: 28% (556 / 1991) Residual chlorine present in stored drinking water of 4% (160/3886) of house-

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				(iii) Bowl to collect rinse water after washing hands (see photo in text or in Najnin 2017 doi.org/10.1093/ije/dyx187) b. Water treatment hardware: Dispenser containing liquid sodium hypochlorite See Figure 2 in Najnin 2017 for photos of both doi.org/10.1093/ije/dyx187 and more details. Participants own water vessels for water treatment Print materials for behaviour change to compounds and households									then 2 times/ month (over nearly 2 years).	holds in the vaccine-plus-behaviour-change compound and none in the other 2 compounds.
Swarthout 2020 (additional)	6 active interven-	Residents of	Improve envi-	Free technologies as appropriate to IG:	Provision and delivery of supplies or installations as de-	Community-based	Face to face in groups	8246 households	Installation and supply	Training tailored	None described	Participant reports	All interventions de-

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tional sources: Arnold 2013, Christensen 2015, Dentz 2017, Null 2018, Pickering 2019)	tions of water, sanitation, and handwashing (WASH), and nutrition components: A. Water (W) B. Sanitation (S) C. Handwashing (H) D. Combined (WSH) E. Nutrition (N) F. Combined (WSHN)	households of villages and for some interventions, particularly pregnant women (Mamas) and their infants and children < 5 years; Landowners of communal water sources and compound heads for latrine upgrades and construction	ronmental conditions to interrupt transmission of respiratory pathogens and improve child malnutrition thereby reducing childhood respiratory illness and improving childhood morbidity based on a literature review, a theory-based approach (health belief,	W: water treated with sodium hypochlorite (1.25% solution / 2 mg/L) using chlorine dispensers installed at communal water source collection points or bottled chlorine (1L for 333 20-l jerry-cans worth)[45] provided to households in compounds Chlorine strips to test chlorine levels S: installation of new or improvement of existing latrines with plastic slab latrines with tight-fitting lids; plastic potties and sani-scoops H: 2 HW stations (2-foot pedal-operated jerry-cans that dispensed soapy and rinse	scribed in Materials column according to intervention type or combination Provision of study materials to promoters Community meetings Household and community visits by promoters who: - delivered intervention-specific behaviour change messaging focusing on themes of nurture, aspiration and self-efficacy, considering convenience and cultural norms to improve adherence using scripts and visual aids; - provided instructions on hardware use and consumable supplies where applicable - advocated: W: drinking water treatment with sodium hypochlorite	health promoters nominated by their local communities and trained in the relevant intervention to be implemented Field enumerators assessed adherence in compounds Study staff trained promoters, provided pe-	(e.g. households or compounds) or individuals (mothers and their children)	and 7960 compounds of rural villages in Bungoma, Kakamega, and Vihiga counties in western Kenya	of materials before community meetings Community meeting 6 weeks after enrolment Monthly visits (45 to 60 min in 1st year) by promoters over 2 years (2012 to 2014) Timing of visits detailed in procedures provided at osf.io/7j9sk/ W: 1 L bottle of chlo-	for different interventions Troubleshooting of solutions to barriers to adherence by promoter and participants as needed Nutrition messaging was tailored to be age-appropriate Materials provided in both in	of visits by promoters in past month Unannounced visits by staff to a random sample of at least 20% of participants in IGs at 2, 6, 10, and 19 months after the interventions began to confirm delivery of materials and monitor availability of intervention materials and recommended behaviours after the interventions be-	livered within 3 months of enrolment Increased adherence indicators of ≥ 30% higher in all IGs relative to the control in the first year Adherence was comparable between the Individual IGs compared with combined IGs. W: 5 chlorine dispensers installed / cluster

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	social cognitive theory and persuasion theory),[42],[43],[44] formative research and the WASH Benefits pilot RCT (Christensen 2015)	water), 1 near food preparation, 1 near latrine. Rinse water provided by households; bar soap for soapy water container N: 2 x 10 g sachets / day / child of lipid-based nutrient supplementation (LNS) "Mwanzobora", (Nutriset, Malaunay, France) (118 kcal/day and 12 essential vitamins and 10 minerals) See Figure 2 of Christensen 2015 for photos of examples of some of the materials Community meeting and household visit summary sheets (in Kiswahili and English) and	S: use of improved latrines for defecation and safe disposal of children's and animals' faeces and use of plastic potties by children < 3 years and sani-scoops for faeces removal H: HW with soap before food preparation and after defecating (including assisting child); helped participants identify compound members to refill taps and manage barriers to use such as running out of soap N: early initiation of breastfeeding, exclusive breastfeeding 0 to 6 months and continued till 24 months; at 6 months, introduction of appropriate and diverse complementary foods; feeding frequency and during illness; supply of LNS to children 6 to 24 months and instruction to mix it was foods twice/day Promoters used visual aids to promote messages: - cue cards provided to Mamas at ini-	riodic observation and supervision and monthly phone calls	rine / 6 months H: bar soap provided every 3 months N: LNS introduced at 6 months of age of child Promoter training: 6 days single IGs. 7 days combined IGs. Refresher training at 6, 12 and 18 months after initial training	Kiswahili and English Chlorine dispensers located based on list of sources participants reported (at baseline) using for water collection Sani-scoops and potties were to be washed by caregivers with soap and water after use	gan (Null 2018) W: monthly tests of chlorine concentration in stored water; negative results prompted discussions to address chlorination barriers S: participant report of access to improved latrine; field enumerators observed if latrine had plastic or cement slab or ventilation pipe;	Year 1: 74% Year 2: 37% households were visited by a promoter in previous month W: Year 1: 42% Year 2: 21% had detectable total chlorine CG: 3% S: Year 1 and 2: > 80% had latrine access CG: 20%		

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	list of materials provided as PDFs at osf.io/7j9sk/ Key messages and visual aids provided at osf.io/7j9sk/ Including ~6 primary key messages per intervention, each with a series of specific topics, visual aids, and engagement activities (e.g. storytelling, mottos, etc.). Visual aids included: - cue card reminders - picture sheets for use by promoters - calendars for households with key messages - stickers for LNS box depicting appropriate feeding and storage	tial visits to hang on walls for reminders - picture sheets used by promoter to explain key concepts or messages - calendars provided to households during first compound visit - stickers attached to LNS box Adherence checking unannounced visits Initial training on intervention-specific behaviour change messages and materials Refresher training Periodic observation and supportive supervision by study staff	Supervision and observation of promoter by study staff at 2, 4, 9, 14 and 21 months and monthly phone calls	and tools kept out of reach of children (see the visual aids provided to participants: osf.io/9r4kg/ for potties and osf.io/mz2c6/ for sani-scoops)	caregiver report that child faeces safely disposed H: field enumerator observed if water and soap available N: report of LNS sachets consumed by child in last week / 14	HW: Year 1: 77% Year 2: 21% had HW materials CG: 9% N: Year 1: 95% Year 2: 115% of expected sachets consumed See Null 2018 for more details		

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

										Promoter Training Materials for trainers and trainees for each intervention for initial training and for refresher training including detailed PDF training manuals available at osf.io/7j9sk/ focusing on key hygiene messages, visitation scripts and visual aids and hardware for each intervention[46]	
										Promoters' supplies: Branded t-shirt, mobile phone, job aids and intervention materials, payment ($US15/month for first 6 months, then $9/month thereafter), detailed plans for every visit (key messages, scripts for visual aids, instructions for activities)	

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

Oral and/or nasal applications												
Almanza-Reyes 2021	Mouthwash and nose rinse with ARGOVIT silver nanoparticles (AgNPs)	Healthcare personnel (doctors, nurses, administrative staff) of a metropolitan hospital caring for patients diagnosed with atypical pneumonia and/or COVID-19	Reduce morbidity in healthcare professionals exposed to SARS-Co V-2 by inhibiting virus replication	Per participant: - 50 ml bottle of RGOVIT® AgNPs mouthwash and nasal rinse [Investigation and Production Center Vector-Vita Ltd., Novosibirsk, Russia] (metallic silver 0.06%, polyvinylpyrrolidone 0.63%, hydrolyzed collagen 0.31%, distilled water 99% wt.) - water - cotton swabs	Individuals provided with spray bottle containing AgNPs solution with 1 wt% concentration (0.6 mg/mL metallic silver) and instructed to do 1 of the following or a combination: a) mix 4 to 6 spray shots (~ 0.5 mL) with 20 mL of water and gargle solution for 15 to 30 seconds at least 3 times/day (gargle) or b) do not dilute with water and cover the oral cavity evenly with 1 to 2 direct spray shots (spray) c) apply the same solution to the inner part of the nasal alae and nasal passage with cotton swab twice a day (nasal rinse)	Researchers supplied materials and instructions Participants self-applied the mouthwash and nasal rinse materials	Individually and face to face	General hospital in Tijuana, Mexico	Over a 9 week period (April to June 2020) 4 to 6 spray shots of AgNP solution (0.5 mL) with 20 mL of water or 1 to 2 spray shots of solution without water for 15 to 30 seconds ≥ 3 times / day and 1 nasal lavage 2 times / day	Participants could choose application method	None described	Weekly self-report of number of: daily gargles; mouthwashes with spray; mouthwashes by gargle + spray; and nasal rinses	Mean applications/day: Gargle only: IG: 2 (n = 28) CG: 2.14 Spray only: IG: 2 (n = 34). Both gargle and spray: IG: 2 gargles, 4 sprays (n = 52) Nasal rinse: IG: 0.70 (n = 64) CG: 0.25
Gutiérrez-García 2022	Nasopharyngeal and oropha-	COVID-19 frontline medical	Reduce risk of COVID-19 in	SES (pH 6.5 to 7.5; REDOX potential 750 - 950 mV;	Written instructions provided to follow a prophylactic rinse protocol with SES 3 times/day for 4 weeks with advice	Not clearly specified; leaders of	Individually and face to face	Mexican COVID-19 hospital	4 nasal sprays (~ 0.4 mL) and 10 mL mouth-	None described	None described	None described	None described

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	ryngeal rinses with a neutral electrolyzed water (SES)	staff (nurses and physicians, males or females)	frontline unvaccinated medical staff	0.0015% of active species of chlorine and oxygen) provided by Esteripharma S.A. de C.V Per participant: - 4 plastic flasks of 240 mL oral SES (ESTERICIDE® Bucofaríngeo, COFEPRIS registration no. 1003C2013 SSA) with a graduated cap and - 4 plastic flasks of 30 mL nasal rinse (Esteri-Flu®, COFEPRIS registration no. 308C2015 SSA), with a valve for spraying	on correct way to use the mouthwashes and sprays and the need to report possible side effects immediately: a) nasal cavity: 4 vertical sprays in each nostril, inhaled deeply at the time of each spray b) oral cavity: mouthwash and gargle 10 mL for 60 seconds, then spit out In addition to standard COVID-19 safety protocols requiring wearing of adequate personal protection equipment at all times,[49] frequent handwashing[50] and disinfection of secondary uniform and footwear[51] and bath at end of working day	nursing and other relevant healthcare department distributed the study information and were the point of contact and monitored the protocol so they may have distributed intervention materials				wash gargle for 60 seconds 3 times / day for 4 weeks (September to November 2020)				
Goodall 2014	2 active interventions:	University students	Decrease the incidence	A. Vitamin D_3: container of 8 capsules of 10,000 IU (pur-	A. Vitamin D: instructed to take 1 pill weekly	Not specified, presum-	Vitamin D_3 supplied indi-	In university student hous-	2 months overall	None described.	None described.	None described.	None described.

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

	A. Vitamin D_3 supplementation B. Gargling water		of URTI through increased vitamin D levels (associated with greater frequency and severity of URTI) and gargling (as preventative measure against URTI)	chased from Euro-Pharm International Canada Inc.) Weekly email reminder B. Gargling: 30 mL of tap water 2/day	B. Gargling: instructed to gargle twice daily for 30 seconds All participants received general lifestyle and health advice on sleep, nutrition, hand hygiene, and exercise.	ably the researchers, including a study pharmacist	vidually, but no further details. Method of lifestyle and health advice provision also not described.	ing (in residences or off-campus) in Canada	Vitamin D_3: weekly supplementation and email reminder Gargling: 30 mL of water for 30 seconds twice daily				
Ide 2014	2 active interventions (no control): A. Green tea gargling B. Water gargling	High school students	Prevent influenza spread and infection in high school students who are at increased	A. Bottled green tea (500 mL) containing a catechin concentration of 37 ± 0.2 mg/dL, including approximately 18% (-)-epigallocatechin gallate (manufactured by the Kakegawa Tea Merchants Association).	A. Provision of green tea B. Advice to gargle with tap water and not to gargle green tea during study A. and B. Advice to gargle at least 3 times/day (after arriving at school, after lunch, and after school) Consumption of green tea and other	Materials supplied by researchers. High schools' vice principals and head teachers as-	Green tea supplied individually to students. Mode of gargling advice not described.	High schools in Japan	Gargling 3 times/day for 90 days	None described.	None described.	Daily questionnaire included questions about daily adherence to gargling regimen. Adherence rate of	Gargling adherence rate: green tea group: 73.7%; water group: 67.2%

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

			risk from close interaction through gargling as a non-pharmaceutical intervention, specifically green tea containing highly bioactive catechin (-)-epigallocatechin gallate, with possible anti-influenza virus properties	Concentration measured by high-performance liquid chromatography based on the average concentration in 10 bottles from the same production lot (September 2011) used for gargling in the study. B. Tap water	tea was not restricted for either group. Safety monitoring carried out throughout the study (not further described).	sisted with safety monitoring.						gargling at or above 75%, and absence of green tea gargling when in the water gargling group.	
Satomura 2005	2 active in-	Healthy adults	Prevent URTIs	A. Water B. 15 to 30 times dilut-	Local administrators instructed participants to:	Local project admin-	Not specified,	18 healthcare	60 days overall	If diluted povi-	3 participants	Completion of gargling	9 participants did not

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Table 1. Description of interventions in included studies, using the items from the Template for Intervention Description and Replication (TIDieR) checklist *(Continued)*

terventions: A. Water gargling B. Povidone-iodine gargling	through gargling water alone, which may wash out pathogens from the pharynx and oral cavity through whirling water or through chlorine, or povidone-iodine for its perceived virucidal properties	ed 7% povidone-iodine (as indicated by manufacturer)	- gargle dose of water or povidone-iodine 3 times/day; - maintain handwashing routine; - not change other hygiene habits; - not take any cold remedies; - complete gargling diary. Weekly monitoring of hygienic actions and encouragement to keep up assigned intervention every week	istrators (18 healthcare professionals) provided instructions and monitoring and encouragement.	but likely to have been face-to-face and individually, at least initially for instructions	sites in Japan (4 in northern region, 9 in central region, 5 in western region)	1. Water gargling: 20 mL for 15 s at least 3 times/day 2. Povidone-iodine gargling: 20 mL of dilution 3 times/day	done-iodine caused serious discomfort or was not available, participants were allowed to gargle with water instead.	assigned to povidone-iodine gargled with water instead as the povidone-iodine "did not agree with them".	diary: frequency of gargling and handwashing Weekly monitoring and encouragement by local administrators	complete diary. Average frequency of gargling / person / day: With water: A: 3.6 B: 0.8 Control: 0.9 With povidone-iodine: A.: < 0.1 B: 2.9 Control: 0.2

ABH: alcohol-based rub
AGNPs: ARGOVIT silver nanoparticles
ARI: acute respiratory infection
CDC: Centers for Disease Control and Prevention
CG: control group
CHG: chlorhexidine gluconate
CHW: community health worker
CO: carbon monoxide
DCCs: daycare centres

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DCT: daily contact testing
FM: face masks
H: handwashing
HCP: healthcare personnel
HCW: healthcare worker
HH: hand hygiene
HSG: hand sanitiser group
HSW: hand-washing with soap and water
HW: hand-washing
HWWS: hand-washing with soap
IG: intervention group
IHIP: integrated environmental home-based intervention package
ILI: influenza-like illness
IU: international units
LFD: lateral flow device
LNS: lipid-based nutrient supplements
LTCFs: long-term care facilities
m: metre
min: minute
N: nutrition
NGOs: non-governmental organisations
NH: nursing home
NHS: National Health Service
no.: number
NPIs: non-pharmaceutical interventions
PCR: polymerase chain reaction
PM2.5: particulate matter of less than 2.5 microns
RAs: research assistants
RIs: respiratory infections
RTIs: respiratory tract infections
S: sanitation
SD: standard deviation
SES: electrolysed water
SSTI: skin and soft-tissue infection
SWG: soap-and-water group
TCID: tissue-culture infectious dose
URTI: upper respiratory tract infection
W: water
WHO: World Health Organization
wk: week
WSH: combined water, sanitation and handwashing
WSHN: combined water, sanitation, handwashing and nutrition
w/w: weight for weight

[1] Filtration efficiency testing was conducted using a Fluke 985 particle counter (volumetric sampling rate of 2.83 litres/ minute. The measurement was taken of particles 0.3–0.5 µm in diameter flowing through the material with a face velocity of 8.5 cm/s. Internal testing found that cloth masks with an external layer made of Pellon 931 polyester fusible

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interface ironed onto interlocking knit with a middle layer of interlocking knit could achieve a 60% filtration efficiency. Upon discussions with the manufacturers, the researchers learned that those materials could not be procured. Using materials that were available, the highest filtration efficiency possible was 37%.
[2] "the exterior and interiors were spunbond and the middle layer was meltblown"
[3] 10 times with bar soap and water
[4] Featured the Honorable Prime Minister of Bangladesh Sheikh Hasina, the head of the Imam Training Academy, and the national cricket star Shakib Al Hasan.
[5] A grassroots organization with a network of volunteers across the country
[6] "consistent with the WHO guideline that defines physical distancing as one meter of separation." www.who.int/westernpacific/emergencies/covid-19/information/physical-distancing (accessed 13 June 2022).
[7] Occupational Safety and Health Administration (OSHA). OSHA technical manual: section VIII: chapter 2: respiratory protection. US Department of Labor. www.osha.gov/dts/osta/otm/otm_viii/otm_viii_2.html (accessed 21 April 2020).
[8] Ministry of Health and Long-Term Care, Public Health Division, Provincial Infectious Diseases Advisory Committee. Preventing respiratory illnesses: protecting patient and staff: infection control and surveillance standards for febrile respiratory illness (FRI) in non-outbreak conditions in acute care hospitals [September 2005] http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_fri_080406.pdf (accessed September 11 2009). [URL inactive]
[9] Before eating, after sneezing, coughing, handling money, using restroom, returning to desk and interacting with others who may be sick
[10] after coming into classroom, before and after lunch, after break, after physical education, when they went home and after coughing, sneezing or blowing their noses
[11] after toileting and when visibly dirty plus a protocol for particular circumstances: after coming into the classroom; before and after lunch; after playing outside; when they went home; after coughing, sneezing, or blowing their noses; and after diapering
[12] 1) when entering into the classroom; 2) after sneezing, coughing, or blowing their nose; 3) after using the toilet/washroom; 4) before eating any food; and 5) when leaving the school at the end of the day
[13] what to do if hands were dirty, why students should wash their hands, benefits of washing hands and using hand sanitiser, procedure for washing hands using hand sanitiser, to cover mouth and nose with upper part of sleeve while coughing and/or sneezing
[14] Boyce JM, Pittet D, Healthcare Infection Control Practices Advisory Committee, HICPAC/ SHEA/APIC/IDSA Hand Hygiene Task Force. Guideline for hand hygiene in healthcare settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/ IDSA Hand Hygiene Task Force. MMWR Recommendations and Reports 2002;51(RR-16):1–45. www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm (accessed 21 April 2020). International Bank for Reconstruction and Development/ World Bank, Bank-Netherlands Water Partnership, Water and Sanitation Program. Hand washing manual: a guide for developing a hygiene promotion program to increase handwashing with soap. http://go.worldbank.org/PJTS4A53C0 (Accessed 16 May 2007). *[URL inactive]* California State Department of Education. *Techniques for Preventing the Spread of Infectious Diseases*. Sacramento (CA): California State Department of Education, 1983. Geiger BF, Artz L, Petri CJ, Winnail SD, Mason JW. *Fun with Handwashing Education*. Birmingham (AL): University of Alabama, 2000. Roberts A, Pareja R, Shaw W, Boyd B, Booth E, Mata JI. A tool box for building health communication capacity. www.globalhealthcommunication.org/tools/29 (Accessed 10 October 2007). *[URL inactive]* Stark P. *Handwashing Technique. Instructor's Packet. Learning Activity Package*. Sacramento (CA): California State Department of Education, 1982.
[15] DIN EN 1500: Chemische Desinfektionsmittel und Antiseptika, Hygienische Händedesinfektion, Prüfverfahren und Anforderungen (Phase 2/Stufe 2). Brüssel (Belgium): CEN, European Comittee for Standardization 1997;1-20.
[16] DIN EN 12791: Chemische Desinfektionsmittel und Antiseptika, Chirugische Händedesinfektionsmittel - Prüfverfahren und Anforderungen (Phase 2/Stufe 2). Brüssel (Belgium): CEN, European Comittee for Standardization 2005;1-31.
[17] after defaecation, after cleaning an infant who had defaecated, before preparing food, before eating, and before feeding infants
[18] non-governmental organisation that supports community-based health and development initiatives
[19] "Healthy Hands" Rules (from Figure 3 in paper): Do use "special soap" when arrive to school, before lunch, after go to bathroom (only if soap and water not available), if rub nose or eyes or if fingers in mouth, if teacher asks. Do not: use "special soap" if hand dirt on them, put "special soap" on another student, play with 'special soap", put hands near eyes after using "special soap".
[20] Calculated by subtracting each day's soap weight from the previous day's weight. Maximum number of grams of soap consumed for each compound was identified and the day on which the maximum soap consumption was recorded. A per capita estimate of daily soap consumption was calculated
[21] National Health and Medical Research Council. Staying Healthy in Child Care. Canberra (Australia): Australian Government Publishing Service, 1994
[22] upon arrival, before and after lunch, and prior to departure
[23] World Health Organization. (2012). Hand hygiene in outpatient and home-based care and long-term care facilities: a guide to the application of the WHO multimodal hand hygiene improvement strategy and the "My Five Moments For Hand Hygiene" approach. World Health Organization. apps.who.int/iris/handle/10665/78060 (accessed 15 June 2022)

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[24] Moment 1 (before touching a resident) = Room In; Moment 4 (after touching a resident) and Moment 5 (after touching a resident's surroundings) = Room Out; Moment 2 (before a clean/antiseptic procedure) = Before Clean; Moment 3 (after body fluid exposure risk) – After Dirty
[25] Handsome: handhygiëne in verpleeghuizen.: Zorg voor beter; 2019 May 03. URL: www.zorgvoorbeter.nl/handsome (accessed 7 June 2022)
[26] Veiligheid en Kwaliteit: Project Handen uit de Mouwen.: Stichting Samenwerkende Rijnmond Ziekenhuizen
[27] Auditor training.: Hand Hygiene Australia URL: www.hha.org.au/audits/auditor-training (accessed 7 June 2022)
[28] no long nails, acrylic nails, or polished nails and not wearing a ring, bracelet, wristwatch, brace, or long sleeves.
[29] Persoonlijke hygiëne: Verpleeghuizen, woonzorgcentra, voorzieningen voor kleinschalig wonen voor ouderen.: Werkgroep Infectie Preventie; 2014. URL: tinyurl.com/wpfqr8p (accessed 7 June 2022)
[30] knowledge and awareness of HH guidelines, perceived importance of performing HH, perceived behavioural control (i.e. perceived ease or difficulty of performing the behaviour), and habit
[31] "According to the Dutch national guidelines, HH is mandatory for caregivers before touching/preparing food, before caregivers themselves ate or assisted children with eating, and before wound care; and after diapering, after toilet use/wiping buttocks, after caregivers themselves coughed/sneezed/wiped their own nose, after contact with body fluids (e.g. saliva, vomit, urine, blood, or mucus when wiping children's noses), after wound care, and after hands were visibly soiled." (p. 2495)
[32] Having touched household items being used by the index patients and/or other symptomatic household contacts, and after coughing/sneezing, before meals, before preparing meals and when returning home
[33] Which addresses "contextual, psychosocial, and technological factors at the societal, community, interpersonal, individual, and habitual levels". (Luby 2018)
[34] Hussain F, Luby SP, Unicomb L, Leontsini E, Naushin T, Buckland AJ, et al. Assessment of the acceptability and feasibility of child potties for safe child feces disposal in rural Bangladesh. The American Journal of Tropical Medicine and Hygiene. 2017;97: 469–76.
[35] Sultana R, Mondal UK, Rimi NA, Unicomb L, Winch PJ, Nahar N, et al. An improved tool for household faeces management in rural Bangladeshi communities. Tropical Medicine & International health 2013;18: 854–60.
[36] Hulland KR, Leontsini E, Dreibelbis R, Unicomb L, Afroz A, Dutta NC, et al. Designing a handwashing station for infrastructure-restricted communities in Bangladesh using the integrated behavioural model for water, sanitation and hygiene interventions (IBM-WASH). BMC Public Health 2013; 13: 877.
[37] Menon P, Nguyen PH, Saha KK, Khaled A, Sanghvi T, Baker J, et al. Combining intensive counseling by frontline workers with a nationwide mass media campaign has large differential impacts on complementary feeding practices but not on child growth: results of a cluster-randomized program evaluation in Bangladesh. The Journal of Nutrition 2016;146:2075–84.
[38] comprised of: senior program manager-intervention delivery, senior program manager-operations, Sanitation Intervention Team leader, senior field research officer, training officer, field research officers, CHW supervisors and CHWs
[39] SODIS: www.sodis.ch/index_EN.html
[40] after defecation, after changing diapers, before food preparation and before eating
[41] 1. Wash both hands with water and soap before eating/ handling food 2. Wash both hands with water and soap/ash after defecation 3. Wash both hands with water and soap/ash after cleaning baby's bottom 4. Use hygienic latrine by all family members including Children 5. Dispose of children's faeces into hygienic latrines 6. Clean and maintain latrine 7. Construct a new latrine if the existing one is full and fill the pit with soil/ash. 8. Safe collection and storage of drinking water 9. Draw drinking water from arsenic safe water point 10. Wash raw fruits and vegetables with safe water before eating and cover food properly 11. Manage menstruation period safely (p.605)
[42] Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the Health Belief Model. Health Education Quarterly 1988;15:175–83.
[43] Glanz K, Rimer BK, 2005. Theory at a Glance: A Guide for Health Promotion Practice. Washington, DC:US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Cancer Institute.
[44] Hovland CI, Janis IL, Kelley HH, 1953. Communication and Persuasion; Psychological Studies of Opinion Change. New Haven, CT: Yale University Press.
[45] Based on family of five, consuming 2L of water per person per day, the bottle would last almost a year
[46] W: key concepts for water treatment and contamination, procedures for refilling dispenser and distributing bottled chlorine, chlorine testing and reporting; H: HW with soap at critical times and creating supportive environment; S: contamination pathways; N: early initiation and exclusive breastfeeding, complementary and supplementary feeding, LNS procedures for collection from health facility and delivery tracking, teaching mamas how to feed Mwanzobora to the child, cooking demonstration, age-specific messaging about nutrition
[47] Department of Health and Social Care. Lateral flow device performance data. July 7, 2021. www.gov.uk/government/publications/lateral-flow-device-performance-data (accessed 15 June 2022).
[48] "applicable to schools as defined in national guidelines were, face to face contact (within 1 metre for any length of time) or skin to skin contact or someone the case coughed on; or within 1 metre for ≥1 minute; or within 1-2 metres for >15 minutes." P.2 of Supplementary appendix

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[49] i.e., surgical uniform, N95 mask, eye-sealing glasses and plastic wallet, disposable cap, latex gloves, rubber footwear for hospital use and disposable shoe covers, while working. Additionally, third level care health professionals wore a full protective mask, Dermacare®, overalls with zipper, and an integrated hood with elastic hand and ankle cuffs, double disposable boot covers and double latex gloves.
[50] With liquid soap (2% chlorhexidine gluconate) and hand disinfection (0.05% chlorhexidine gluconate and 60-80% ethyl alcohol).
[51] With 80% ethyl alcohol

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Table 2. Results from trials of hand hygiene compared to control

Study	Comparison (see Table 1 for details of interventions)	Reported outcomes	Results
Alzaher 2018 cluster-RCT Saudi Arabia	Hand-washing workshop and posters versus usual practice	% absence days due to URI	0.39% and 0.72% in intervention group schools; 0.86% and 1.39% in control schools
Arbogast 2016 cluster-RCT USA	Hand sanitiser + wipes + hand foam versus none Both groups received education + signage about hand-washing	1. Health insurance claims for preventable illnesses per employee 2. Absences per employee	1. 0.30 claims in intervention; 0.37 in control (27% relative reduction; P = 0.03) 2. 1.45 in intervention; 1.53 in control (5.0% relative reduction in intervention; P = 0.30)
Ashraf 2020 cluster-RCT Bangladesh	6 intervention arms: water quality, sanitation, hand washing, combined WSH, nutrition, nutrition + WSH	7-day prevalence of acute respiratory illness (ARI).	Hand washing reduced ARI cases by 32% (RR 0.68, 95% CI 0.52 to 0.88)
Azor-Martinez 2016 RCT Spain	Hand-washing with soap and-water plus hand sanitiser versus usual hand-washing practices	% absence days due to URI	1.15% in intervention; 1.68% in control. Significantly lower in intervention (P < 0.001)
Azor-Martinez 2018 cluster-RCT Spain	Education and hand hygiene with soap and water versus hand hygiene with sanitiser versus usual hand-washing procedures	1. URI incidence rate ratio (primary) 2. Percentage difference in absenteeism days	1. HH soap versus control 0.94 (95% CI 0.82 to 1.08); HH sanitiser versus control 0.77 (95% CI 0.68 to 0.88); HH soap versus HH sanitiser 1.21 (95% CI 1.06 to 1.39) 2. HH soap 3.9% versus control 4.2% (P < 0.001); HH sanitiser 3.25% versus control 4.2% (P = 0.026); HH soap 3.9% versus HH sanitiser 3.25% (P < 0.001)
Biswas 2019 cluster-RCT Bangladesh	Hand sanitiser and respiratory hygiene education and cough/sneeze hygiene versus no intervention	1. ILI incidence rate (at least 1 episode) 2. Laboratory-confirmed influenza	1. 22 per 1000 student-weeks in intervention; 27 per 1000 student-weeks in control, not statistically significantly different 2. 3 per 1000 student-weeks in intervention; 6 per 1000 student-weeks in control, P = 0.01
Correa 2012 cluster-RCT Colombia	Alcohol-based hand sanitiser in addition to hand-washing versus usual hand-washing practice	ARIs in 3rd trimester of follow-up	Hazard ratio for intervention to control 0.69 (95% CI 0.57 to 0.83)
Cowling 2008 cluster-RCT Hong Kong	Hand hygiene (36 households) versus face mask (mask) versus education (control)	Secondary attack rate for: 1. laboratory-confirmed influenza; 2. ILI definition 1; 3. ILI definition 2;	1. HH 0.06; mask 0.07; control 0.06 2. HH 0.18; mask 0.18; control 0.18 3. HH 0.11; mask 0.10; control 0.11 4. HH 0.04; mask 0.08; control 0.04

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Table 2. Results from trials of hand hygiene compared to control *(Continued)*

		4. ILI definition 3.	
Cowling 2009 cluster-RCT Hong Kong	Hand hygiene (HH) versus face mask + hand hygiene (HH + mask) versus education (control)	Secondary attack rate for: 1. laboratory-confirmed influenza; 2. ILI definition 1; 3. ILI definition 2.	1. HH 5; HH + mask 7; control 10 2. HH 16; HH + mask 21; control 19 3. HH 4; HH + mask 7; control 5
DiVita 2011 (conference abstract) RCT Bangladesh	Hand-washing stations with soap and motivation vs none	1. SAR for laboratory-confirmed influenza 2. SAR for ILI	1. SAR higher in intervention group (11.0% versus 7.5%) 2. SAR higher in intervention group (14.2% versus 11.9%)
Feldman 2016 cluster-RCT Israel	Hand disinfection + soap and water installed versus none	1. Number of respiratory infections 2. Number of off-duty days	1. 11 in each group 2. 112 in intervention; 104 in control
Gwaltney 1980 RCT USA	Virucidal hand wash versus placebo	1. Number with illness after immediate exposure 2. Number with illness after 2-hour delay in exposure	1. 0 of 8 in intervention; 7 of 7 in control 2. 1 of 10 in intervention; 6 of 10 in control
Hubner 2010 RCT Germany	Hand disinfection provided versus none	Odds ratios (95% CI) (intervention:control) 1. Influenza 2. Common cold 3. Sinusitis 4. Sore throat 5. Fever 6. Cough	1. 1.02 (0.20 to 5.23) 2. 0.35 (0.17 to 0.71) 3. 1.87 (0.52 to 6.74) 4. 0.62 (0.31 to 1.25) 5. 0.38 (0.14 to 0.99) 6. 0.45 (0.22 to 0.91)
Ladegaard 1999 RCT Denmark	Hand hygiene and education versus none	Sick days during the "effect period"	22 days/child in the intervention group versus 36 days/child in the control group
Larson 2010 cluster-RCT USA	Education versus education with alcohol-based hand sanitiser versus education with hand sanitiser and face masks	Incidence rate ratios (episodes per 1000 person-weeks) for: 1. URI; 2. ILI; 3. influenza. Secondary attack rates for: 4. URI/ILI/influenza; 5. ILI/influenza.	1. HS 29; HS + masks 39; control 35 2. HS 1.9; HS + masks 1.6; control 2.3 3. HS 0.6; HS + masks 0.5; control 2.3 4. HS 0.14; HS + masks 0.12; control 0.14 5. HS 0.02; HS + masks 0.02; control 0.02

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Table 2. Results from trials of hand hygiene compared to control *(Continued)*

Little 2015 RCT England	Bespoke automated web-based hand hygiene motivational intervention with tailored feedback versus none	Number of participants with 1 or more episodes of URI	Risk ratio for intervention to control 0.86 (95% CI 0.83 to 0.89; P < 0.001)
Luby 2005 RCT Pakistan	Antibacterial soap and education about hand-washing versus plain soap and education versus none	1. Cough or difficulty breathing in children < 15 yrs (episodes/100 person-weeks) 2. Congestion or coryza in children < 15 yrs (episodes/100 person-weeks) 3. Pneumonia in children < 5 yrs (episodes/100 person-weeks)	All outcomes significantly lower than control 1. 4.21 in antibacterial soap group; 4.16 in plain soap group; 8.50 in control group 2. 7.32 in antibacterial soap group; 6.87 in plain soap group; 14.78 in control group 3. 2.42 in antibacterial soap group; 2.20 in plain soap group; 4.40 in control group
Millar 2016 cluster-RCT USA	Standard educational promotion of hand-washing versus enhanced promotion versus promotion plus a once-weekly application of chlorhexidine-based body wash	Incidence rates of ARI over 20 months	37.7 enhanced + body wash; 29.3 enhanced; 35.3 standard; RR for enhanced + body wash to standard 1.07 (95% CI 1.03 to 1.11); RR for enhanced to enhanced + body wash 0.78 (95% CI 0.75 to 0.81)
Morton 2004 cluster-RCT cross-over study USA	Alcohol gel plus education versus regular hand-washing	Absence due to infectious illness	Results not stated numerically
Nicholson 2014 cluster-RCT India	Combination hand-washing promotion with provision of free soap versus none	Target children: 1. Episodes of ARI (per 100 person-weeks) 2. School absence episodes (per 100 person-days) Families: 3. Episodes of ARI	1. 16 in intervention; 19 in control 2. 1.2 in intervention; 1.7 in control 3. 10 in intervention; 11 in control
Priest 2014 cluster-RCT New Zealand	Hand hygiene education and hand sanitiser versus education alone	1. % absence days due to respiratory illness 2. % absence days due to any illness	1. 0.84% in intervention group; 0.80% in control (P = 0.44) 2. 1.21% in intervention group; 1.16% in control (P = 0.35)
Ram 2015 RCT Bangladesh	Education to promote intensive hand-washing in households plus soap provision versus none	1. Secondary attack ratio for intervention to control for ILI 2. Laboratory-confirmed influenza	1. 1.24 (95% CI 0.93 to 1.65) 2. 2.40 (95% CI 0.68 to 8.47)
Roberts 2000 cluster-RCT	Hand-washing programme with training for staff and children versus none	Incidence rate ratio for ARI	IRR 0.92 for intervention to control (95% CI 0.86 to 0.99)

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Table 2. Results from trials of hand hygiene compared to control *(Continued)*

Australia			
Sandora 2008 cluster-RCT USA	Hand sanitiser and education versus none	Incidence rates for ARI (episodes per person-month)	0.43 in intervention; 0.42 in control
Savolainen-Kopra 2012 cluster-RCT Finland	Hand hygiene with soap and water (IR1 group) versus with alcohol-based hand rub (IR2 group) versus control (none); intervention groups also received education	1. Number of respiratory infection episodes/week 2. Number of reported infection episodes/week 3. Number of reported sick leave episodes/week	1. 0.076 in IR1; 0.085 in IR2; 0.080 in control, NS 2. 0.097 in IR1; 0.107 in IR2; 0.104 in control, NS 3. 0.042 in IR1; 0.035 in IR2; 0.035 in control. Significantly higher in IR1 compared with control
Simmerman 2011 cluster-RCT Thailand	Hand-washing (HW) versus hand-washing plus paper surgical face masks (HW + FM) versus control (none)	Odds ratios for secondary attack rates for influenza	OR for HW: control 1.20 (95% CI 0.76 to 1.88) OR for HW + masks: control 1.16 (95% CI 0.74 to 1.82) OR for HW + masks: HW 0.72 (95% CI 0.21 to 2.48)
Stebbins 2011 cluster-RCT USA	Training in hand and respiratory (cough) hygiene + hand sanitiser versus none	Incidence rate ratios for intervention to control for: 1. laboratory-confirmed influenza (RT-PCR); 2. influenza-A; 3. absence.	1. IRR 0.81 (95% CI 0.54 to 1.23) 2. IRR 0.48 (95% CI 0.26 to 0.87) 3. IRR 0.74 (95% CI 0.56 to 0.97)
Swarthout 2020 cluster-RCT Kenya	There were 6 intervention groups: chlorinated drinking water (W), improved sanitation (S), handwashing with soap (H), combined WSH, improved nutrition (N) through counselling lipid based nutrient supplementation (LNS) combined WSHN There were 2 control groups passive control (no promotional visits), a double-sized active control (monthly visits to measure mid–upper arm circumference)	Prevalence of ARIs in children	No evidence of an effect: RR 0.97, 95% CI 0.90 to 1.04.
Talaat 2011 cluster-RCT Egypt	Mandatory hand-washing intervention + education versus none	1. Number of absence days due to ILI 2. Number of absence days	1. 917 in intervention; 1671 in control (P < 0.001) 2. 13,247 in intervention; 19,094 in control (P < 0.001)
Teesing 2021 cluster-RCT Netherlands	Hand hygiene enhancement activities versus no activities.	Incidence of gastroenteritis, influenza-like illness (ILI), assumed pneumonia, urinary tract infections (UTIs), and infections caused MRSA in residents	Hand hygiene reduced risk of ILI (RR 0.51, 95% CI 0.31 to 0.83)

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Table 2. Results from trials of hand hygiene compared to control *(Continued)*

Temime 2018 cluster-RCT France	Hand hygiene with alcohol-based hand rub, promotion, staff education, and local work groups versus none	Incidence rate of ARI clusters (5 or more people in same nursing home)	2 ARI clusters in intervention; 1 in control
Turner 2012 RCT USA	Antiviral hand treatment versus no treatment	1. Number of rhinovirus infections 2. Common cold infections 3. Rhinovirus-associated illnesses	1. 49 in intervention; 49 in control, NS 2. 56 in intervention; 72 in control, NS 3. 26 in intervention; 24 in control, NS
White 2001 DB-RCT USA	Hand rub with benzalkonium chloride (hand sanitiser) versus placebo	ARI symptoms Laboratory: testing of virucidal and bactericidal activity of the product	30% to 38% decrease of illness and absenteeism (RR for illness absence incidence 0.69; RR for absence duration 0.71)
Yeung 2011 cluster-RCT Hong Kong	Alcohol-based hand gel + materials + education versus control (basic life support workshop)	Difference between pre-study period and post study in pneumonia infections recorded in residents	0.63/1000 reduction in intervention group; 0.16/1000 increase in control
Zomer 2015 cluster-RCT Netherlands	4 components: 1. Hand hygiene products, paper towel dispensers, soap, alcohol-based hand sanitiser, and hand cream provided for 6 months 2. Training and booklet 3. 2 team training sessions aimed at hand hygiene improvement 4. Posters and stickers for caregivers and children as reminders. Combination versus usual practice	Incidence rate ratio for intervention to control for common cold	IRR 1.07 (95% CI 0.97 to 1.19) 8.2 episodes per child-year in intervention; 7.4 episodes per child-year in control

ARI: acute respiratory infection
CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
DB-RCT: double-blind randomised controlled trial
HH: hand hygiene
HS: hand sanitiser
HW: hand-washing
ILI: influenza-like illness
IRR: incidence rate ratio
NS: non-significant
OR: odds ratio
RCT: randomised controlled trial
RR: risk ratio
RT-PCR: reverse-transcriptase polymerase chain reaction
SAR: secondary attack rate

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URI: upper respiratory infection
yrs: years

Table 3. Results from trials of hand hygiene + medical/surgical masks compared to control

Study	Comparison (see Table 1 for details of interventions)	Reported outcomes	Results
Aelami 2015 (conference abstract) RCT Saudi Arabia	Hand hygiene education + alcohol-based hand rub + soap + surgical masks vs none	Proportion with ILI (defined as presence of ≥ 2 of the following during their stay: fever, cough, and sore throat)	52% in intervention; 55.3% in control (P < 0.001)
Aiello 2010 cluster-RCT USA	Face mask use (FM) vs face masks + hand hygiene (FM + HH) vs control Note that this study is not included in meta-analysis as each treatment group included only 1 cluster.	1. ILI 2. Laboratory-confirmed influenza A or B	Significant reduction in ILI cases in both intervention groups compared with control over weeks 3 to 6 No significant differences between FM and FM + HH
Aiello 2012 cluster-RCT USA	Face mask use (FM) vs face masks + hand hygiene (FM + HH) vs control	1. Clinical ILI 2. Laboratory-confirmed influenza A or B	1. Non-significant reductions in FM group compared with control over all weeks. Significant reduction in FM + HH group compared with control in weeks 3 to 6 2. Non-significant reductions in both intervention groups compared with control
Cowling 2009 cluster-RCT Hong Kong	Hand hygiene (HH) vs hand hygiene plus face masks (HH + mask) vs control	Secondary attack ratio for: 1. laboratory-confirmed influenza; 2. ILI definition 1; 3. ILI definition 2.	1. HH 5; HH + mask 7; control 10 2. HH 16; HH + mask 21; control 19 3. HH 4; HH + mask 7; control 5
Larson 2010 cluster-RCT USA	Education (control) vs education with alcohol-based hand sanitiser (HS) vs education + HS + face masks (HS + mask)	Incidence rate ratios (episodes per 1000 person-weeks) for: 1. URI; 2. ILI; 3. influenza. Secondary attack rates for: 4. URI/ILI/influenza; 5. ILI/influenza.	1. HS 29; HS + mask 39; control 35 2. HS 1.9; HS + mask 1.6; control 2.3 3. HS 0.6; HS + mask 0.5; control 2.3 4. HS 0.14; HS + mask 0.12; control 0.14 5. HS 0.02; HS + mask 0.02; control 0.02
Simmerman 2011 cluster-RCT Thailand	Control vs hand-washing (HW) vs hand-washing + paper surgical face masks (HW + mask)	Odds ratio for secondary attack rates for influenza	OR for HW: control 1.20 (95% CI 0.76 to 1.88) OR for HW + mask: control 1.16 (95% CI 0.74 to 1.82) OR for HW + mask: HW 0.72 (95% CI 0.21 to 2.48)
Suess 2012 cluster-RCT Germany	Face mask + hand hygiene (mask + HH) vs face masks only (mask) vs none (control)	Secondary attack rates in household contacts: 1. Laboratory-confirmed influenza 2. ILI	1. Mask 9; mask + HH 15; control 23 2. Mask 9; mask + HH 9; control 17

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CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
FM: face mask
HH: hand hygiene
HS: hand sanitiser
HW: hand-washing
ILI: influenza-like illness
OR: odds ratio
RCT: randomised controlled trial
URI: upper respiratory infection
vs: versus

Table 4. Results from trials of soap + water compared to hand sanitisers

Study	Comparison (see Table 1 for details of interventions)	Reported outcomes	Results
Azor-Martinez 2018 cluster-RCT Spain	Education and hand hygiene with soap and water (HH soap) vs hand hygiene with sanitiser (HH sanitiser) vs usual hand-washing procedures	1. URI incidence rate ratio (primary) 2. Percentage difference in absenteeism days	1: HH soap vs control 0.94 (95% CI 0.82 to 1.08); HH sanitiser vs control 0.77 (95% CI 0.68 to 0.88); HH soap vs HH sanitiser 1.21 (95% CI 1.06 to 1.39) 2: HH soap 3.9% vs control 4.2% (P < 0.001); HH sanitiser 3.25% vs control 4.2% (P = 0.026); HH soap 3.9% vs HH sanitiser 3.25% (P < 0.001)
Pandejpong 2012 cluster-RCT Thailand	Alcohol hand gel applied every 60 minutes vs every 120 minutes vs once before lunch (3 groups).	Absent days due to confirmed ILI/ present days	0.017 in every hour group; 0.025 in every 2 hours group; 0.026 in before lunch group. Statistically significant difference between every hour group and before lunch group, and between every hour and every 2 hours groups
Savolainen-Kopra 2012 cluster-RCT Finland	Hand hygiene with soap and water (IR1 group) vs with alcohol-based hand rub (IR2 group) vs control (none); intervention groups also received education	1. Number of respiratory infection episodes/week 2. Number of reported infection episodes/week 3. Number of reported sick leave episodes/week	1. 0.076 in IR1; 0.085 in IR2; 0.080 in control, NS 2: 0.097 in IR1; 0.107 in IR2; 0.104 in control, NS 3: 0.042 in IR1; 0.035 in IR2; 0.035 in control. Significantly higher in IR1 compared with control
Turner 2004a and- Turner 2004b RCT Canada	Study 1. Ethanol vs salicylic acid 3.5% vs salicylic acid 1% and pyroglutamic acid 3.5% Study 2. Skin cleanser wipe vs ethanol (control)	% of volunteers infected with rhinovirus	7% in each intervention group; 32% in control (study 1) 22% in intervention, 30% in control (study 2)

CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
HH: hand hygiene
ILI: influenza-like illness
NS: non-significant
RCT: randomised controlled trial
URI: upper respiratory infection
vs: versus

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Table 5. Results from trials of surface/object disinfection (with or without hand hygiene) compared to control

Study	Comparison (see Table 1 for details of interventions)	Reported outcomes	Results
Ban 2015 cluster-RCT China	Hand hygiene products, surface cleaning and disinfection provided to families and kindergartens vs none	1. Respiratory illness 2. Cough and expectoration	1. OR 0.47 for intervention to control (95% CI 0.38 to 0.59) 2. OR 0.56 (95% CI 0.48 to 0.65)
Carabin 1999 cluster-RCT Canada	One-off hygiene education and disinfection of toys with bleach vs none	Difference in incidence rate for URTI (cluster-level result)	0.28 episodes per 100 child-days lower in intervention group (95% CI 1.65 lower to 1.08 higher); URTI incidence rate IRR 0.80 (95% CI 0.68 to 0.93)
Ibfelt 2015 cluster-RCT Denmark	Disinfectant washing of linen and toys by commercial company every 2 weeks vs usual care	Presence of respiratory viruses on surfaces	Statistically significant reduction in intervention group in adenovirus, rhinovirus, RSV, metapneumovirus, but not other viruses including coronavirus
Kotch 1994 RCT USA	Training in hand-washing and diapering and disinfection of surfaces vs none	Respiratory illness incidence rate in: 1. children < 24 months; 2. children >= 24 months.	1. 14.78 episodes per child-year in intervention; 15.66 in control 2. 12.87 in intervention; 11.77 in control
McConeghy 2017 RCT USA	Staff education, cleaning products, and audit of compliance and feedback vs none	Infection rates	Upper respiratory infections not reliably recorded or reported.
Sandora 2008 cluster-RCT USA	Hand sanitiser and disinfection of classroom surfaces vs materials about good nutrition (control)	Absence due to respiratory illness (multivariable analysis)	Rate ratio 1.10 for intervention to control (95% CI 0.97 to 1.24)

CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
IRR: incident rate ratio
OR: odds ratio
RCT: randomised controlled trial
RSV: respiratory syncytial virus
URTI: upper respiratory tract infection
vs: versus

Table 6. Results from trials of complex interventions compared to control

Study	Comparison (see Table 1 for details of interventions)	Reported outcomes	Results
Complex hygiene and sanitation interventions compared to control			
Chard 2019 cluster-RCT	Complex sanitation intervention and education vs none	Pupil-reported symptoms of res-	NS difference between groups. 29% of intervention group; 32% control group; adjusted risk ratio 1.08 (95% CI 0.95 to 1.23)

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Table 6. Results from trials of complex interventions compared to control *(Continued)*

Laos		piratory infection over 1 week	
Hartinger 2016 cluster-RCT Peru	Cooking and sanitation provision and education vs none	Number of ARI episodes per child-year	NS difference between groups. Risk ratio for intervention to control 0.95 (95% CI 0.82 to 1.10)
Huda 2012 cluster-RCT Bangladesh	Sanitation provision and education vs none	Respiratory illness	12.6% in intervention group; 13.0% in control group. Not adjusted for multiple outcome measurements. No CIs reported.
Najnin 2019 cluster-RCT Bangladesh	Sanitation and behaviour change intervention (plus cholera vaccine) vs none	Respiratory illness in past 2 days	2.8% in intervention group; 2.9% in control group

ARI: acute respiratory infection
CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
NS: non-significant
RCT: randomised controlled trial
vs: versus

Table 7. Results from trials of virucidal tissues compared to control

Study	Comparison	Reported outcomes	Results
Virucidal tissues compared with placebo or no tissues			
Farr 1988a and Farr 1988b cluster-RCT USA Trial 1 and Trial 2	Trial 1. Virucidal nasal tissues vs placebo vs none Trial 2. Virucidal nasal tissues vs placebo	Respiratory illnesses per person over 24 weeks Trial 1 Trial 2	Trial 1: 3.4 in tissues group; 3.9 in placebo group; 3.6 in no-tissues group Trial 2: 3.4 in tissues group; 3.6 in placebo group NS
Longini 1988 DB-PC RCT USA	Virucidal nasal tissues vs placebo	Secondary attack rate of viral infections (number of infections in household members of index case)	10.0 in intervention; 14.3 in placebo; NS

cluster-RCT: cluster-randomised controlled trial
DB-PC: double-blind, placebo-controlled
NS: non-significant
RCT: randomised controlled trial
vs: versus

Table 8. Summary of main results of the review for the primary outcomes

Interventions	RCT/cluster-RCT (N = 78)
Medical/surgical masks	**Masks (medical/surgical) compared to no masks**

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Table 8. Summary of main results of the review for the primary outcomes *(Continued)*

	9 trials in the community showed no effect on ILI (RR 0.95, 0.84 to 1.09) (Abaluck 2022; Aiello 2010; Alfelali 2020; Barasheed 2014; Canini 2010; Cowling 2008;; MacIntyre 2009;; MacIntyre 2016; Suess 2012); and 6 trials in the community showed no effect on laboratory-confirmed influenza 95% CI RR 1.01 (0.72 to 1.42) (Aiello 2012; Alfelali 2020; Bundgaard 2021; Cowling 2008; MacIntyre 2009; Suess 2012). Two trials in health care workers where the control group wore masks if they were required provided inconclusive results with very wide confidence intervals (Jacobs 2009; MacIntyre 2015). **Medical/surgical masks versus other (non-N95) masks:** 1 trial showed more ILI with cloth mask (RR 13.25, 1.74 to 100.97) (MacIntyre 2015); 1 trial showed no effect of catechin-treated masks on influenza (adjusted OR 2.35, 0.40 to 13.72) (Ide 2016).
N95 respirator	**N95 respirators compared to medical/surgical masks** 3 trials showed no difference for clinical respiratory illness (RR 0.70, 0.45 to 1.10) (MacIntyre 2011; MacIntyre 2013; Radonovich 2019); 4 trials showed no difference for ILI (95% CI RR 0.81, 0.62 to 1.05) (Loeb 2009; MacIntyre 2009; MacIntyre 2011; Radonovich 2019); and 4 trials showed no difference for laboratory-confirmed influenza (95% CI RR 1.06, 0.81 to 1.38) (Loeb 2009; MacIntyre 2009; MacIntyre 2011; Radonovich 2019). 4 trials conducted in HCWs: 3 trials showed no difference for clinical respiratory illness (RR 0.70, 0.45 to 1.10) (MacIntyre 2011; MacIntyre 2013; Radonovich 2019); 3 trials showed no difference for ILI (RR 0.64, 0.32 to 1.31) (Loeb 2009; MacIntyre 2011; Radonovich 2019); and 3 trials showed no difference for laboratory-confirmed ILI (RR 1.02, 0.73 to 1.43) (Loeb 2009; MacIntyre 2011; Radonovich 2019).
Hand hygiene	**Hand hygiene compared to control** 19 trials found an effect on combined outcome (ARI or ILI or influenza) (RR 0.89, 0.83 to 0.94) (Ashraf 2020; Azor-Martinez 2018; Biswas 2019; Correa 2012; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Little 2015; Millar 2016; Nicholson 2014; Ram 2015; Roberts 2000; Sandora 2005; Simmerman 2011; Stebbins 2011; Swarthout 2020; Teesing 2021; Zomer 2015); 9 trials showed an effect on ARI (RR 0.86, 0.81 to 0.90) (Ashraf 2020; Azor-Martinez 2018; Correa 2012; Larson 2010; Little 2015; Millar 2016; Nicholson 2014; Sandora 2005; Swarthout 2020); 11 trials showed no effect on ILI (RR 0.94, 0.81 to 1.09) (Biswas 2019; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Little 2015; Ram 2015; Roberts 2000; Simmerman 2011; Teesing 2021; Zomer 2015); and 8 trials no effect on laboratory-confirmed influenza (RR 0.91, 95% CI 0.63 to 1.30) (Biswas 2019; Cowling 2008; Cowling 2009; Hubner 2010; Larson 2010; Ram 2015; Simmerman 2011; Stebbins 2011).
Hand hygiene + medical/surgical masks	**Hand hygiene + medical/surgical masks compared to control** 7 trials showed no effect on ILI (95% CI RR 0.97, 0.80 to 1.19) (Aelami 2015; Aiello 2010; Aiello 2012; Cowling 2009; Larson 2010; Simmerman 2011; Suess 2012); and 4 trials showed no effect on laboratory-confirmed influenza (RR 0.97, 0.69 to 1.36) (Cowling 2009; Larson 2010; Simmerman 2011; Suess 2012). **Hand hygiene + medical/surgical masks compared to hand hygiene** 3 trials showed no effect on ILI (RR 1.03, 0.69 to 1.53) or laboratory-confirmed influenza (RR 0.99, 0.69 to 1.44) (Cowling 2009; Larson 2010; Simmerman 2011).
Soap + water compared to sanitiser, and comparisons of different types of sanitiser	**Soap + water compared to sanitiser, and comparisons of different types of sanitiser** 1 trial hand sanitiser was more effective than soap and water (Azor-Martinez 2018); 1 trial there was no difference (Savolainen-Kopra 2012). 2 trials in children antiseptic was more effective (Morton 2004; White 2001); 1 trial in children antiseptic = soap (Luby 2005). 1 trial hand sanitisers were better than placebo, but no difference between sanitisers (Turner 2004a); 1 trial no difference between different wipes (Turner 2004b).

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Table 8. Summary of main results of the review for the primary outcomes *(Continued)*

Surface/object disinfection (with or without hand hygiene) compared to control	**Surface/object disinfection compared to control** 2 trials were effective on ARI (Ban 2015; Carabin 1999); 1 trial was effective for viruses detected on surfaces (Ibfelt 2015); 2 trials showed no difference in ARIs (Kotch 1994; McConeghy 2017).
Disinfection of living quarters	-
Complex interventions	**Complex interventions compared to control** 4 trials in low-income countries found no effect on respiratory viral illness (Chard 2019; Hartinger 2016; Huda 2012; Najnin 2019).
Physical interventions (masks, gloves, gowns combined)	-
Gloves	-
Gowns	-
Physical distancing	**Physical distancing compared to self-isolation** 1 trial reported 1 positive SARS-CoV-2 case in the fitness centre access arm versus 0 in the no access arm (risk difference 0.05%, 95% CI − 0.05 to 0.16%) (Helsingen 2021)
Quarantine in the community	**Quarantine compared to control** 1 trial effective for influenza (Cox hazard ratio 0.799, 95% CI 0.66 to 0.97) (Miyaki 2011). **Daily contact testing compared to self-isolation** 1 trial showed non-inferiority of daily contact testing of school-based contacts compared to self-isolation for SARS-CoV-2 (RR 0.96, 95% CI 0.75 to 1.22) (Young 2021)
Eye protection	**Glasses compared to no glasses** 1 pragmatic RCT conducted in Norway wearing any type of eyeglasses when close to other people outside their home (on public transport, in shopping malls etc.), over a 14-day period. Positive COVID-19 tests based on self-reporting were 9.6% and 11.5% (RR 0.83, 95% CI 0.69 to 1.00) (Fretheim 2022a).
Gargling	**Gargling compared to control** 1 trial gargling with tap water was effective, povidone-iodine was not effective (Satomura 2005); 1 trial gargling with green tea was not more effective than tap water (Ide 2014); 1 trial gargling with water was not effective (Goodall 2014); pooling of 2 trials showed no effect of gargling (RR 0.91, 95% CI 0.63 to 1.31) (Goodall 2014; Satomura 2005). **Mouth/nose rinse compared to control** 2 trials found a large protective effect on SARS-CoV-2 (RR 0.07, 0.01 to 0.23) (Almanza-Reyes 2021; Gutiérrez-García 2022).
Virucidal tissues	**Virucidal tissues compared to control** 1 trial had a small effect (Farr 1988a) ("The study authors conclude that virucidal tissues have only a small impact upon the overall rate of natural acute respiratory illnesses"); 2 trials showed a non-significant difference (Farr 1988b; Longini 1988).
Nose wash	-

ARI: acute respiratory infection
CI: confidence interval

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HCW: healthcare worker
ILI: influenza-like illness
OR: odds ratio
RCT: randomised controlled trial
RR: risk ratio

Table 9. Trial authors' outcome definitions

Study	Outcome definitions
Masks (n = 16)	
Abaluck 2022 cluster-RCT Bangladesh	COVID-19 symptoms as per the WHO case definition of probable COVID-19 given epidemiological risk factors: (i) fever and cough; (ii) 3 or more of the following symptoms (fever, cough, general weakness and/or fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia, nausea, and/or vomiting, diarrhoea, and altered mental status); or (iii) loss of taste or smell. The owner of the household's primary phone completed surveys by phone or in-person at weeks 5 and 9 after the start of the intervention. They were asked to report symptoms experienced by any household member consistent with the WHO. COVID-19 case definition. Laboratory: seropositivity was defined by having detectable IgG antibodies in blood samples against SARS-CoV-2, using the SCoV-2 Detect™ IgG ELISA kit (InBios, Seattle, Washington). This assay detects IgG antibodies against the spike protein subunit (S1) of SARS-CoV-2. Safety: harms were not directly assessed in this study, but it is stated no adverse events were reported.
Alfelali 2020 cluster-RCT Haj in Makkah, Saudi Arabia	Laboratory: swabs were placed it into UTM™ (COPAN) viral transport media. Swabs labelled with the participant's unique barcode number were stored in an icebox at –20 ˚C before being re-stored by day's end in a –80 ˚C freezer at the laboratory of the Hajj Research Center at Umm Al-Qura University, Makkah. After Hajj, these swabs were shipped in refrigerated or cold containers to the Centre for Infectious Disease and Microbiology Laboratory Services, Westmead Hospital, NSW, Australia. There, nucleic acid was extracted with the Qiagen bioROBOT EZ instrument (Qiagen, Valencia, CA), and amplification was performed using the Roche LC 480 (Roche Diagnostics GmbH, Mannheim, Germany) instrument. Respiratory viruses were detected using a real-time, multiplex reverse transcription polymerase chain reaction assay targeting human coronaviruses (OC43, 229E and NL63), influenza A and B viruses, respiratory syncytial virus (RSV), parainfluenza viruses 1 to 3, human metapneumovirus, rhinovirus, enterovirus and adenovirus. Middle East respiratory syndrome coronavirus (MERS-CoV) assay targeting the upstream region of the E gene (upE) was also performed. Safety: harms of using face masks were difficulty in breathing (26.2%); discomfort (22%); and a small minority (3%) reported feeling hot, sweating, a bad smell or blurred vision with eyeglasses.
Bundgaard 2021 RCT Denmark	Laboratory: viral RNA was extracted from swab samples in DNA/RNA Shield (Zymo Research) using Quick-RNA Microprep Kit (Zymo Research) with the below modifications. 200 µl samples were incubated for 1 min with proteinase K (Qiagen) in a final concentration of 0.2 µg/µl prior to treatment with lysis buffer (Quick-RNA Microprep Kit). Only a single washing step using 400 µl RNA Wash Buffer (Quick-RNA Microprep Kit) was performed before elution in 15µl RNase free water. Participants tested for SARS-CoV-2 IgM and IgG antibodies in whole blood using a point-of-care test (Lateral Flow test [Zhuhai Livzon Diagnostics]) according to the manufacturer's recommendations. After puncturing a fingertip with a lancet, they withdrew blood into a capillary tube and placed 1 drop of blood followed by 2 drops of saline in the test chamber in each of the 2 test plates (IgM and IgG). Safety: harms were not mentioned as an outcome in the methods, but psychological adverse effects were mentioned, and 14% reported adverse reactions from other people regarding wearing a face mask.

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Table 9. Trial authors' outcome definitions *(Continued)*

Cowling 2008 cluster-RCT Hong Kong	Laboratory: QuickVue Influenza A+B rapid test Viral culture on MDCK (Madin-Darby canine kidney cells) Samples were harvested using NTS, but the text refers to a second procedure from June 2007 onwards with testing for influenza viruses on index participants with a negative QuickVue result but a fever ≥ 38 °C who were also randomised and further followed up. Data on clinical signs and symptoms were collected for all participants, and an additional NTS was collected for later confirmation of influenza infection by viral culture. It is noteworthy that dropout was higher in households of index participants who had a negative result on the rapid influenza test (25/44, 57%) compared to those who had a positive result (45/154, 29%). Effectiveness: secondary attack ratios (SAR): SAR is the proportion of household contacts of an index case who subsequently were ill with influenza (symptomatic contact individuals with at least 1 NTS positive for influenza by viral culture or PCR) 3 clinical definitions were used for secondary analysis: 1. fever ≥ 38 °C or at least 2 of the following symptoms: headache, coryza, sore throat, muscle aches and pains; 2. at least 2 of the following S/S: fever ≥ 37.8 °C, cough, headache, sore throat and muscle aches and pains; and 3. fever of ≥ 37.8 °C plus cough or sore throat. Safety: harms were not mentioned as an outcome in the methods, but it was reported in the results that there were no adverse events.
Jacobs 2009 RCT Japan	Laboratory-confirmation not reported. Effectiveness: URTI is defined on the basis of a symptom score with a score > 14 being a URTI according to Jackson's 1958 criteria ("Jackson score"). These are not explained in text, although the symptoms are listed in Table 3 (any, sore throat, runny nose, stuffy nose, sneeze, cough, headache, earache, feel bad) together with their mean and scores (SD) by intervention arm. Safety: the text does not mention or report harms. These appear to be indistinguishable from URTI symptoms (e.g. headache, which is reported as of significantly longer duration in the intervention arm). Compliance is self-reported as high (84.3% of participants).
Loeb 2009 cluster-RCT HCW Canada	Clinical respiratory illness, influenza-like illness, and laboratory-confirmed respiratory virus infection. 1. Clinical respiratory illness, defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom. 2. Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom. 3. Laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex RT-PCR for 17 respiratory viruses. Safety: harms were not mentioned as an outcome in the methods, but it is stated in the results that no adverse events were reported by participants.
MacIntyre 2009 cluster-RCT Australia	Eligibility criteria were stipulated as follows: 1. the household contained > 2 adults > 16 years of age and 1 child 0 to 15 years of age; 2. the index child had fever (temperature > 37.8 °C) and either a cough or sore throat; 3. the child was the first and only person to become ill in the family in the previous 2 weeks; 4. adult caregivers consented to participate in the study; and 5. the index child was not admitted to the hospital. Definitions used for outcomes:

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Table 9. Trial authors' outcome definitions *(Continued)*

	1. ILI defined by the presence of fever (temperature > 37.8 °C), feeling feverish or a history of fever, > 2 symptoms (sore throat, cough, sneezing, runny nose, nasal congestion, headache), or 1 of the symptoms listed plus laboratory confirmation of respiratory viral infection. 2. Laboratory confirmation: multiplex RT-PCR tests to detect influenza A and B and RSV, PIV types 1 to 3, picornaviruses (enteroviruses or rhinoviruses), adenoviruses, coronaviruses 229E and OC43, and hMPV plus ≥ 1 symptom Effectiveness: presence of ILI or a laboratory diagnosis of respiratory virus infection within 1 week of enrolment. Safety: harms not mentioned as an outcome in the methods, but it is reported in the results that more than 50% of participants reported concerns with mask wearing, mainly that wearing a face mask was uncomfortable, but there were no significant differences between the P2 (N95) and surgical mask groups. Other concerns were that the child did not want the parent wearing a mask.
Aiello 2010 cluster-RCT USA	Laboratory details are described in appendix. Effectiveness: ILI, defined as cough and at least 1 constitutional symptom (fever/feverishness, chills, headache, myalgia). ILI cases were given contact nurses phone numbers to record the illness and paid USD 25 to provide a throat swab. 368 participants had ILI, 94 of which had a throat swab analysed by PCR. 10 of these were positive for influenza (7 for A and 3 for B), respectively by arm 2, 5 and 3 using PCR, 7 using cell culture. Safety: no outcomes on harms planned or reported.
Canini 2010 cluster-RCT USA	The primary endpoint was the proportion of household contacts who developed an ILI during the 7 days following inclusion. Exploratory cluster-level efficacy outcome, the proportion of households with 1 or more secondary illness in household contacts. A temperature over 37.8 °C with cough or sore throat was used as primary clinical case definition. The authors also used a more sensitive case definition based on a temperature over 37.8 °C or at least 2 of the following: sore throat, cough, runny nose, or fatigue. Safety: adverse reactions due to mask wearing were reported, with 38 (75%) participants in the intervention arm experiencing discomfort with mask use due to warmth (45%), respiratory difficulties (33%), and humidity (33%). Children wearing children face masks reported feeling pain more frequently than other participants wearing adult face masks (P = 0.036).
Aiello 2012 cluster-RCT in halls of residence in the USA	Clinically verified ILI - case definition (presence of cough and at least 1 or more of fever/feverishness, chills, or body aches) Laboratory-confirmed influenza A or B. Throat swab specimens were tested for influenza A or B using real-time PCR. Safety: no outcomes on harms planned or reported.
Barasheed 2014 cluster-RCT Saudi Arabia	Laboratory: 2 nasal swabs from all ILI cases and contacts. 1 for influenza POCT using the QuickVue Influenza (A+B) assay (Quidel Corporation, San Diego, USA) and 1 for later NAT for influenza and other respiratory viruses. However, there was a problem with getting POCT on time during Hajj. Effectiveness: to assess the effectiveness of face masks in the prevention of transmission of ILI. ILI was defined as subjective (or proven) fever plus 1 respiratory symptom (e.g. dry or productive cough, runny nose, sore throat, shortness of breath). Safety: no outcomes on harms planned or reported.
MacIntyre 2011 cluster-RCT China	Clinical respiratory illness Influenza-like illness Laboratory-confirmed viral respiratory infection

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Table 9. Trial authors' outcome definitions *(Continued)*

	Laboratory-confirmed influenza A or B 1. Clinical respiratory illness, defined as 2 or more respiratory or 1 respiratory symptom and a systemic symptom. 2. Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom (i.e. cough, runny nose, etc.). 3. Laboratory-confirmed viral respiratory infection (detection of adenoviruses, human metapneumovirus, coronavirus 229E/NL63, parainfluenza viruses 1, 2, and 3, influenza viruses A and B, respiratory syncytial virus A and B, rhinovirus A/B and coronavirus OC43/HKU1 by multiplex PCR). 4. Laboratory-confirmed influenza A or B. 5. Adherence with mask/respirator use. Safety: adherence and adverse effects of mask wearing were collected at exit interviews 4 weeks' post study. Significantly higher adverse events with N95 respirator compared to medical mask for discomfort, headache, difficulty breathing, nose pressure, trouble communicating, not wearing, and unspecified "other" side effects. Over 50% of those wearing N95 respirators reported adverse events. Of those wearing medical masks versus N95 respirators, 85.5% (420/491) versus 47.4% (447/943) reported no adverse events (P < 0.001), respectively.
MacIntyre 2013 cluster-RCT China	Laboratory: 1. Laboratory-confirmed viral respiratory infection in symptomatic participants, defined as detection of adenoviruses; human metapneumovirus; coronaviruses 229E/NL63 and OC43/HKU1; parainfluenza viruses 1, 2, and 3; influenza viruses A and B; respiratory syncytial viruses A and B; or rhinoviruses A/B by NAT using a commercial multiplex PCR (Seegen, Inc., Seoul, Korea). 2. Laboratory-confirmed influenza A or B in symptomatic participants. 3. Laboratory-confirmed bacterial colonisation in symptomatic participants, defined as detection of *Streptococcus pneumoniae*, *Legionella*, *Bordetella pertussis*, *Chlamydia*, *Mycoplasma pneumoniae*, *or Haemophilus influenzae* type B by multiplex PCR (Seegen, Inc.). Effectiveness: clinical respiratory illness defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom. ILI defined as fever (38 °C) plus 1 respiratory symptom. Safety: adverse effects measured using a semi-structured questionnaire. Investigators stated that there was higher reported adverse effects and discomfort of N95 respirators compared with the other 2 arms. In terms of comfort, 52% (297 of 571) of the medical mask arm reported no problems, compared with 62% (317 of 512) of the targeted arm and 38% (217 of 574) of the N95 arm (P < 0.001).
MacIntyre 2015 cluster-RCT Vietnam	Clinical respiratory illness, influenza-like illness, and laboratory-confirmed respiratory virus infection. 1. Clinical respiratory illness, defined as 2 or more respiratory symptoms or 1 respiratory symptom and a systemic symptom. 2. Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom. 3. Laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex RT-PCR for 17 respiratory viruses. Safety: adverse events associated with face mask use were reported in 40.4% (227/562) of HCWs in the medical/surgical mask arm and 42.6% (242/568) in the cloth mask arm (P = 0.45). The most frequently reported adverse events were: general discomfort (35.1%; 397/1130) and breathing problems (18.3%; 207/1130). The rate of ILI was higher in the cloth mask arm compared to medical/surgical masks (RR 13.25, 95% CI 1.74 to 100.97).
MacIntyre 2016 cluster-RCT China	Clinical respiratory illness, influenza-like illness, and laboratory-confirmed viral respiratory infection. 1. Clinical respiratory illness, defined as 2 or more respiratory symptoms (cough, nasal congestion, runny nose, sore throat, or sneezes) or 1 respiratory symptom and a systemic symptom (chill, lethargy, loss of appetite, abdominal pain, muscle or joint aches).

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Table 9. Trial authors' outcome definitions *(Continued)*

	2. Influenza-like illness, defined as fever ≥ 38 °C plus 1 respiratory symptom. 3. Laboratory-confirmed viral respiratory infection, defined as detection of adenoviruses, human metapneumovirus, coronaviruses 229E/NL63 and OC43/HKU1, parainfluenza viruses 1, 2, and 3, influenza viruses A and B, respiratory syncytial virus A and B, or rhinovirus A/B by NAT using a commercial multiplex PCR. Safety: no outcomes on harms planned or reported.
Radonovich 2019 cluster-RCT USA	Laboratory. Primary outcome: incidence of laboratory-confirmed influenza, defined as: 1. detection of influenza A or B virus by RT-PCR in an upper respiratory specimen collected within 7 days of symptom onset; 2. detection of influenza from a randomly obtained swab from an asymptomatic participant; and 3. influenza seroconversion (symptomatic or asymptomatic), defined as at least a 4-fold rise in haemagglutination inhibition antibody titres to influenza A or B virus between pre-season and postseason serological samples deemed not attributable to vaccination. Effectiveness. Secondary outcomes: incidence of 4 measures of viral respiratory illness or infection as follows: 1. acute respiratory illness with or without laboratory confirmation; 2. laboratory-detected respiratory infection, defined as detection of a respiratory pathogen by PCR or serological evidence of infection with a respiratory pathogen during the study surveillance period(s), which was added to the protocol prior to data analysis; and 3. laboratory-confirmed respiratory illness, identified as previously described (defined as self-reported acute respiratory illness plus the presence of at least PCR–confirmed viral pathogen in a specimen collected from the upper respiratory tract within 7 days of the reported symptoms and/or at least a 4-fold rise from pre-intervention to postintervention serum antibody titres to influenza A or B virus). Influenza-like illness, defined as temperature of at least 100 °F (37.8 °C) plus cough and/or a sore throat, with or without laboratory confirmation. Safety: 19 participants reported skin irritation or worsening acne during years 3 and 4 at 1 site in the N95 respirator group.
Hand and hygiene (n = 35)	
Alzaher 2018 cluster-RCT Saudi Arabia	Episode of URI was defined as having 2 of the following symptoms for a day or 1 of the symptoms for 2 or more consecutive days: 1) a runny nose, 2) a stuffy or blocked nose or noisy breathing, 3) sneezing, 4) a cough, 5) a sore throat, and 6) feeling hot, having a fever or a chill.
Arbogast 2016 cluster-RCT USA	ICD-9 used: 46611: acute bronchiolitis due to respiratory syncytial virus, 46619: acute bronchiolitis due to other infectious organisms, 4800: pneumonia due to adenovirus, 4809: viral pneumonia, unspecified, 4870: influenza with pneumonia, 07999: unspecified viral infection, 4658: acute upper respiratory infections of other multiple sites, 4659: acute upper respiratory infections of unspecified site, 4871: influenza with other respiratory manifestations.
Ashraf 2020 cluster-RCT Bangladesh	Main outcome: 7-day prevalence of acute respiratory infection (ARI), defined as caregiver-reported symptoms of persistent cough or panting, wheezing, or difficulty breathing (1 or 2) in the 7 days before the interview.
Azor-Martinez 2016 RCT Spain	Upper respiratory illness was defined as 2 of the following symptoms during 1 day, or 1 of the symptoms for 2 consecutive days: (1) runny nose; (2) stuffy or blocked nose or noisy breathing; (3) cough; (4) feeling hot or feverish or having chills; (5) sore throat; or (6) sneezing.

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Table 9. Trial authors' outcome definitions *(Continued)*

Azor-Martinez 2018 RCT Spain	Respiratory illness (RI) was defined as the presence of 2 of the following symptoms during 1 day or the presence of 1 of the symptoms for 2 consecutive days: (1) runny nose, (2) stuffy or blocked nose or noisy breathing, (3) cough, (4) feeling hot or feverish or having chills, (5) sore throat, or (6) sneezing. ICD-10 and ICD-9 diagnosis codes used: nonspecific upper respiratory tract infection (465.9), otitis media (382.9), pharyngotonsillitis (463), lower respiratory tract infections (485 and 486), acute bronchitis (490), and bronchiolitis (466.19). Study authors combined the bronchopneumonia code (485) and pneumonia code (486) under the label "lower respiratory tract infections." If > 1 antibiotic was prescribed during an episode, they used the first prescription for analysis. The final diagnosis was done by the medical researchers on the basis of the symptoms described above and a review of the medical history of children with RIs.
Biswas 2019 cluster-RCT Bangladesh	Influenza-like illness: an ILI episode was defined as measured fever > 38 °C or subjective fever and cough. Laboratory-confirmed influenza Nasal swabs for real-time RT-PCR.
Correa 2012 cluster-RCT Colombia	Acute respiratory infection was defined as 2 or more of the following symptoms for at least 24 hours, lasting at least 2 days: runny, stuffy, or blocked nose or noisy breathing; cough; fever, hot sensation, or chills; and/or sore throat. Ear pain alone was considered ARI alternately.
Cowling 2009 cluster-RCT Hong Kong	Laboratory-confirmed of influenza virus infection by RT-PCR for influenza A and B virus. Clinical influenza-like illness: used 2 clinical definitions of influenza based on self-reported data from the symptom diaries as secondary analyses. The first definition of clinical influenza was at least 2 of the following signs and symptoms: temperature 37.8 °C or greater, cough, headache, sore throat, and myalgia; the second definition was temperature 37.8 °C or greater plus cough or sore throat.
DiVita 2011 (conference abstract) RCT Bangladesh	Influenza-like illness was defined as fever in children < 5 years old and fever with cough or sore throat in individuals > 5 years old.
Feldman 2016 cluster-RCT Israel	Infectious diseases grouped into diarrhoeal, respiratory, and skin infection. Based on ICD-9, but no supplementary material was accessible for further definition (Supplementary Material C lists all ICD-9 diagnoses tallied in this "outcome").
Gwaltney 1980 RCT USA	Viral cultures and serology if rhinovirus in laboratory-inoculation
Hubner 2010 RCT Germany	Assessing illness rates due to common cold and diarrhoea. Collecting data on illness symptoms (common cold, sinusitis, sore throat, fever, cough, bronchitis, pneumonia, influenza, diarrhoea) and associated absenteeism at the end of every month. Definitions of symptoms were given to the participants as part of the individual information at the beginning of the study. Whilst most symptoms are quite self-explanatory, "influenza" and "pneumonia" are specific diagnoses that were confirmed by professional diagnosis only. Similarly, (self-) diagnosis of "fever" required objective measurement with a thermometer.
Ladegaard 1999	Laboratory: serological evidence

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Table 9. Trial authors' outcome definitions *(Continued)*

RCT Denmark	Effectiveness: influenza-like illness (described as fever, history of fever or feeling feverish in the past week, myalgia, arthralgia, sore throat, cough, sneezing, runny nose, nasal congestion, headache). However, a positive laboratory finding for influenza converts the ILI definition into one of influenza.
Larson 2010 cluster-RCT USA	Study goals: rates of symptoms and secondary transmission of URIs, incidence of virologically confirmed influenza, knowledge of prevention and treatment strategies for influenza and URIs, and rates of influenza vaccination. 1. Laboratory-confirmed influenza: nasal swabs to test for influenza types A and B as well as other common respiratory viruses by rapid culture (R-Mix, Diagnostic Hybrids, Inc., Athens, OH, USA). PCR and subtyping of the samples was done during the second half of the second year of the study. 2. Influenza-like illness: CDC definition of ILI from the Sentinel Physicians' Network was used to determine when masks should be worn: "temperature of ≥37.8°C and cough and/or sore throat in the absence of a known cause other than influenza". 3. Episodes of URI = upper respiratory infection: not clear, no explicitly stated definition, reported that the most commonly reported URI symptoms are cough or rhinorrhoea.
Little 2015 RCT England	Respiratory tract infections defined as 2 symptoms of an RTI for at least 1 day or 1 symptom for 2 consecutive days. For reported ILI, study authors did not use WHO or CDC definitions because these definitions require measured temperature, and thus were not appropriate (participants were not included after a clinical examination), and they did not use the European Centre for Disease Prevention and Control definition (1 systemic and 1 respiratory symptom) because, according to the international influenza collaboration, this definition does not necessarily differentiate ILI from a common cold. Influenzanet suggests making high temperature a separate element. Their pragmatic definition of ILI therefore required a high temperature (feeling very hot or very cold; or measured temperature > 37.5 °C), a respiratory symptom (sore throat, cough, or runny nose), and a systemic symptom (headache, severe fatigue, severe muscle aches, or severe malaise).
Luby 2005 RCT Pakistan	Defined pneumonia in children according to the WHO clinical case definition: cough or difficulty breathing with a raised respiratory rate (> 60 per minute in individuals younger than 60 days old, > 50 per minute for those aged 60 to 364 days, and > 40 per minute for those aged 1 to 5 years)
Millar 2016 cluster-RCT USA	Medically attended, outpatient cases of acute respiratory infection in the study population. The case definition was any occurrence of the following International Classification of Disease, 9 Revision, Clinical Modification (ICD-9) symptom or disease-specific codes: 460 to 466, 480 to 488, and specifically 465.9, 482.9, 486, and 487.1. **Acute respiratory infections (460 to 466)** 460 Acute nasopharyngitis (common cold) 461 Acute sinusitis 462 Acute pharyngitis 463 Acute tonsillitis 464 Acute laryngitis and tracheitis 465 Acute upper respiratory infections of multiple or unspecified sites 466 Acute bronchitis and bronchiolitis **Pneumonia and influenza (480 to 488)** 480 Viral pneumonia 481 Pneumococcal pneumonia (*Streptococcus pneumoniae* pneumonia) 482 Other bacterial pneumonia

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Table 9. Trial authors' outcome definitions *(Continued)*

	483 Pneumonia due to other specified organism 484 Pneumonia in infectious diseases classified elsewhere 485 Bronchopneumonia, organism unspecified 486 Pneumonia, organism unspecified 487 Influenza 488 Influenza due to identified avian influenza virus 465.9 Acute upper respiratory infections of unspecified site 482.9 Bacterial pneumonia NOS 487.1 Diagnosis of influenza with other respiratory manifestations
Morton 2004 cluster-RCT Cross-over study USA	Respiratory illnesses defined by symptoms of upper respiratory infections such as nasal congestion, cough, or sore throat, in any combination, with or without fever
Nicholson 2014 cluster-RCT India	Acute respiratory infections Operational definitions for all the illnesses were taken from Black's Medical Dictionary. ARIs defined as "Pneumonia, cough, fever, chest pain and shortness of breath, cold, inflammation of any or all of the airways, that is, nose, sinuses, throat, larynx, trachea and bronchi".
Pandejpong 2012 cluster-RCT Thailand	Influenza-like illness defined if 2 or more symptoms of stuffy nose, cough, fever or chills, sore throat, headache, diarrhoea, presence of hand, foot, or mouth ulcers.
Priest 2014 cluster-RCT New Zealand	Respiratory illness was defined as an episode of illness that included at least 2 of the following caregiver-reported symptoms for 1 day, or 1 of these symptoms for 2 days (but not fever alone): runny nose, stuffy or blocked nose or noisy breathing, cough, fever, sore throat, or sneezing.
Ram 2015 RCT Bangladesh	Influenza-like illness Age-specific definitions of ILI. For individuals ≥ 5 years old, ILI was defined as history of fever with cough or sore throat. For children < 5 years old, ILI was defined as fever; study authors used this relatively liberal case definition in order to include influenza cases with atypical presentations in children. Laboratory-confirmed influenza infection Oropharyngeal swabs from index case patients for laboratory testing for influenza. All swabs were tested by PCR for influenza A and B, with further subtyping of influenza A isolates.
Roberts 2000 cluster-RCT Australia	The symptoms of acute upper respiratory illness elicited from parents were: a runny nose, a blocked nose, and cough. Study authors used a definition of colds based on a community intervention trial of virucidal impregnated tissues. A cold was defined as either 2 symptoms for 1 day or 1 of the respiratory symptoms for at least 2 consecutive days, but not including 2 consecutive days of cough alone. Study authors defined a

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Table 9. Trial authors' outcome definitions *(Continued)*

	new episode of a cold as the occurrence of respiratory symptoms after a period of 3 symptom-free days.
Sandora 2005 cluster-RCT USA	The overall rates of secondary respiratory and GI illness. Respiratory illness was defined as 2 of the following symptoms for 1 day or 1 of the symptoms for 2 consecutive days: (1) runny nose; (2) stuffy or blocked nose or noisy breathing; (3) cough; (4) fever, feels hot, or has chills; (5) sore throat; and (6) sneezing. An illness was considered new or separate when a period of at least 2 symptom-free days had elapsed since the previous illness. An illness was defined as a secondary case when it began 2 to 7 days after the onset of the same illness type (respiratory or GI) in another household member.
Savolainen-Kopra 2012 cluster-RCT Finland	Nasal and pharyngeal stick samples from participants with respiratory symptoms
Simmerman 2011 cluster-RCT Thailand	Influenza-like illness defined by WHO as fever plus cough or sore throat, based on self-reported symptoms. Laboratory-confirmed secondary influenza virus infections amongst household members described as the secondary attack rate. The secondary influenza virus infection was defined as a positive rRT-PCR result on days 3 or 7 or a four-fold rise in influenza HI antibody titres with the virus type and subtype matching the index case.
Stebbins 2011 cluster-RCT USA	The primary outcome was an absence episode associated with an influenza-like illness that was subsequently laboratory-confirmed as influenza A or B. The following CDC definition for ILI was used: fever ≥ 38 °C with sore throat or cough.
Swarthout 2020 cluster-RCT Kenya	The primary outcome in this study is ARI symptoms - defined as having caregiver-reported cough or difficulty breathing, including panting or wheezing, within 7 days before the interview - in children younger than 3 years. Prespecified secondary outcomes in this study include difficulty breathing, including panting or wheezing, in the past 7 days (a more specific indicator of respiratory infection than a cough alone); ARI symptoms presenting with fever in the past 7 days (a potentially more severe infection); and enumerator-observed runny nose (an objective outcome).
Talaat 2011 cluster-RCT Egypt	Nasal swab for QuickVue test for influenza A and B viruses. Influenza-like illness (defined as fever > 38 °C and either cough or sore throat).
Teesing 2021 cluster-RCT The Netherlands	Incidence of gastroenteritis, ILI, assumed pneumonia, UTIs using the McGeer criteria, and infections caused by MRSA.
Temime 2018 cluster-RCT France	ARIs were defined as the combination of at least 1 respiratory symptom and 1 symptom of systemic infection.
Turner 2004b RCT Canada	Virologic assays

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Table 9. Trial authors' outcome definitions *(Continued)*

Turner 2012 RCT USA	Laboratory-confirmed rhinovirus infection by PCR assay. Common cold illness was defined as the presence of any of the symptoms of nasal obstruction, rhinorrhoea, sore throat, or cough on at least 3 consecutive days. Illnesses separated by at least 3 symptom-free days were considered as separate illnesses.
Yeung 2011 cluster-RCT Hong Kong	Pneumonia
Zomer 2015 cluster-RCT Netherlands	Incidence of gastrointestinal and respiratory infections in children monitored by parents. The common cold was defined as a blocked or runny nose with at least 1 of the following symptoms: coughing, sneezing, fever, sore throat, or earache.
Hand hygiene and masks (n = 6)	
Aelami 2015 (conference abstract) RCT Saudi Arabia	Influenza-like illness was defined as the presence of at least 2 of the following during their stay: fever, cough, and sore throat. Safety: no outcomes on harms planned or reported.
Aiello 2010 cluster-RCT USA	Influenza-like illness case definition (presence of cough and at least 1 constitutional symptom (fever/feverishness, chills, or body aches). Safety: no outcomes on harms planned or reported.
Cowling 2009 cluster-RCT Hong Kong	2 clinical definitions of influenza. First definition was at least 2 of the following signs and symptoms: temperature 37.8 °C or greater, cough, headache, sore throat, and myalgia. The second was temperature 37.8 °C or greater plus cough or sore throat. Safety: no outcomes on harms planned or reported.
Larson 2010 cluster-RCT USA	Study goals: rates of symptoms and secondary transmission of URIs, incidence of virologically-confirmed influenza, knowledge of prevention and treatment strategies for influenza and URIs, and rates of influenza vaccination. 1. Laboratory-confirmed influenza: nasal swabs to test for influenza types A and B as well as other common respiratory viruses by rapid culture (R-Mix, Diagnostic Hybrids, Inc., Athens, OH, USA). PCR and subtyping of the samples was done during the second half of the second year of the study. 2. Influenza-like illness: CDC definition of ILI from the Sentinel Physicians' Network was used to determine when masks should be worn: "temperature of ≥37.8°C and cough and/or sore throat in the absence of a known cause other than influenza". 3. Episodes of URI = upper respiratory infection: not clear, no explicitly stated definition, reported that the most commonly reported URI symptoms are cough or rhinorrhoea. Safety: no outcomes on harms planned or reported.
Simmerman 2011 cluster-RCT Thailand	Laboratory-confirmed secondary influenza virus infections amongst household members described as the secondary attack rate. The secondary influenza virus infection was defined as a positive rRT-PCR result on days 3 or 7 or a four-fold rise in influenza HI antibody titres with the virus type and subtype matching the index case. Influenza-like illness defined by WHO as fever plus cough or sore throat, based on self-reported symptoms.

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Table 9. Trial authors' outcome definitions *(Continued)*

	Safety: no outcomes on harms planned or reported.
Suess 2012 cluster-RCT Germany	Quantitative RT-PCR for samples of nasal wash. Influenza virus infection as a laboratory-confirmed influenza infection in a household member who developed fever (> 38.0 °C), cough, or sore throat during the observation period. Also secondary outcome measure of the occurrence of ILI as defined by WHO as fever plus cough or sore throat. Safety: the study reported that the majority of participants (107/172, 62%) did not report any problems with mask wearing. This proportion was significantly higher in the group of adults (71/100, 71%) compared to the group of children (36/72, 50%) (P = 0.005). The main problem stated by participants (adults and children) was "heat/humidity" (18/34, 53% of children; 10/29, 35% of adults) (P = 0.1), followed by "pain" and "shortness of breath" when wearing a face mask.
Surface/object disinfection (with or without hand hygiene)(n = 8)	
Ban 2015 cluster-RCT China	Acute respiratory illness classified as the appearance of 2 or more of the following symptoms: fever, cough and expectoration, runny nose and nasal congestion.
Carabin 1999 cluster-RCT Canada	The presence of nasal discharge (runny nose) accompanied by 1 or several of the following symptoms: fever, sneezing, cough, sore throat, ear pain, malaise, irritability. A URTI was defined as a cold for 2 consecutive days.
Chard 2019 cluster-RCT Laos	Pupils were considered to have symptoms of respiratory infection if they reported cough, runny nose, stuffy nose, or sore throat.
Ibfelt 2015 cluster-RCT Denmark	Laboratory confirmation of 16 respiratory viruses: influenza A; influenza B; coronavirus NL63229E, OC43 and HKU1; parainfluenza virus 1, 2, 3, and 4; rhinovirus; RSV A/B; adenovirus; enterovirus; parechovirus; and bocavirus using quantitative PCR
Kotch 1994 RCT USA	Respiratory symptoms include coughing, runny nose, wheezing or rattling in the chest, sore throat, or earache.
McConeghy 2017 RCT USA	Classified infections as lower respiratory tract infections (i.e. pneumonia, bronchitis, or chronic obstructive pulmonary disease exacerbation) or other.
Sandora 2008 cluster-RCT USA	RI was defined as an acute illness that included > 1 of the following symptoms: runny nose, stuffy or blocked nose, cough, fever or chills, sore throat, or sneezing.
White 2001 DB-RCT USA	RI was defined as: cough, sneezing, sinus trouble, bronchitis, fever alone, pink-eye, headache, mononucleosis, and acute exacerbation of asthma.

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Table 9. Trial authors' outcome definitions *(Continued)*

Other (miscellaneous) interventions (n = 5)	
Fretheim 2022a pragmatic RCT Norway	Respiratory infection was defined as having 1 respiratory symptom (stuffed or runny nose, sore throat, cough, sneezing, heavy breathing) and fever, or 1 respiratory symptom and at least 2 more symptoms (body ache, muscular pain, fatigue, reduced appetite, stomach pain, headache, loss of smell.
Hartinger 2016 cluster-RCT Peru	ARI was defined as a child presenting cough or difficulty breathing, or both. ALRI was defined as a child presenting cough or difficulty breathing, with a raised respiratory rate > 50 per minute in children aged 6 to 11 months and > 40 per minute in children aged > 12 months on 2 consecutive measurements. An episode was defined as beginning on the first day of cough or difficulty breathing and ending with the last day of the same combination, followed by at least 7 days without those symptoms.
Huda 2012 cluster-RCT Bangladesh	Study authors classified acute respiratory illness as having cough and fever or difficulty breathing and fever within 48 h prior to interview.
Najnin 2019 cluster-RCT Bangladesh	Classified participants as having respiratory illness if they reported having fever plus either cough or nasal congestion or fever plus breathing difficult.
Satomura 2005 RCT Japan	Upper respiratory tract infection defined as all of the following conditions: 1. both nasal and pharyngeal symptoms; 2. severity of at least 1 symptom increased by 2 grades or more; and 3. worsening of a symptom of 1 increment or more for > 3 days. Because of the difference in the mode of transmission, study authors excluded influenza-like diseases featured by moderate or severe fever; anti-influenza vaccination in the preseason and arthralgia, and treated them separately. The incidence was determined by 1 study physician who was blinded to group assignment.
Virucidal tissues (n = 2)	
Farr 1988a cluster-RCT USA trial 1 and trial 2	RI defined as: occurrence of at least 2 respiratory symptoms on the same day or the occurrence of a single respiratory symptom on 2 consecutive days (except for sneezing). The respiratory symptoms were as follows: sneezing, nasal congestion, nasal discharge, sore throat, scratchy throat, hoarseness, coughing, malaise, headache, feverishness, chilliness and myalgia.
Longini 1988 DB-PC RCT USA	Respiratory illness defined as 1 or more of the following symptoms occurring during the course of acute episode: coryza, sore throat or hoarseness, earache, cough, pain on respiration, wheezy breathing or phlegm from the chest.

ALRI: acute lower respiratory infection
ARIs: acute respiratory infections
CDC: Centers for Disease Control and Prevention
CI: confidence interval
cluster-RCT: cluster-randomised controlled trial
CRI: clinical respiratory illness
DB-PC: double-blind, placebo-controlled
DB-RCT: double-blind randomised controlled trial
DNA: deoxyribonucleic acid

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ELISA: enzyme-linked immunosorbent assay
GI: gastrointestinal
h: hours
HCW: healthcare workers
HI: haemagglutinin
hMPV: human metapneumo virus
ICD-9: International Classification of Disease, 9th Revision, Clinical Modification
ICD-10: International Classification of Disease, 10th Revision, Clinical Modification
IgG: immunoglobulin G
IgM: immunoglobulin M
ILI: influenza-like illness
min: minutes
MRSA: methicillin-resistant Staphylococcus aureus
NAT: nucleic acid testing
NOS: not otherwise specified
NTS: nasal and throat swab
PCR: polymerase chain reaction
PIV: parainfluenza virus
POCT: point-of-care testing
RCT: randomised controlled trial
RI: respiratory infection
RNA: ribonucleic acid
RR: risk ratio
rRT-PCR: real-time reverse transcriptase polymerase chain reaction
RSV: respiratory syncytial virus
RTI: respiratory tract infection
RT-PCR: reverse transcriptase polymerase chain reaction
SAR: secondary attack ratios
SD: standard deviation
S/S: signs and symptoms
URI: upper respiratory infection
URTI: upper respiratory tract infection
UTI: urinary tract infection
WHO: World Health Organization

APPENDICES

Appendix 1. Cochrane Central Register of Controlled Trials (CENTRAL) search string

([mh "Influenza, Human"] OR [mh "Influenzavirus A"] OR [mh "Influenzavirus B"] OR [mh "Influenzavirus C"] OR Influenza:ti,ab OR [mh "Respiratory Tract Diseases"] OR Influenzas:ti,ab OR “Influenza-like”:ti,ab OR ILI:ti,ab OR Flu:ti,ab OR Flus:ti,ab OR [mh ^"Common Cold"] OR "common cold":ti,ab OR colds:ti,ab OR coryza:ti,ab OR [mh coronavirus] OR [mh "sars virus"] OR coronavirus:ti,ab OR Coronaviruses:ti,ab OR [mh "coronavirus infections"] OR [mh "severe acute respiratory syndrome"] OR "severe acute respiratory syndrome":ti,ab OR "severe acute respiratory syndromes":ti,ab OR sars:ti,ab OR [mh "respiratory syncytial viruses"] OR [mh "respiratory syncytial virus, human"] OR [mh "Respiratory Syncytial Virus Infections"] OR "respiratory syncytial virus":ti,ab OR "respiratory syncytial viruses":ti,ab OR rsv:ti,ab OR parainfluenza:ti,ab OR “Respiratory illness”:ti,ab OR ((Transmission) AND (Coughing OR Sneezing)) OR ((respiratory:ti,ab AND Tract) AND (infection:ti,ab OR Infections:ti,ab OR illness:ti,ab)))
AND
([mh "Hand Hygiene"] OR handwashing:ti,ab OR “hand-washing”:ti,ab OR ((Hand:ti,ab OR Alcohol:ti,ab) AND (wash:ti,ab OR Washing:ti,ab OR Cleansing:ti,ab OR Rinses:ti,ab OR hygiene:ti,ab OR rub:ti,ab OR Rubbing:ti,ab OR sanitizer:ti,ab OR sanitiser:ti,ab OR cleanser:ti,ab OR disinfected:ti,ab OR Disinfectant:ti,ab OR Disinfect:ti,ab OR antiseptic:ti,ab OR virucid:ti,ab)) OR [mh "gloves, protective"] OR Glove:ti,ab OR Gloves:ti,ab OR [mh Masks] OR [mh "respiratory protective devices"] OR facemask:ti,ab OR Facemasks:ti,ab OR mask:ti,ab OR Masks:ti,ab OR respirator:ti,ab OR respirators:ti,ab OR [mh ^"Protective Clothing"] OR [mh "Protective Devices"] OR "patient isolation":ti,ab OR ((school:ti,ab OR Schools:ti,ab) AND (Closure:ti,ab OR Closures:ti,ab OR Closed:ti,ab)) OR [mh Quarantine] OR quarantine:ti,ab OR "Hygiene intervention":ti,ab OR [mh Mouthwashes] OR gargling:ti,ab OR "nasal tissues":ti,ab OR [mh "Eye Protective Devices"] OR Glasses:ti,ab OR Goggle:ti,ab OR "Eye protection":ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab)
AND

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([mh "Communicable Disease Control"] OR [mh "Disease Outbreaks"] OR [mh "Disease Transmission, Infectious"] OR [mh "Infection Control"] OR "Communicable Disease Control":ti,ab OR "Secondary transmission":ti,ab OR ((Reduced:ti,ab OR Reduce:ti,ab OR Reduction:ti,ab OR Reducing:ti,ab OR Lower:ti,ab) AND (Incidence:ti,ab OR Occurrence:ti,ab OR Transmission:ti,ab OR Secondary:ti,ab))

Appendix 2. PubMed search string

("Influenza, Human"[Mesh] OR "Influenzavirus A"[Mesh] OR "Influenzavirus B"[Mesh] OR "Influenzavirus C"[Mesh] OR Influenza[tiab] OR "Respiratory Tract Diseases"[Mesh] OR "Bacterial Infections/transmission"[Mesh] OR Influenzas[tiab] OR “Influenza-like”[tiab] OR ILI[tiab] OR Flu[tiab] OR Flus[tiab] OR "Common Cold"[Mesh:NoExp] OR "common cold"[tiab] OR colds[tiab] OR coryza[tiab] OR coronavirus[Mesh] OR "sars virus"[Mesh] OR coronavirus[tiab] OR Coronaviruses[tiab] OR "coronavirus infections"[Mesh] OR "severe acute respiratory syndrome"[Mesh] OR "severe acute respiratory syndrome"[tiab] OR "severe acute respiratory syndromes"[tiab] OR sars[tiab] OR "respiratory syncytial viruses"[Mesh] OR "respiratory syncytial virus, human"[Mesh] OR "Respiratory Syncytial Virus Infections"[Mesh] OR "respiratory syncytial virus"[tiab] OR "respiratory syncytial viruses"[tiab] OR rsv[tiab] OR parainfluenza[tiab] OR “Respiratory illness”[tiab] OR ((Transmission[tiab]) AND (Coughing[tiab] OR Sneezing[tiab])) OR ((respiratory[tiab] AND Tract[tiab]) AND (infection[tiab] OR Infections[tiab] OR illness[tiab])))
AND
("Hand Hygiene"[Mesh] OR handwashing[tiab] OR hand-washing[tiab] OR ((Hand[tiab] OR Alcohol[tiab]) AND (wash[tiab] OR Washing[tiab] OR Cleansing[tiab] OR Rinses[tiab] OR hygiene[tiab] OR rub[tiab] OR Rubbing[tiab] OR sanitizer[tiab] OR sanitiser[tiab] OR cleanser[tiab] OR disinfected[tiab] OR Disinfectant[tiab] OR Disinfect[tiab] OR antiseptic[tiab] OR virucid[tiab])) OR "gloves, protective"[Mesh] OR Glove[tiab] OR Gloves[tiab] OR Masks[Mesh] OR "respiratory protective devices"[Mesh] OR facemask[tiab] OR Facemasks[tiab] OR mask[tiab] OR Masks[tiab] OR respirator[tiab] OR respirators[tiab] OR "Protective Clothing"[Mesh:NoExp] OR "Protective Devices"[Mesh] OR "patient isolation"[tiab] OR ((school[tiab] OR Schools[tiab]) AND (Closure[tiab] OR Closures[tiab] OR Closed[tiab])) OR Quarantine[Mesh] OR quarantine[tiab] OR “Hygiene intervention”[tiab] OR "Mouthwashes"[Mesh] OR gargling[tiab] OR “nasal tissues”[tiab] OR "Eye Protective Devices"[Mesh] OR Glasses[tiab] OR Goggle[tiab] OR “Eye protection”[tiab] OR Faceshield[tiab] OR Faceshields[tiab] OR Goggles[tiab] OR “Face shield”[tiab] OR “Face shields”[tiab] OR Visors[tiab])
AND
("Communicable Disease Control"[Mesh] OR "Disease Outbreaks"[Mesh] OR "Disease Transmission, Infectious"[Mesh] OR "Infection Control"[Mesh] OR Transmission[sh] OR “Prevention and control”[sh] OR "Communicable Disease Control"[tiab] OR “Secondary transmission”[tiab] OR ((Reduced[tiab] OR Reduce[tiab] OR Reduction[tiab] OR Reducing[tiab] OR Lower[tiab]) AND (Incidence[tiab] OR Occurrence[tiab] OR Transmission[tiab] OR Secondary[tiab])))
AND
(Randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR placebo[tiab] OR "drug therapy"[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab])
NOT
(Animals[Mesh] not (Animals[Mesh] and Humans[Mesh]))
NOT
(“Case Reports”[pt] OR Editorial[pt] OR Letter[pt] OR Meta-Analysis[pt] OR “Observational Study”[pt] OR “Systematic Review”[pt] OR “Case Report”[ti] OR “Case series”[ti] OR Meta-Analysis[ti] OR “Meta Analysis”[ti] OR “Systematic Review”[ti])

Appendix 3. Embase (Elsevier) search string

('influenza'/exp OR Influenza:ti,ab OR 'Respiratory Tract Disease'/exp OR Influenzas:ti,ab OR Influenza-like:ti,ab OR ILI:ti,ab OR Flu:ti,ab OR Flus:ti,ab OR 'Common Cold'/de OR "common cold":ti,ab OR colds:ti,ab OR coryza:ti,ab OR 'coronavirus'/exp OR 'SARS coronavirus'/exp OR coronavirus:ti,ab OR Coronaviruses:ti,ab OR 'coronavirus infection'/exp OR 'severe acute respiratory syndrome'/exp OR "severe acute respiratory syndrome":ti,ab OR "severe acute respiratory syndromes":ti,ab OR sars:ti,ab OR 'Pneumovirus'/exp OR 'Human respiratory syncytial virus'/exp OR "respiratory syncytial virus":ti,ab OR "respiratory syncytial viruses":ti,ab OR rsv:ti,ab OR parainfluenza:ti,ab OR “Respiratory illness”:ti,ab OR ((Transmission) AND (Coughing OR Sneezing)) OR ((respiratory:ti,ab AND Tract) AND (infection:ti,ab OR Infections:ti,ab OR illness:ti,ab)))
AND
('hand washing'/exp OR handwashing:ti,ab OR hand-washing:ti,ab OR ((Hand:ti,ab OR Alcohol:ti,ab) AND (wash:ti,ab OR Washing:ti,ab OR Cleansing:ti,ab OR Rinses:ti,ab OR hygiene:ti,ab OR rub:ti,ab OR Rubbing:ti,ab OR sanitizer:ti,ab OR sanitiser:ti,ab OR cleanser:ti,ab OR disinfected:ti,ab OR Disinfectant:ti,ab OR Disinfect:ti,ab OR antiseptic:ti,ab OR virucid:ti,ab)) OR 'protective glove'/exp OR Glove:ti,ab OR Gloves:ti,ab OR 'mask'/exp OR 'gas mask'/exp OR facemask:ti,ab OR Facemasks:ti,ab OR mask:ti,ab OR Masks:ti,ab OR respirator:ti,ab OR respirators:ti,ab OR 'protective clothing'/de OR 'protective equipment'/exp OR "patient isolation":ti,ab OR ((school:ti,ab OR Schools:ti,ab) AND (Closure:ti,ab OR Closures:ti,ab OR Closed:ti,ab)) OR 'Quarantine'/exp OR quarantine:ti,ab OR "Hygiene intervention":ti,ab OR 'mouthwash'/exp OR gargling:ti,ab OR "nasal tissues":ti,ab OR ‘eye protective device'/exp OR Glasses:ti,ab OR Goggle:ti,ab OR "Eye protection":ti,ab OR Faceshield:ti,ab OR Faceshields:ti,ab OR Goggles:ti,ab OR "Face shield":ti,ab OR "Face shields":ti,ab OR Visors:ti,ab)
AND
('Communicable Disease Control'/exp OR 'epidemic'/exp OR 'disease transmission'/exp OR 'Infection Control'/exp OR "Communicable Disease Control":ti,ab OR "Secondary transmission":ti,ab OR ((Reduced:ti,ab OR Reduce:ti,ab OR Reduction:ti,ab OR Reducing:ti,ab OR Lower:ti,ab) AND (Incidence:ti,ab OR Occurrence:ti,ab OR Transmission:ti,ab OR Secondary:ti,ab)))
AND

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(random* OR factorial OR crossover OR placebo OR blind OR blinded OR assign OR assigned OR allocate OR allocated OR 'crossover procedure'/exp OR 'double-blind procedure'/exp OR 'randomized controlled trial'/exp OR 'single-blind procedure'/exp NOT ('animal'/exp NOT ('animal'/exp AND 'human'/exp)))

Appendix 4. CINAHL (EBSCO) search string

((MH "Influenza, Human+") OR (MH "Orthomyxoviridae+") OR TI Influenza OR AB Influenza OR (MH "Respiratory Tract Diseases+") OR TI Influenzas OR AB Influenzas OR TI Influenza-like OR AB Influenza-like OR TI ILI OR AB ILI OR TI Flu OR AB Flu OR TI Flus OR AB Flus OR (MH "Common Cold+") OR TI "common cold" OR AB "common cold" OR TI colds OR AB colds OR TI coryza OR AB coryza OR (MH "coronavirus+") OR (MH "sars virus+") OR TI coronavirus OR AB coronavirus OR TI Coronaviruses OR AB Coronaviruses OR (MH "coronavirus infections+") OR (MH "severe acute respiratory syndrome+") OR TI "severe acute respiratory syndrome" OR AB "severe acute respiratory syndrome" OR TI "severe acute respiratory syndromes" OR AB "severe acute respiratory syndromes" OR TI sars OR AB sars OR (MH "respiratory syncytial viruses+") OR TI "respiratory syncytial virus" OR AB "respiratory syncytial virus" OR TI "respiratory syncytial viruses" OR AB "respiratory syncytial viruses" OR TI rsv OR AB rsv OR TI parainfluenza OR AB parainfluenza OR TI “Respiratory illness” OR AB “Respiratory illness” OR ((Transmission) AND (Coughing OR Sneezing)) OR ((TI respiratory OR AB respiratory AND Tract) AND (TI infection OR AB infection OR TI Infections OR AB Infections OR TI illness OR AB illness)))
AND
((MH "Handwashing+") OR TI handwashing OR AB handwashing OR TI hand-washing OR AB hand-washing OR ((TI Hand OR AB Hand OR TI Alcohol OR AB Alcohol) AND (TI wash OR AB wash OR TI Washing OR AB Washing OR TI Cleansing OR AB Cleansing OR TI Rinses OR AB Rinses OR TI hygiene OR AB hygiene OR TI rub OR AB rub OR TI Rubbing OR AB Rubbing OR TI sanitizer OR AB sanitiser OR TI sanitizer OR AB sanitiser OR TI cleanser OR AB cleanser OR TI disinfected OR AB disinfected OR TI Disinfectant OR AB Disinfectant OR TI Disinfect OR AB Disinfect OR TI antiseptic OR AB antiseptic OR TI virucid OR AB virucid)) OR (MH "gloves+") OR TI Glove OR AB Glove OR Gloves OR (MH "Masks+") OR (MH "respiratory protective devices+") OR TI facemask OR AB facemask OR TI Facemasks OR AB Facemasks OR TI mask OR AB mask OR TI Masks OR AB Masks OR TI respirator OR AB respirator OR TI respirators OR AB respirators OR (MH "Protective Clothing") OR (MH "Protective Devices+") OR TI "patient isolation" OR AB "patient isolation" OR ((TI school OR AB school OR TI Schools OR AB Schools) AND (TI Closure OR AB Closure OR TI Closures OR AB Closures OR TI Closed OR AB Closed)) OR (MH "Quarantine+") OR TI quarantine OR AB quarantine OR TI "Hygiene intervention" OR AB "Hygiene intervention" OR (MH "Mouthwashes+") OR TI gargling OR AB gargling OR TI "nasal tissues" OR AB "nasal tissues" OR (MH "Eye Protective Devices+") OR TI Glasses OR AB Glasses OR TI Goggle OR AB Goggle OR TI "Eye protection" OR AB "Eye protection" OR TI Faceshield OR AB Faceshield OR TI Faceshields OR AB Faceshields OR TI Goggles OR AB Goggles OR TI "Face shield" OR AB "Face shield" OR TI "Face shields" OR AB "Face shields" OR TI Visors OR AB Visors)
AND
((MH "Infection Control+") OR (MH "Disease Outbreaks+") OR (MH "Infection Control+") OR TI "Communicable Disease Control" OR AB "Communicable Disease Control" OR TI "Secondary transmission" OR AB "Secondary transmission" OR ((TI Reduced OR AB Reduced OR TI Reduce OR AB Reduce OR TI Reduction OR AB Reduction OR TI Reducing OR AB Reducing OR TI Lower OR AB Lower) AND (TI Incidence OR AB Incidence OR TI Occurrence OR AB Occurrence OR TI Transmission OR AB Transmission OR TI Secondary OR AB Secondary)))
AND
((MH "Clinical Trials+") OR (MH "Quantitative Studies") OR TI placebo* OR AB placebo* OR (MH "Placebos") OR (MH "Random Assignment") OR TI random* OR AB random* OR TI ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR AB ((singl* or doubl* or tripl* or trebl*) W1 (blind* or mask*)) OR TI clinic* trial* OR AB clinic* trial* OR PT clinical trial)

Appendix 5. Previous search strategies (pre-2010)

Details of the 2010 update and the search strategy used in the original review and the 2009 search strategy updates for MEDLINE, CENTRAL, EMBASE and CINAHL

In the 2010 update we searched, as we have done previously, the Cochrane Central Register of Controlled Trials (CENTRAL) 2010, Issue 3, which includes the Acute Respiratory Infections Group's Specialised Register, MEDLINE (April 2009 to October week 2, 2010), EMBASE (April 2009 to October 2010) and CINAHL (January 2009 to October 2010). Details of previous searches are in Appendix 1. In addition, to include more of the literature of low-income countries in this update, we ran searches in LILACS (2008 to October 2010), Indian MEDLARS (2008 to October 2010) and IMSEAR (2008 to October 2010).

We used the following search strategy (updated to include new and emerging respiratory viruses) to search MEDLINE and CENTRAL. We combined the MEDLINE search strategy with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Ovid format) (Lefebvre 2011). We also included an additional search strategy based on the work of Fraser, Murray and Burr (Fraser 2006) to identify observational studies.

1 Influenza, Human/
2 exp Influenzavirus A/
3 exp Influenzavirus B/
4 Influenzavirus C/
5 (influenza* or flu).tw.
6 Common Cold/
7 common cold*.tw.

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8 Rhinovirus/
9 rhinovir*.tw.
10 adenoviridae/ or mastadenovirus/ or adenoviruses, human/
11 adenoviridae infections/ or adenovirus infections, human/
12 adenovir*.tw.
13 coronavirus/ or coronavirus 229e, human/ or coronavirus oc43, human/ or infectious bronchitis virus/ or sars virus/
14 coronavir*.tw.
15 coronavirus infections/ or severe acute respiratory syndrome/
16 (severe acute respiratory syndrome* or sars).tw.
17 respiratory syncytial viruses/ or respiratory syncytial virus, human/
18 Respiratory Syncytial Virus Infections/
19 (respiratory syncytial virus* or rsv).tw.
20 Pneumovirus Infections/
21 parainfluenza virus 1, human/ or parainfluenza virus 3, human/
22 parainfluenza virus 2, human/ or parainfluenza virus 4, human/
23 (parainfluenza* or para-influenza* or para influenza).tw.
24 enterovirus a, human/ or exp enterovirus b, human/ or enterovirus c, human/ or enterovirus d, human/
25 Enterovirus Infections/
26 enterovir*.tw.
27 Human bocavirus/
28 bocavirus*.tw.
29 Metapneumovirus/
30 metapneumovir*.tw.
31 Parvovirus B19, Human/
32 parvoviridae infections/ or erythema infectiosum/
33 parvovirus*.tw.
34 Parechovirus/
35 parechovirus*.tw.
36 acute respiratory tract infection*.tw.
37 acute respiratory infection*.tw.
38 or/1-37
39 Handwashing/
40 (handwashing or hand washing or hand-washing).tw.
41 hand hygiene.tw.
42 (sanitizer* or sanitiser*).tw.
43 (cleanser* or disinfectant*).tw.
44 gloves, protective/ or gloves, surgical/
45 glov*.tw.
46 masks/ or respiratory protective devices/
47 (mask or masks or respirator or respirators).tw.
48 Protective Clothing/
49 Protective Devices/
50 Patient Isolators/
51 Patient Isolation/
52 patient isolat*.tw.
53 (barrier* or curtain* or partition*).tw.
54 negative pressure room*.tw.
55 ((reverse barrier or reverse-barrier) adj3 (nurs* or unit or isolation)).tw.
56 Cross Infection/pc [Prevention & Control]
57 (cross infection* adj2 prevent*).tw.
58 Communicable Disease Control/
59 Infection Control/
60 (school* adj3 (clos* or dismissal*)).tw.
61 temporary closur*.tw.
62 mass gathering*.tw.
63 (public adj2 (gathering* or event*)).tw.
64 (bans or banning or banned or ban).tw.
65 (outbreak adj3 control*).tw.
66 distancing*.tw.
67 Quarantine/
68 quarantine*.tw.
69 (protective adj2 (cloth* or garment* or device* or equipment)).tw.

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70 ((protective or preventive) adj2 (procedure* or behaviour* or behavior*)).tw.
71 personal protect*.tw.
72 (isolation room* or isolation strateg*).tw.
73 (distance adj2 patient*).tw.
74 ((spatial or patient) adj separation).tw.
75 cohorting.tw.
76 or/39-75
77 38 and 76
78 (animals not (animals and humans)).sh.
79 77 not 78

Ovid MEDLINE

1 Influenza, Human/
2 exp Influenzavirus A/
3 exp Influenzavirus B/
4 Influenzavirus C/
5 (influenza* or flu).tw.
6 Common Cold/
7 common cold*.tw.
8 Rhinovirus/
9 rhinovir*.tw.
10 adenoviridae/ or mastadenovirus/ or adenoviruses, human/
11 adenoviridae infections/ or adenovirus infections, human/
12 adenovir*.tw.
13 coronavirus/ or coronavirus 229e, human/ or coronavirus oc43, human/ or infectious bronchitis virus/ or sars virus/
14 coronavir*.tw.
15 coronavirus infections/ or severe acute respiratory syndrome/
16 (severe acute respiratory syndrome* or sars).tw.
17 respiratory syncytial viruses/ or respiratory syncytial virus, human/
18 Respiratory Syncytial Virus Infections/
19 (respiratory syncytial virus* or rsv).tw.
20 Pneumovirus Infections/
21 parainfluenza virus 1, human/ or parainfluenza virus 3, human/
22 parainfluenza virus 2, human/ or parainfluenza virus 4, human/
23 (parainfluenza* or para-influenza* or para influenza).tw.
24 enterovirus a, human/ or exp enterovirus b, human/ or enterovirus c, human/ or enterovirus d, human/
25 Enterovirus Infections/
26 enterovir*.tw.
27 Human bocavirus/
28 bocavirus*.tw.
29 Metapneumovirus/
30 metapneumovir*.tw.
31 Parvovirus B19, Human/
32 parvoviridae infections/ or erythema infectiosum/
33 parvovirus*.tw.
34 Parechovirus/
35 parechovirus*.tw.
36 acute respiratory tract infection*.tw.
37 acute respiratory infection*.tw.
38 or/1-37
39 Handwashing/
40 (handwashing or hand washing or hand-washing).tw.
41 hand hygiene.tw.
42 (sanitizer* or sanitiser*).tw.
43 (cleanser* or disinfectant*).tw.
44 gloves, protective/ or gloves, surgical/
45 glov*.tw.
46 masks/ or respiratory protective devices/
47 (mask or masks or respirator or respirators).tw.
48 Protective Clothing/
49 Protective Devices/

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50 Patient Isolators/
51 Patient Isolation/
52 patient isolat*.tw.
53 (barrier* or curtain* or partition*).tw.
54 negative pressure room*.tw.
55 ((reverse barrier or reverse-barrier) adj3 (nurs* or unit or isolation)).tw.
56 Cross Infection/pc [Prevention & Control]
57 (cross infection* adj2 prevent*).tw.
58 Communicable Disease Control/
59 Infection Control/
60 (school* adj3 (clos* or dismissal*)).tw.
61 temporary closur*.tw.
62 mass gathering*.tw.
63 (public adj2 (gathering* or event*)).tw.
64 (bans or banning or banned or ban).tw.
65 (outbreak adj3 control*).tw.
66 distancing*.tw.
67 Quarantine/
68 quarantine*.tw.
69 (protective adj2 (cloth* or garment* or device* or equipment)).tw.
70 ((protective or preventive) adj2 (procedure* or behaviour* or behavior*)).tw.
71 personal protect*.tw.
72 (isolation room* or isolation strateg*).tw.
73 (distance adj2 patient*).tw.
74 ((spatial or patient) adj separation).tw.
75 cohorting.tw.
76 or/39-75
77 38 and 76
78 (animals not (animals and humans)).sh.
79 77 not 78

Embase.com search strategy, October 2010
The search strategy was broadened in 2010 to be more inclusive of new and emerging viruses.

#3 #1 AND #25899
#2 766172
#2.8 #2.3 NOT #2.7766172
#2.7 #2.4 NOT #2.6
#2.6 #2.4 AND #2.5
#2.5 'human'/de AND [embase]/lim
#2.4 'animal'/de OR 'nonhuman'/de OR 'animal experiment'/de AND [embase]/lim
#2.3 #2.1 OR #2.2
#2.2 random*:ab,ti OR placebo*:ab,ti OR crossover*:ab,ti OR 'cross over':ab,ti OR allocat*:ab,ti OR trial:ti OR (doubl* NEXT/1 blind*):ab,ti AND [embase]/lim
#2.1 'randomized controlled trial'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp AND [embase]/lim

#1 74545
#1.65 #1.28 AND #1.6474545
#1.64 #1.29 OR #1.30 OR #1.31 OR #1.32 OR #1.33 OR #1.34 OR #1.35 OR #1.36 OR #1.37 OR #1.38 OR #1.39 OR #1.40 OR #1.41 OR #1.42 OR #1.43 OR #1.44 OR #1.45 OR #1.46 OR #1.47 OR #1.48 OR #1.49 OR #1.50 OR #1.51 OR #1.52 OR #1.53 OR #1.54 OR #1.55 OR #1.56 OR #1.57 OR #1.58 OR #1.59 OR #1.60 OR #1.61 OR #1.62 OR #1.63
#1.63 cohorting:ab,ti OR 'cohort isolation':ab,ti AND [embase]/lim
#1.62 ((spatial OR patient*) NEAR/2 separation):ab,ti AND [embase]/lim
#1.61 (distance NEAR/2 patient*):ab,ti AND [embase]/lim
#1.60 (isolation NEXT/1 (room* OR strateg*)):ab,ti AND [embase]/lim
#1.59 'personal protection':ab,ti AND [embase]/lim
#1.58 ((protective OR preventive) NEAR/2 (procedure* OR behaviour* OR behavior*)):ab,ti AND [embase]/lim
#1.57 (protective NEAR/2 (cloth* OR garment* OR device* OR equipment)):ab,ti AND [embase]/lim
#1.56 quarantin*:ab,ti AND [embase]/lim

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#1.55 distancing:ab,ti AND [embase]/lim
#1.54 ((outbreak* OR transmission OR infection*) NEAR/2 control):ab,ti AND [embase]/lim
#1.53 bans:ab,ti OR banning:ab,ti OR banned:ab,ti OR ban:ab,ti AND [embase]/lim
#1.52 (public NEAR/2 (gathering* OR event*)):ab,ti AND [embase]/lim
#1.51 'mass gathering':ab,ti OR 'mass gatherings':ab,ti AND [embase]/lim
#1.50 (temporar* NEAR/2 closur*):ab,ti AND [embase]/lim
#1.49 (school* NEAR/3 (clos* OR dismissal*)):ab,ti AND [embase]/lim
#1.48 'infection control'/de AND [embase]/lim
#1.47 'epidemic'/dm_pc AND [embase]/lim
#1.46 (('cross infection' OR 'cross infections') NEAR/2 prevent*):ab,ti AND [embase]/lim
#1.45 'cross infection'/dm_pc AND [embase]/lim
#1.44 (('reverse barrier' OR 'reverse-barrier') NEAR/3 (nurs* OR unit OR isolat*)):ab,ti AND [embase]/lim
#1.43 'negative pressure room':ab,ti OR 'negative pressure rooms':ab,ti AND [embase]/lim
#1.42 barrier*:ab,ti OR curtain*:ab,ti OR partition*:ab,ti AND [embase]/lim
#1.41 (patient* NEAR/2 isolat*):ab,ti AND [embase]/lim
#1.40 'patient isolator'/de AND [embase]/lim
#1.39 'protective equipment'/de AND [embase]/lim
#1.38 'protective clothing'/de AND [embase]/lim
#1.37 facemask*:ab,ti OR mask:ab,ti OR masks:ab,ti OR goggles:ab,ti
OR respirator*:ab,ti OR respirators:ab,ti AND [embase]/lim
#1.36 'face mask'/exp OR 'mask'/de OR 'surgical mask'/de AND [embase]/lim
#1.35 glov*:ab,ti AND [embase]/lim
#1.34 'surgical glove'/de AND [embase]/lim
#1.33 cleanser*:ab,ti OR disinfect*:ab,ti OR antiseptic*:ab,ti OR virucid*:ab,ti AND [embase]/lim
#1.32 sanitizer*:ab,ti OR sanitiser*:ab,ti AND [embase]/lim
#1.31 (alcohol NEAR/2 rub*):ab,ti AND [embase]/lim
#1.30 handwash*:ab,ti OR (hand* NEAR/2 (wash* OR cleans* OR hygiene)):ab,ti AND [embase]/lim
#1.29 'hand washing'/de AND [embase]/lim
#1.28 #1.1 OR #1.2 OR #1.3 OR #1.4 OR #1.5 OR #1.6 OR #1.7 OR #1.8 OR #1.9 OR #1.10 OR #1.11 OR #1.12 OR #1.13 OR #1.14 OR #1.15 OR
#1.16 OR #1.17 OR #1.18 OR #1.19 OR #1.20 OR #1.21 OR #1.22 OR #1.23
OR #1.24 OR #1.25 OR #1.26 OR #1.27
#1.27 (respiratory NEAR/2 (infect* OR illness* OR virus* OR pathogen* OR acute)):ab,ti AND [embase]/lim
#1.26 parechovirus*:ab,ti AND [embase]/lim
#1.25 'parechovirus'/de AND [embase]/lim
#1.24 parvovirus*:ab,ti AND [embase]/lim
#1.23 'parvovirus infection'/de OR 'erythema infectiosum'/exp AND [embase]/lim
#1.22 'parvovirus'/de OR 'human parvovirus b19'/de AND [embase]/lim
#1.21 'human metapneumovirus'/de OR 'human metapneumovirus infection'/de AND [embase]/lim
#1.20 'bocavirus'/de OR 'bocavirus infection'/de AND [embase]/lim
#1.19 enterovir*:ab,ti AND [embase]/lim
#1.18 'enterovirus infection'/de OR 'coxsackie virus infection'/de OR 'echovirus infection'/de AND [embase]/lim
#1.17 'enterovirus'/de OR 'coxsackie virus'/exp OR 'echo virus'/de AND [embase]/lim
#1.16 parainfluenza:ab,ti OR 'para influenza':ab,ti OR 'para-influenza':ab,ti AND [embase]/lim
#1.15 'parainfluenza virus'/exp AND [embase]/lim
#1.14 'pneumovirus infection'/de AND [embase]/lim
#1.13 'respiratory syncytial virus':ab,ti OR 'respiratory syncytial viruses':ab,ti OR rsv:ab,ti AND [embase]/lim
#1.12 'respiratory syncytial pneumovirus'/de OR 'respiratory syncytial virus infection'/exp AND [embase]/lim
#1.11 coronavir*:ab,ti OR sars:ab,ti OR 'severe acute respiratory syndrome':ab,ti AND [embase]/lim
#1.10 'coronavirus infection'/de OR 'severe acute respiratory syndrome'/de AND [embase]/lim
#1.9 'coronavirus'/de OR 'human coronavirus nl63'/de OR 'sars coronavirus'/de OR 'transmissible gastroenteritis virus'/de
#1.8 adenovir*:ab,ti AND [embase]/lim
#1.7 'adenovirus infection'/de OR 'human adenovirus infection'/de OR 'human adenovirus'/exp AND [embase]/lim
#1.6 rhinovir*:ab,ti AND [embase]/lim
#1.5 'rhinovirus infection'/de OR 'human rhinovirus'/de AND [embase]/lim
#1.4 'common cold':ab,ti OR 'common colds':ab,ti OR coryza:ab,ti OR colds:ab,ti AND [embase]/lim
#1.3 'common cold'/de OR 'common cold symptom'/de AND [embase]/lim
#1.2 influenza*:ab,ti OR flu:ab,ti AND [embase]/lim
#1.1 'influenza'/exp AND [embase]/lim

CINAHL (EBSCO) search strategy, October 2010

The search strategy was broadened in 2010 to be more inclusive of new and emerging viruses.

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S54 S32 and S53
S53 S44 or S52
S52 S45 or S46 or S47 or S48 or S49 or S50 or S51
S51 TI observational stud* or AB observational stud*
S50 TI cohort stud* or AB cohort stud*
S49 (MH "Cross Sectional Studies")
S48 (MH "Nonconcurrent Prospective Studies")
S47 (MH "Correlational Studies")
S46 (MH "Case Control Studies+")
S45 (MH "Prospective Studies")
S44 S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43
S43 TI allocat* N1 random* or AB allocat* N1 random*
S42 (MH "Quantitative Studies")
S41 TI placebo* or AB placebo*
S40 (MH "Placebos")
S39 TI random* allocation* or AB random* allocation*
S38 (MH "Random Assignment")
S37 TI (randomised control* trial* or randomized control* trial*) or AB (randomised control* trial* or randomized control* trial)
S36 TI ((singl* W1 blind*) or (singl* W1 mask*) or (doubl* W1 blind*) or (doubl* W1 mask*) or (trebl* W1 blind*) or (trebl* W1 mask*) or (tripl* W1 blind*) or (tripl* W1 mask*)) or AB ((singl* W1 blind*) or (singl* W1 mask*) or (doubl* W1 blind*) or (doubl* W1 mask*) or (trebl* W1 blind*) or (trebl* W1 mask*) or (tripl* W1 blind*) or (tripl* W1 mask*))
S35 TI clinic* W1 trial* or AB clinic* W1 trial*
S34 PT clinical trial
S33 (MH "Clinical Trials+")
S32 S15 and S31
S31 S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30
S30 TI (bans or banning or banned or ban or "outbreak control" or "outbreak controls" or distancing* or quarantine* or "protective clothing" or "protective garment" or "protective garments" or "protective gown" or "protective gowns" or "protective device" or "protective devices" or "protective equipment" or "protective behaviour" or "protective behavior" or "protective behaviours" or "protective behaviors" or "protective procedure" or "protective procedures" or "preventive behaviours" or "preventive behaviour" or "preventive behavior" or "preventive behaviors" or "preventive procedure" or "preventive procedures" or "personal protective" or "isolation room" or "isolation rooms" or "isolation strategy" or "isolation strategies" or "patient distance" or "patient distancing" or "patient separation" or "spatial separation") or AB (handwashing or "hand washing" or hand-washing or "hand hygiene" or sanitizer or sanitiser or cleanser* or disinfectant* or glov* or mask or masks or respirator or respirators or "patient isolation" or "patient isolators" or barrier* or curtain* or partition* or "negative pressure room" or "negative pressure rooms" or "reverse barrier nursing" or "reverse barrier unit" or "reverse barrier isolation" or "cross infection" or "infection control" or "disease control" or "school closure" or "school closures" or "school dismissal" or "school dismissals" or "temporary closure" or "temporary closures" or "mass gathering" or "mass gatherings" or "public gathering" or "public gatherings" or "public event" or "public events")
S29 TI (handwashing or "hand washing" or hand-washing or "hand hygiene" or sanitizer or sanitiser or cleanser* or disinfectant* or glov* or mask or masks or respirator or respirators or "patient isolation" or "patient isolators" or barrier* or curtain* or partition* or "negative pressure room" or "negative pressure rooms" or "reverse barrier nursing" or "reverse barrier unit" or "reverse barrier isolation" or "cross infection" or "infection control" or "disease control" or "school closure" or "school closures" or "school dismissal" or "school dismissals" or "temporary closure" or "temporary closures" or "mass gathering" or "mass gatherings" or "public gathering" or "public gatherings" or "public event" or "public events") or AB (handwashing or "hand washing" or hand-washing or "hand hygiene" or sanitizer or sanitiser or cleanser* or disinfectant* or glov* or mask or masks or respirator or respirators or "patient isolation" or "patient isolators" or barrier* or curtain* or partition* or "negative pressure room" or "negative pressure rooms" or "reverse barrier nursing" or "reverse barrier unit" or "reverse barrier isolation" or "cross infection" or "infection control" or "disease control" or "school closure" or "school closures" or "school dismissal" or "school dismissals" or "temporary closure" or "temporary closures" or "mass gathering" or "mass gatherings" or "public gathering" or "public gatherings" or "public event" or "public events")
S28 (MH "Sterilization and Disinfection")
S27 (MH "Quarantine")
S26 (MH "Area Restriction (Iowa NIC)") OR (MH "Infection Protection (IowaNIC)")
S25 (MH "Infection Control")
S24 (MH "Cross Infection/PC")
S23 (MH "Isolation, Reverse")
S22 (MH "Patient Isolation")
S21 (MH "Protective Devices")
S20 (MH "Protective Clothing")
S19 (MH "Respiratory Protective Devices")
S18 (MH "Masks")
S17 (MH "Gloves")
S16 (MH "Handwashing+")

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S15 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14
S14 TI ("acute respiratory tract infection" or "acute respiratory tract infections" or "acute respiratory infection" or "acute respiratory infections") or AB (influenza* or flu or "common cold" or "common colds" or rhinovir* or adenovir* or coronavir* or sars or "severe acute respiratory syndrome" or "respiratory syncytial virus" or "respiratory syncytial viruses" or rsv or pneumovir* or parainfluenza* or "para influenza" or para-influenza or enterovir* or bocavir* or metapneumovir* or parvovir* or parechovir*)
S13 TI (influenza* or flu or "common cold" or "common colds" or rhinovir* or adenovir* or coronavir* or sars or "severe acute respiratory syndrome" or "respiratory syncytial virus" or "respiratory syncytial viruses" or rsv or pneumovir* or parainfluenza* or "para influenza" or para-influenza or enterovir* or bocavir* or metapneumovir* or parvovir* or parechovir*) or AB (influenza* or flu or "common cold" or "common colds" or rhinovir* or adenovir* or coronavir* or sars or "severe acute respiratory syndrome" or "respiratory syncytial virus" or "respiratory syncytial viruses" or rsv or pneumovir* or parainfluenza* or "para influenza" or para-influenza or enterovir* or bocavir* or metapneumovir* or parvovir* or parechovir*)
S12 (MH "Respiratory Tract Infections+")
S11 (MH "Parvovirus Infections+")
S10 (MH "Enterovirus Infections+")
S9 (MH "Enteroviruses+")
S8 (MH "Respiratory Syncytial Virus Infections")
S7 (MH "Respiratory Syncytial Viruses")
S6 (MH "SARS Virus")
S5 (MH "Severe Acute Respiratory Syndrome")
S4 (MH "Coronavirus Infections+")
S3 (MH "Coronavirus+") OR (MH "Coronavirus Infections")
S2 (MH "Common Cold")
S1 (MH "Influenza+") OR (MH "Influenza A H5N1") OR (MH "Influenza A

LILACS (Latin America and Caribbean) search strategy
(mh:"Influenza, Human" OR "Gripe Humana" OR "Influenza Humana" OR influenza* OR flu OR grippe OR gripe OR mh:"Influenzavirus A" OR mh:b04.820.545.405* OR mh:b04.909.777.545.405* OR mh:"Influenzavirus B" OR mh:b04.820.545.407* OR mh:b04.909.777.545.407* OR "influenzavirus B" OR mh:"Influenzavirus C" OR "Influenzavirus C" OR mh:"Common Cold" OR "common cold" OR "common colds" OR "Resfriado Común" OR "Resfriado Comum" OR coryza OR "Coriza Aguda") AND (mh:handwashing OR "Lavado de Manos" OR "Lavagem de Mãos" OR "Desinfección de Manos" OR "Desinfecção de Mãos" OR "Higienização de Mãos Pré-Cirúrgica" OR handwash* OR "hand washing" OR "hand hygiene" OR "hand cleaning" OR "hand cleanse" OR "hand cleansing" OR higiene OR sanitizer* OR sanitiser* OR cleanser* OR disinfect* OR esteriliza* OR desinfectar* OR virucid* OR antiseptic* OR mh:"Gloves, Protective" OR "protective glove" OR "protective gloves" OR "Guantes Protectores" OR "Luvas Protetoras" OR mh:e07.700.600.400* OR mh:j01.637.215.600.400* OR mh:j01.637.708.600.400* OR glov* OR guantes OR luvas OR mh:masks OR mask* OR máscaras OR mascarillas OR facemask* OR goggles OR respirator* OR mh:"Respiratory Protective Devices" OR "Dispositivos de Protección Respiratoria" OR "Dispositivos de Proteção Respiratória" OR mh:"Protective Clothing" OR "Ropa de Protección" OR "Roupa de Proteção" OR mh:e07.700.600* OR mh:j01.637.215.600* OR mh:j01.637.708.600* OR mh:"Protective Devices" OR "Equipos de Seguridad" OR "Equipamentos de Proteção" OR mh:e07.700* OR mh:j01.637.708* OR mh:vs2.006.001.001* OR mh:vs4.002.001.001.007.002.002* OR mh:"Patient Isolation" OR "patient isolation" OR "Aislamiento de Pacientes" OR "Isolamento de Pacientes" OR mh:"Patient Isolators" OR "patient isolators" OR "Aisladores de Pacientes" OR "Isoladores de Pacientes" OR barrier* OR curtain* OR partition* OR barrera OR barreira OR cortina OR tabique OR mh:"Cross Infection" OR "cross infection" OR "Infección Hospitalaria" OR "Infecção Hospitalar" OR "Infecciones en Hospitales" OR "Infecciones Nosocomiales" OR "Infecções Nosocomiais" OR mh:"Infection Control" OR mh:n06.850.780.200.450* OR "Control de Infecciones" OR "Controle de Infecções" OR mh:"Communicable Disease Control" OR "Control de Enfermedades Transmisibles" OR "Controle de Doenças Transmissíveis" OR mh:n06.850.780.200* OR mh:sp8.946.819.811* OR mh:"Disease Outbreaks/prevention & control" OR mh:quarantine OR cuarentena OR quarentena OR "personal protection" OR "isolation room" OR "sala de aislamiento" OR "quarto de isolamento" OR "patient distance" OR "distancia del paciente" OR "spatial separation" OR cohort* OR ban OR bans OR banning OR banned OR prohibici* OR proibi* OR "outbreak control" OR distanc* OR "school closure" OR "school closures" OR "temporary closure" OR "temporary closures" OR "cierre de la escuela" OR "fechamento da escola" OR "public gathering" OR "public gatherings" OR "reunion publica" OR "reverse barrier nursing" OR "reverse barrier unit" OR "reverse barrier isolation" OR "negative pressure room" OR "negative pressure rooms" OR "patient separation") AND db:("LILACS") AND type_of_study:("clinical_trials" OR "cohort" OR "case_control")

Indian MEDLARS search strategy
(influenza$ or flu or common cold$ or rhinovir$ or coronavir$ or adenovir$ or severe acute respiratory syndrome$ or sars or respiratory syncytial virus$ or rsv or parainfluenza$ or enterovir$ or metapneumovir$ or parvovir$ or bocavir$ or parechovir$) and (handwashing or hand washing or mask$ or glov$ or protect$ or isolat$ or barrier$ or curtain$ or partition$ or cross infection$ or infection control$ or disease control$ or school$ or quarantine$ or ban$ or cohort$ or distanc$ or spatial separation$)
IMSEAR (Index Medicus for the South East Asia Region) search strategy
(influenza or flu or common cold or rhinovirus or coronavirus or adenovirus or severe acute respiratory syndrome or sars or respiratory syncytial virus or rsv or parainfluenza or enterovirus or bocavirus or metapneumovirus or parvovirus or parechovirus) and (handwashing or hand washing or hand hygiene or sanitizer or sanitiser or cleanser or disinfectant or gloves or masks or mask or protective clothing or protective devices or patient isolation or barrier or curtain or partition or cross infection or disease control or infection control or school or schools or bans or banning or banned or ban or distancing or quarantine or isolation or spatial separation or cohorting or cohort isolation)

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In the first publication of this review we searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, issue 4); MEDLINE (1966 to November 2006); OLDMEDLINE (1950 to 1965); EMBASE (1990 to November 2006) and CINAHL (1982 to November 2006). The MEDLINE search terms were modified for OLDMEDLINE, EMBASE and CINAHL.

In this 2009 update we searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2009, issue 2); Ovid MEDLINE (2006 to May Week 1 2009); OLDMEDLINE (1950 to 1965); Ovid EMBASE (2006 to Week 18, 2009) and Ovid CINAHL (2006 to May Week 1 2009).

Ovid MEDLINE
1 exp Influenza/
2 influenza.tw.
3 flu.tw.
4 exp Common Cold/
5 common cold.tw.
6 exp Rhinovirus/
7 rhinovirus*.tw.
8 exp Adenoviridae/
9 adenovirus*.tw.
10 exp Coronavirus/
11 exp Coronavirus Infections/
12 coronavirus*.tw.
13 exp Respiratory Syncytial Viruses/
14 exp Respiratory Syncytial Virus Infections/
15 respiratory syncytial virus*.tw.
16 respiratory syncythial virus.tw.
17 exp Parainfluenza Virus 1, Human/
18 exp Parainfluenza Virus 2, Human/
19 exp Parainfluenza Virus 3, Human/
20 exp Parainfluenza Virus 4, Human/
21 (parainfluenza or para-influenza or para influenza).tw.
22 exp Severe Acute Respiratory Syndrome/
23 (severe acute respiratory syndrome or SARS).tw.
24 acute respiratory infection*.tw.
25 acute respiratory tract infection*.tw.
26 or/1-25 (59810)
27 exp Hand Washing/
28 (handwashing or hand washing or hand-washing).tw.
29 hand hygiene.tw.
30 (sanitizer* or sanitiser*).tw.
31 (cleanser* or disinfectant*).tw.
32 exp Gloves, Protective/
33 exp Gloves, Surgical/
34 glov*.tw.
35 exp Masks/
36 mask*1.tw.
37 exp Patient Isolators/
38 exp Patient Isolation/
39 patient isolat*.tw.
40 (barrier* or curtain* or partition*).tw.
41 negative pressure room*.tw.
42 reverse barrier nursing.tw.
43 Cross Infection/pc [Prevention]
44 school closure*.tw.
45 (clos* adj3 school*).tw.
46 mass gathering*.tw.
47 public gathering*.tw.
48 (ban or bans or banned or banning).tw.
49 (outbreak* adj3 control*).tw.
50 distancing.tw.
51 exp Quarantine/
52 quarantine*.tw.
53 or/27-49

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54 26 and 53
55 (animals not (humans and animals)).sh.
56 54 not 55

CENTRAL search strategy

#1 MeSH descriptor Influenza, Human explode all trees
#2 influenza:ti,ab,kw
#3 flu:ti,ab,kw
#4 MeSH descriptor Common Cold explode all trees
#5 "common cold":ti,ab,kw
#6 MeSH descriptor Rhinovirus explode all trees
#7 rhinovirus*:ti,ab,kw
#8 MeSH descriptor Adenoviridae explode all trees
#9 adenovirus*:ti,ab,kw
#10 MeSH descriptor Coronavirus explode all trees
#11 MeSH descriptor Coronavirus Infections explode all trees
#12 coronavirus*:ti,ab,kw
#13 MeSH descriptor Respiratory Syncytial Viruses explode all trees
#14 MeSH descriptor Respiratory Syncytial Virus Infections explode all trees
#15 respiratory syncytial virus*:ti,ab,kw
#16 respiratory syncythial virus*:ti,ab,kw
#17 MeSH descriptor Parainfluenza Virus 1, Human explode all trees
#18 MeSH descriptor Parainfluenza Virus 2, Human explode all trees
#19 MeSH descriptor Parainfluenza Virus 3, Human explode all trees
#20 MeSH descriptor Parainfluenza Virus 4, Human explode all trees
#21 (parainfluenza or para-influenza or para influenza):ti,ab,kw
#22 MeSH descriptor Severe Acute Respiratory Syndrome explode all trees
#23 (severe acute respiratory syndrome or SARS):ti,ab,kw
#24 acute respiratory infection*:ti,ab,kw
#25 acute respiratory tract infection*:ti,ab,kw
#26 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25)
#27 MeSH descriptor Handwashing explode all trees
#28 (handwashing or hand washing or hand-washing):ti,ab,kw
#29 hand hygiene:ti,ab,kw
#30 (sanitizer* or sanitiser*):ti,ab,kw
#31 (cleanser* or disinfectant*):ti,ab,kw
#32 MeSH descriptor Gloves, Protective explode all trees
#33 MeSH descriptor Gloves, Surgical explode all trees
#34 glov*:ti,ab,kw
#35 MeSH descriptor Masks explode all trees
#36 mask*:ti,ab,kw
#37 MeSH descriptor Patient Isolators explode all trees
#38 MeSH descriptor Patient Isolation explode all trees
#39 (barrier* or curtain* or partition*):ti,ab,kw
#40 negative NEXT pressure NEXT room*:ti,ab,kw
#41 "reverse barrier nursing":ti,ab,kw
#42 MeSH descriptor Cross Infection explode all trees with qualifier: PC
#43 school NEXT closure*:ti,ab,kw
#44 (clos* NEAR/3 school*):ti,ab,kw
#45 mass NEXT gathering*:ti,ab,kw
#46 public NEXT gathering*:ti,ab,kw
#47 ("ban" or "bans" or banned or banning):ti,ab,kw
#48 (outbreak* NEAR/3 control*):ti,ab,kw
#49 distancing:ti,ab,kw
#50 MeSH descriptor Quarantine explode all trees
#51 quarantine*:ti,ab,kw
#52 (#27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51)
#53 (#26 AND #52)

Ovid Embase search strategy

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1 exp Influenza/
2 influenza.tw.
3 flu.tw.
4 exp Common Cold/
5 common cold.tw.
6 exp Human Rhinovirus/
7 rhinovirus*.tw.
8 exp Adenovirus/
9 adenovirus*.tw.
10 exp Coronavirus/
11 coronavirus*.tw.
12 exp Respiratory Syncytial Pneumovirus/
13 respiratory syncytial virus*.tw.
14 respiratory syncythial virus.tw.
15 (parainfluenza or para-influenza or para influenza).tw.
16 exp Severe Acute Respiratory Syndrome/
17 (severe acute respiratory syndrome or SARS).tw.
18 acute respiratory infection*.tw.
19 acute respiratory tract infection*.tw.
20 or/1-19
21 exp Hand Washing/
22 (handwashing or hand washing or hand-washing).tw.
23 hand hygiene.tw.
24 (sanitizer$ or sanitiser$).tw.
25 (cleanser$ or disinfectant$).tw.
26 exp Glove/
27 exp Surgical Glove/
28 glov*.tw.
29 exp Mask/
30 mask*1.tw.
31 patient isolat*.tw.
32 (barrier* or curtain* or partition*).tw.
33 negative pressure room*.tw.
34 reverse barrier nursing.tw.
35 Cross Infection/pc [Prevention]
36 school closure*.tw.
37 (clos* adj3 school*).tw.
38 mass gathering*.tw.
39 public gathering*.tw. (5)
40 (ban or bans or banned or banning).tw.
41 (outbreak* adj3 control*).tw.
42 distancing.tw.
43 quarantine*.tw.
44 or/21-43
45 20 and 44

EBSCO CINAHL search strategy

S26 S10 and S24
S25 S10 and S24
S24 S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or 23 or S24
S23 TI outbreak* N3 control* or AB outbreak* N3 control*
S22 TI (school closure* or mass gathering* or public gathering* or ban or bans or banned or banning or distancing or quarantine*) or AB (school closure* or mass gathering* or public gathering* or ban or bans or banned or banning or distancing or quarantine*)
S21 TI (patient isolat* or barrier* or curtain* or partition* or negative pressure room* or reverse barrier nursing) or AB (patient isolat* or barrier* or curtain* or partition* or negative pressure room* or reverse barrier nursing)
S20 TI (glov* or mask*) or AB (glov* or mask*)
S19 TI (handwashing or hand washing or hand-washing or hand hygiene) or AB (handwashing or hand washing or hand-washing or hand hygiene)
S18 (MH "Quarantine")
S17 (MM "Cross Infection")
S16 (MH "Isolation, Reverse")
S15 (MH "Patient Isolation+")

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S14 (MH "Respiratory Protective Devices")
S13 (MH "Masks")
S12 (MH "Gloves")
S11 (MH "Handwashing+")
S10 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9
S9 TI (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory syndrome or SARS or respiratory viral infection* or viral respiratory infection*) or AB (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory syndrome or SARS or respiratory viral infection* or viral respiratory
infection*)TI (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory (syndrome or SARS or respiratory viral infection* or viral respiratory infection*) or AB (influenza or flu or rhinovirus* or adenovirus* or coronavirus* or respiratory syncytial virus* or respiratory syncythial virus* or parainfluenza or para-influenza or para influenza or severe acute respiratory syndrome or SARS or respiratory viral infection* or viral
respiratory infection*)
S8 (MH "SARS Virus")
S7 (MH "Severe Acute Respiratory Syndrome")
S6 (MH "Respiratory Syncytial Virus Infections")
S5 (MH "Respiratory Syncytial Viruses")
S4 (MH "Coronavirus+")
S3 (MH "Coronavirus Infections+")
S2 (MH "Common Cold")
S1 (MH "Influenza+")

WHAT'S NEW

Date	Event	Description
4 April 2023	Amended	John Conly's declaration of interest statement has been clarified in response to a feedback comment.

HISTORY

Protocol first published: Issue 4, 2006
Review first published: Issue 4, 2007

Date	Event	Description
27 January 2023	New citation required but conclusions have not changed	Our conclusions remain unchanged.
27 January 2023	New search has been performed	Searches updated. We included 11 new trials (Abaluck 2022; Alfelali 2020; Almanza-Reyes 2021; Ashraf 2020; Bundgaard 2021; Fretheim 2022a; Gutiérrez-García 2022; Helsingen 2021; Swarthout 2020; Teesing 2021; Young 2021), and excluded 20 new trials (Ahmadian 2022; Chen 2022; Costa 2021; Cyril Vitug 2021; Dalakoti 2022; Egger 2022; Ferrer 2021; Gharebaghi 2020; Giuliano 2021; Karakaya 2021; Kawyannejad 2020; Lim 2022; Malaczek 2022; Meister 2022; Mo 2022; Montero-Vilchez 2022; Munoz-Basagoiti 2022; Sanchez Barrueco 2022; Seneviratne 2021; Sevinc Gul 2022). We identified two new ongoing trials (Brass 2021; NCT04471766), and five trials awaiting classification (Contreras 2022; Croke 2022; Delaguerre 2022; Loeb 2022; Varela 2022).

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Date	Event	Description
1 April 2020	New search has been performed	Searches updated. In this 2020 update we only searched for RCTs and cluster-RCTs. We included 44 new trials (Aelami 2015; Aiello 2012; Alzaher 2018; Arbogast 2016; Azor-Martinez 2016; Azor-Martinez 2018; Ban 2015; Barasheed 2014; Biswas 2019; Canini 2010; Chard 2019; Correa 2012; DiVita 2011; Feldman 2016; Goodall 2014; Hartinger 2016; Hubner 2010; Huda 2012; Ibfelt 2015; Ide 2014; Ide 2016; Little 2015; MacIntyre 2011; MacIntyre 2013; MacIntyre 2015; MacIntyre 2016; McConeghy 2017; Millar 2016; Miyaki 2011; Najnin 2019; Nicholson 2014; Pandejpong 2012; Priest 2014; Radonovich 2019; Ram 2015; Savolainen-Kopra 2012; Simmerman 2011; Stebbins 2011; Suess 2012; Talaat 2011; Temime 2018; Turner 2012; Yeung 2011; Zomer 2015). We excluded 12 new trials (Azor-Martinez 2014; Bowen 2007; Chami 2012; Denbak 2018; Lennell 2008; Nandrup-Bus 2009; Patel 2012; Rosen 2006; Slayton 2016; Stedman-Smith 2015; Uhari 1999; Vessey 2007). We identified 5 new ongoing trials (NCT03454009; NCT04267952; NCT04296643; NCT04337541; Wang 2015) one of which – NCT04337541 - published as this review was going to press. We focused on RCTs and cluster-RCTs only and removed observational studies from this update.
1 April 2020	New citation required and conclusions have changed	There is now sufficient randomised controlled trial (RCT) evidence to show that hand hygiene is likely to provide a modest- benefit. Uncertainty remains for the other interventions. Further RCT evidence is needed.
22 October 2010	New citation required but conclusions have not changed	We updated the review again at the behest of the World Health Organization (WHO). External sources of support amended. External support from the WHO. The WHO interim guidelines document on 'Infection Prevention and Control of Epidemic and Pandemic Prone Acute Respiratory Diseases in Health Care' was published in 2007 to provide infection control guidance to help prevent the transmission of acute respiratory diseases in health care. The update of these guidelines will be evidence-based, and an update of this review was requested to assist in informing the evidence base for the revision of the WHO guidelines. Dr John Conly, Dr Mark Jones, and Sarah Thorning joined the review team.
22 October 2010	New search has been performed	Searches conducted. We included 7 new trials: 4 randomised controlled trials and 3 non-randomised comparative studies. We excluded 36 new trials.
7 May 2009	New search has been performed	For the 2009 update, we included 3 cluster-randomised controlled trials, Cowling 2009; MacIntyre 2009; Sandora 2008, and 1 individual randomised controlled trial (Satomura 2005, with its linked publication Kitamura 2007). We also included 1 retrospective cohort study (Foo 2006), 1 case-control study (Yu 2007), and 2 prospective cohort studies (Wang 2007; Broderick 2008). The content and conclusions of the 2007 review changed little, but the additional 8 studies add more information and certainty. Our meta-analysis remains unchanged as there were no new studies for pooling.

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Date	Event	Description
30 April 2009	New citation required but conclusions have not changed	New author joined the review team.
8 July 2008	Amended	Converted to new review format.
20 August 2007	Amended	Review first published Issue 4, 2007.

CONTRIBUTIONS OF AUTHORS

For this 2022 update:
Co-ordinated the update: LD
Updated Background section: LD, MJ, LA
Updated searches: JC
Excluded irrelevant citations and disputed resolutions for trial registry searches: GB, LA
Screened titles and abstracts: EB, GB, LA, TJ
Selected studies: PG, GB, JMC
Extracted study data: MJ, TH, GB, JMC, EF, TJ
Adjudicated data extraction: PG, JMC
Assessed of risk of bias: MJ, GB, EF
Analysed data: MJ
Contributed to writing the update: PG, MJ, LD, TH, GB, JMC, JC, EF, MVD, LA, TJ
Approved final draft: EB, LD, PG, MJ, TH, GB, JMC, JC, EF, MVD, LA, TJ

DECLARATIONS OF INTEREST

LAA: has declared that they have no conflict of interest.
GAB: reports working at King Saud University, Medical City, Riyadh, Saudi Arabia as clinical faculty in the College of Pharmacy, collaborating with pharmacy services to provide clinical pharmacy services in primary care clinics (non-paid).
EMB: has declared that they have no conflict of interest.
JC: is an Information Specialist at the Cochrane Acute Respiratory Infections Group but was not involved in the editorial process for this review.
JMC: has held or holds peer reviewed grants from the Canadian Institutes for Health Research (CIHR) on acute and primary care preparedness for COVID-19 in Alberta, Canada and has received components of funding from a CIHR funded study via McMaster University for a randomised trial of medical masks versus N95 respirators for preventing COVID-19 amongst healthcare workers. He has also been engaged in WHO funded studies using integrated human factors and ethnography approaches to identify and scale innovative IPC guidance implementation supports in primary care with a focus on low-resource settings and using drone aerial systems to deliver medical supplies and PPE to remote First Nations communities during the COVID-19 pandemic and was the primary local Investigator for a *Staphylococcus aureus* vaccine study funded by Pfizer for which all funding was provided only to the University of Calgary. He has received travel support from the Centers for Disease Control and Prevention (CDC) to attend an Infection Control Think Tank Meeting and from bioMerieux Canada to speak at a symposium on antimicrobial resistance co-hosted by the University of Toronto and bioMerieux Canada. He also reports being a member and Chair of the WHO Infection Prevention and Control Research and Development Expert Group for COVID-19 and reports being a member of the WHO Health Emergencies Programme (WHE) Ad-hoc COVID-19 IPC Guidance Development Group, both of which provide multidisciplinary advice to the WHO, for which no funding is received and from which no funding recommendations are made for any WHO contracts or grants. He reports declaring an opinion on topics in this review in *Clinical Microbiology and Infection* and *Antimicrobial Resistance and Infection Control*; reports being engaged as a co-author on a randomised trial of medical masks versus N95 respirators for preventing COVID-19 amongst healthcare workers published in the *Annals of Internal Medicine* in 2022 and mentioned in this current Cochrane Review, but no extraction or risk of bias assessment or data pooling or other assessment was undertaken by him nor will it be in any future updates. He has also been a member of the W21C since 2004 and served as its Medical Director from 2012-2022. W21C is a not-for-profit healthcare systems research and innovation initiative based in the University of Calgary's O'Brien Institute for Public Health and the Calgary Zone of Alberta Health Services. He reports working as an Infectious Diseases Consultant at Alberta Health Services, Calgary, Canada.
LD: is a Managing Editor at the Cochrane Acute Respiratory Infections Group but was not involved in the editorial process for this review.
EF: has declared that they have no conflict of interest.
PG: reports a grant from the National Health and Medical Research Council, Australia.
TH: is a member of the Cochrane Stroke Group Editorial Board but was not involved in the editorial process for this review.

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TJ: reports declaring an opinion on the topic of the review in articles for popular media. TJ is an Editor at the Cochrane Acute Respiratory Infections Group but was not involved in the editorial process for this review. See full statement here: https://restoringtrials.org/competing-interests-tom-jefferson/
MAJ: reports a grant from the National Institute for Health Research, UK. MAJ is Co-ordinating Editor at the Cochrane Acute Respiratory Infections Group but was not involved in the editorial process for this review.
MLvD: reports being a primary care panel member for the National COVID-19 Clinical Evidence Taskforce, Australia. MLvD is Deputy Co-ordinating Editor at the Cochrane Acute Respiratory Infections Group but was not involved in the editorial process for this review.

SOURCES OF SUPPORT

Internal sources

- No sources of support provided

External sources

- National Institute of Health Research (NIHR), UK

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- National Health and Medical Research Council (NHMRC), Australia

  Competitive grant to Chris Del Mar and Tom Jefferson, 2009
- World Health Organization, Geneva, Switzerland

  Requested and provided support to The Cochrane Collaboration for the 2011 update
- Sabbatical year (2010 to 2011) for John Conly while at the World Health Organization in Geneva, Switzerland was supported by the University of Calgary, Calgary, Canada

  2020/1011941
- National Institute of Health Research (NIHR), UK

  This Cochrane Review update is funded by the NIHR Incentive Scheme Award Reference 130721. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.
- World Health Organization, Geneva, Switzerland

  Provided financial support for the 2020 update of this review. Reference number 2020/1011941
- National Institute of Health Research (NIHR), UK

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed the title of the review in 2010 (see Published notes below).
For the 2020 update, we added one additional outcome: adverse events related to the intervention, and we split the outcomes into primary and secondary outcomes. We also focused only on randomised controlled trials (RCTs) and cluster-RCTs and removed observational studies.

NOTES

In Issue 1, 2010, the title of the review was changed from 'Interventions for the interruption or reduction of the spread of respiratory viruses' to 'Physical interventions to interrupt or reduce the spread of respiratory viruses'.

The original review was subsequently published as Jefferson T, Foxlee R, Del Mar C, Dooley L, Ferroni E, Hewak B, Prabhala A, Nair S, Rivetti A. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ 2008;336:77-80 and Jefferson T, Del Mar C, Dooley L, Ferroni E, Al-Ansary LA, Bawazeer GA, van Driel ML, Foxlee R, Rivetti A. Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ 2009;339:b3675. DOI: 10.1136/bmj.b3675.

INDEX TERMS

Medical Subject Headings (MeSH)

*Communicable Disease Control [methods]; COVID-19 [epidemiology] [prevention & control]; Global Health [statistics & numerical data]; Influenza A Virus, H1N1 Subtype; Influenza, Human [epidemiology] [prevention & control]; Randomized Controlled Trials as Topic; *Respiratory Tract Infections [epidemiology] [prevention & control]; SARS-CoV-2

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MeSH check words

Aged; Child, Preschool; Humans

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Cognitive Research: Principles and Implications

ORIGINAL ARTICLE Open Access

Face masks disrupt holistic processing and face perception in school-age children

Andreja Stajduhar[1], Tzvi Ganel[3], Galia Avidan[2,3], R. Shayna Rosenbaum[1,4] and Erez Freud[1*]

Abstract

Face perception is considered a remarkable visual ability in humans that is subject to a prolonged developmental trajectory. In response to the COVID-19 pandemic, mask-wearing has become mandatory for adults and children alike. Recent research shows that mask-wearing hinders face recognition abilities in adults, but it is unknown if the same holds true in school-age children in whom face perception is not fully developed. Here we tested children ($n = 72$, ages 6–14 years old) on the Cambridge Face Memory Test – Kids (CFMT-K), a validated measure of face perception performance. Faces were presented with or without masks and across two orientations (upright/inverted). The inclusion of face masks led to a profound deficit in face perception abilities. This decrement was more pronounced in children compared to adults, but only when task difficulty was adjusted across the two age groups. Additionally, children exhibited reliable correlations between age and the CFMT-K score for upright faces for both the mask and no-mask conditions. Finally, as previously observed in adults, children also showed qualitative differences in the processing of masked versus non-masked faces. Specifically, holistic processing, a hallmark of face perception, was disrupted for masked faces as suggested by a reduced face-inversion effect. Together, these findings provide evidence for substantial quantitative and qualitative alterations in the processing of masked faces in school-age children.

Keywords: Face perception, Holistic processing, COVID-19, Inversion effect, Masks

Significance statement

Mask-wearing is an effective tool in reducing the novel coronavirus transmission and became prevalent in diverse social contexts including culture events, public transportation, and educational institutions. Previous research showed that masks hinder face perception ability and also change the way faces are processed: relative to unmask faces, the holistic processing of masked faces is severely reduced. Notably, school-age children constantly interact with masked peers and teachers, but it is not clear whether masks hinder their face perception abilities to a similar extent. Here, we address this gap by testing school-age children using the children-adjusted version of a canonical face recognition measure (The Cambridge Face Memory Test-K). We provide empirical evidence that compared with adults, children's face perception is more negatively impacted by the inclusion of masks. We also find evidence for a reduced holistic processing of the masked faces across ages. In conclusion, our study finds qualitative and quantitative changes in the processing of masked faces among school-age children and adults.

Introduction

Faces are among the most significant visual stimuli in human perception. A quick glance at a person's face reveals a plethora of socially relevant information, including their race, age, gender, and emotional state (Tsao & Livingstone, 2008). In response to the COVID-19 pandemic, governments around the world have mandated mask-wearing in public spaces in an effort to curb virus transmission (Canada, 2020). Mask-wearing became mandatory for children and adults

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alike and was presented as a necessary step to enable the safe re-opening of educational institutions. Recent research has demonstrated that masks hinder face processing abilities in adults, including the ability to perceive the identity of faces (Carragher & Hancock, 2020; Freud et al., 2020) their emotional expression (Calbi et al., 2021), and to recognize voices (Mheidly et al., 2020). The occlusion of the lower part of the face is also expected to hinder face processing abilities in children (for example, see Carbon & Serrano, 2021 that recently showed that children are impaired in their ability to recognize emotions from masked faces), however the extent of this impairment is yet to be determined.

Typical human face perception is characterized by a holistic processing, which emphasizes processing the face as an entire unit rather than relying on its specific features (Farah et al., 1998). Previous research has shown a relationship between face perception abilities and the degree of holistic processing in adults. In particular, face recognition accuracy was found to be correlated with different measures of holistic processing of faces (Richler et al., 2011; Wang et al., 2012; but see Konar et al., 2010 for different findings). The importance of holistic processing for face perception is further emphasized by neuropsychological evidence from both acquired and congenital prosopagnosia, where impairments in face perception abilities are accompanied by alterations of holistic processing (Avidan et al., 2011; Ramon et al., 2010; Tanzer et al., 2013). Indeed, even in typical observers, experimental manipulations that disrupt holistic processing, such as face inversion (Face Inversion Effect, FEI; Yin, 1969; but see Richler et al., 2011) and face alignment (Composite Effect; Young et al., 2013), lead to a robust decrement in face perception abilities.

Face masks conceal the lower half of the face (e.g., the mouth and part of the nose area), making it difficult to process the face in a holistic manner. In accordance with the terminology suggested by Maurer et al. (2002), masks can interfere with the detection of first-order relations that define faces (for example, two eyes above a nose and mouth), with the integration of those features into a coherent gestalt and, more importantly, with the processing of the second-order, fine-grained spatial relations between the features. Consistent with this logic, a number of studies showed reduction in face recognition performance due to disruptions in holistic processing with partially occluded faces (Carragher & Hancock, 2020; Kret & De Gelder, 2012; but see Ruba & Pollak, 2020). Recent studies conducted during the COVID-19 pandemic similarly found that face masks interfere with holistic processing and lead to a reduced face inversion effect (Freud et al. 2020, 2021).

Partial occlusion, as occurs with face masks, and even selective blurring of certain facial features have long been shown to disrupt holistic face processing. Studies have shown that judgements of sex and familiarly by adult participants are hindered when facial features like the nose are masked or manipulated (i.e., outstretched), as the obstruction and manipulation of critical facial features hinders encoding of topographical and textural information about the face and featural interrelationships (Bruce et al., 1993; Roberts & Bruce, 1988). The importance of salient internal facial features like the mouth, nose, and particularly the eyes to the configural processing and successful encoding of faces is further supported in studies that have manipulated interocular distance (Leder et al., 2001) and masked these critical regions (Ellis et al., 1979; Goldstein & Mackenberg, 1966; McKelvie, 1976; Young, 1984; Young et al., 1985).

Despite the wealth of research on the correspondence between holistic processing and face perception in adults, the developmental trajectory of this correspondence has not been directly addressed. Previous studies reported that children's face perception abilities generally develop slowly, improving precipitously between the ages of 4–11 (Bruce et al., 2000; Geldart et al., 2002) but only showing adult-like levels in performance in adolescence, after years of experience differentiating faces (Carey et al., 1980; Mondloch et al., 2002). Other studies, however, show evidence of adult-like holistic face processing in children as young as four years of age (Cassia et al., 2009; de Heering et al., 2007; Meinhardt-Injac et al., 2017; Pellicano & Rhodes, 2003). Nevertheless, the emerging view is that face perception mechanisms are already present at birth (at least partially) and mature throughout childhood, along the development of cognitive factors that support face perception, such as memory and attention (McKone et al., 2012; see Weigelt et al., 2014).

Given a gradual refinement in face perception abilities from early childhood to adolescence, we predicted that children will be adversely affected by face masks similar to, or even more than adults. We also predicted that face masks will alter holistic processing in children as was previously observed for adults. To test these predictions, we used the Cambridge Face Memory Test-Kids (CFMT-K; Dalrymple et al., 2012), which is considered a reliable test of face recognition abilities in children. The main advantage of using this test for children is that its difficulty has been adjusted from the adult version of the CFMT test, making it a perfect candidate for comparing the effects of face masks across the two populations. In this test, children are asked to recognize children's faces across increasing levels of difficulty. We generated an adjusted version of the test which included face masks and compared performance in children who completed

the masked version of the test with those who completed the unmasked (standard) version. To examine whether any reduction in face perception is accompanied by a qualitative change in holistic face processing, we constructed upright and inverted versions of the CFMT-K and administered them to both groups of children.

Methods

Participants

Table 1 summarizes the demographic details of the participants across the different conditions. Seventy-two participants (33 females) with a mean age of 10.7 (SD = 2.3, range 6–14) were recruited using snowball sampling during the period of November/December 2020. This age range was chosen as it covers the age range of elementary school children in Canada. Participants were randomly assigned to the mask/no-mask condition and were compensated for their time ($10 CAD Amazon gift card for 15 min). Thirty-seven participants (19 females) with a mean age of 10.6 (SD = 2.5, range 8–10) were randomly assigned to the masked condition and thirty-five participants (14 females) with a mean age of 10.7 (SD = 2.1, range 7–10) were randomly assigned to the non-masked condition. All participants and their parents/legal guardians provided informed consent prior to participating in the experiment.

A group of 495 adult participants with a mean age of 26.3 years (SD = 8.7, range 18–66) was recruited online (https://www.prolific.co/) during the period of January 2021 and completed the standard CFMT (see details below). Participants were randomly assigned to the mask/no-mask condition and were compensated for their time (~ $6 CAD for 25 min).

Finally, an additional group of 72 adults (37 females) with a mean age of 28.5 years (SD = 6.4, range 18–44) was recruited online (https://www.prolific.co/) during the month of April 2021 and completed the CFMT-K. Participation in the experiment was restricted to participants living in Canada and only those who fall between the ages of 18–45. An equal number of participants participated in both the masked and non-masked conditions (masked condition: M_{age} = 28.2, SD = 5.7, range 19–42; non-masked condition: M_{age} = 28.8, SD = 7.0, range 18–44), and none of the participants partaking in this experiment were previously tested in January 2021.

All experiments were performed in accordance with relevant guidelines and regulations according to the protocol approved by the ethics review board. All participants provided informed consent. Data and analysis code are available on the Open-Source Framework (https://osf.io/yj38h/) under CC-By Attribution 4.0 International license.

Materials

The CFMT-K (Dalrymple et al., 2012) was used to assess face perception abilities in the group of children and in one group of adults. The CFMT-K is based on the adult version of the task (Duchaine & Nakayama, 2006). Unlike the adult version, the CFMT-K is shorter and uses children's faces instead of adult faces. The CFMT-K includes three phases (total of 48 trials) with increasing levels of difficulty. Prior to the beginning of the task, participants are presented with a practice trial with one target cartoon face shown from three different viewpoints, followed by a three-alternative forced-choice task (3-AFC). The first phase (easy) involves learning to recognize four unfamiliar male faces from three different viewpoints (right, front, left) and subsequently testing recognition of these faces in a three-AFC. The second phase (medium) involves a refresher of the four targets presented together from one viewpoint (frontal) followed by testing from novel viewpoints and different lighting conditions. The third phase (difficult) is similar to the second phase but includes test images with added visual noise. The adult version of the CFMT is identical in structure to the CFMT-K, except for the use of adult faces instead of children's faces and an additional two targets (total of six target faces; total 72 trials).

Participants were randomly assigned to one of two groups. The first group completed the original CFMT (faces without masks), while the second group completed a modified version of the CFMT in which an identical face mask was added to all faces. To explore holistic processing of faces with and without masks, each participant completed the test twice, once with upright faces and once with inverted faces. Block order (upright/inverted) was counterbalanced between participants.

Table 1 Demographic details of participants for the different experimental conditions

	Children CFMT-K		Adults CFMT		Adult CFMT-K	
	Masked	Non-masked	Masked	Non-masked	Masked	Non-masked
N (female)	37 (19)	35 (14)	248 (128)	247 (124)	36 (19)	36 (18)
Age (SD)	10.7 (2.5)	10.7 (2.1)	25.4 (7.6)	27.1 (9.7)	28.2 (5.7)	28.86 (7.0)

Procedure

The CFMT-K was built using jsPsych, an open-source JavaScript plugin library (de Leeuw, 2015), and was hosted on Pavlovia (https://pavlovia.org/). The parents of the children were contacted first via email to obtain consent for their child's participation. Participants completed the experiment at home and were emailed an experiment link which they could access at any time to complete the experiment. Participants were instructed to complete the experiment independently; for children under the age of 10, parents/legal guardians were encouraged to help their children read the experiment instructions. Participants were randomly assigned to one of two groups. The first group completed the CFMT-K with non-masked faces, while the second group completed a modified version of the CFMT-K in which an identical face mask was added to all faces (Fig. 1). To explore whether holistic processing was employed on faces with and without face masks, each participant completed the task twice, once with upright faces and once with inverted faces. Block order (upright/inverted) was counterbalanced between participants. Accuracy scores (0%–100%) for the upright and inverted faces were computed and served as the dependent variable. Data was processed using Python and statistical analyses were conducted using JASP (*JASP Team*, 2020).

Results

We explored the extent to which face masks impaired face recognition abilities. To this end, participants completed the CFMT-K with upright and inverted faces (within-subject) while the faces were either masked or non-masked (between-subjects). Participant sex/gender also served as a between-subject variable, as previous research has documented an advantage in face recognition abilities in female participants (Herlitz & Lovén, 2013). In the first two sections below, we report the results from the children group. In the third section, we compare the children to two groups of adults to estimate whether the mask effect was modulated in older ages.

Figure 2a shows the group averages across conditions on the CFMT-K. We found a robust alteration in face recognition abilities for masked compared to non-masked faces, such that for upright masked faces there was a decrease of about 20% in the CFMT-K score. Consistent with previous studies, a strong inversion effect was observed for the no-mask condition. This effect was also observed for the masked condition, albeit to a lesser degree.

A repeated measures ANOVA with mask type (mask/no-mask) and orientation (upright/inverted) showed a main effect of mask [$F_{(1,68)} = 14.31$, $p < 0.001$, $\eta_p^2 = 0.17$]. The mask effect was accompanied by a strong inversion effect [$F_{(1,68)} = 55.31$, $p < 0.001$, $\eta_p^2 = 0.44$] reflecting the well-documented advantage for upright faces.

Importantly, these main effects were qualified by a two-way interaction between face orientation and group [$F_{(1,68)} = 5.38$, $p = 0.02$, $\eta_p^2 = 0.07$]. Planned comparison showed that the face inversion effect (FIE) was evident for both non-masked [mean FIE: 23%; $F_{(1,68)} = 31.74$, $p < 0.001$] and masked faces [mean FIE: 15%; $F_{(1,68)} = 23.16$, $p < 0.001$], but it was significantly smaller for the latter, pointing to a qualitative difference in the processing of masked faces. In particular, the size of the inversion effect is suggested to reflect the extent of holistic processing of faces, hence a reduced inversion effect reflects a shift toward a more local/analytical processing (Farah et al., 1995). Importantly, the reduced inversion effect for masked faces could not be attributed to a floor



Fig. 1 Examples of masked and unmasked faces similar to those used in the experiment. Faces were presented in upright and inverted orientations to evaluate differences in holistic processing associated with inversion and mask wearing. The picture was taken and published with permission from the child and their legal guardians

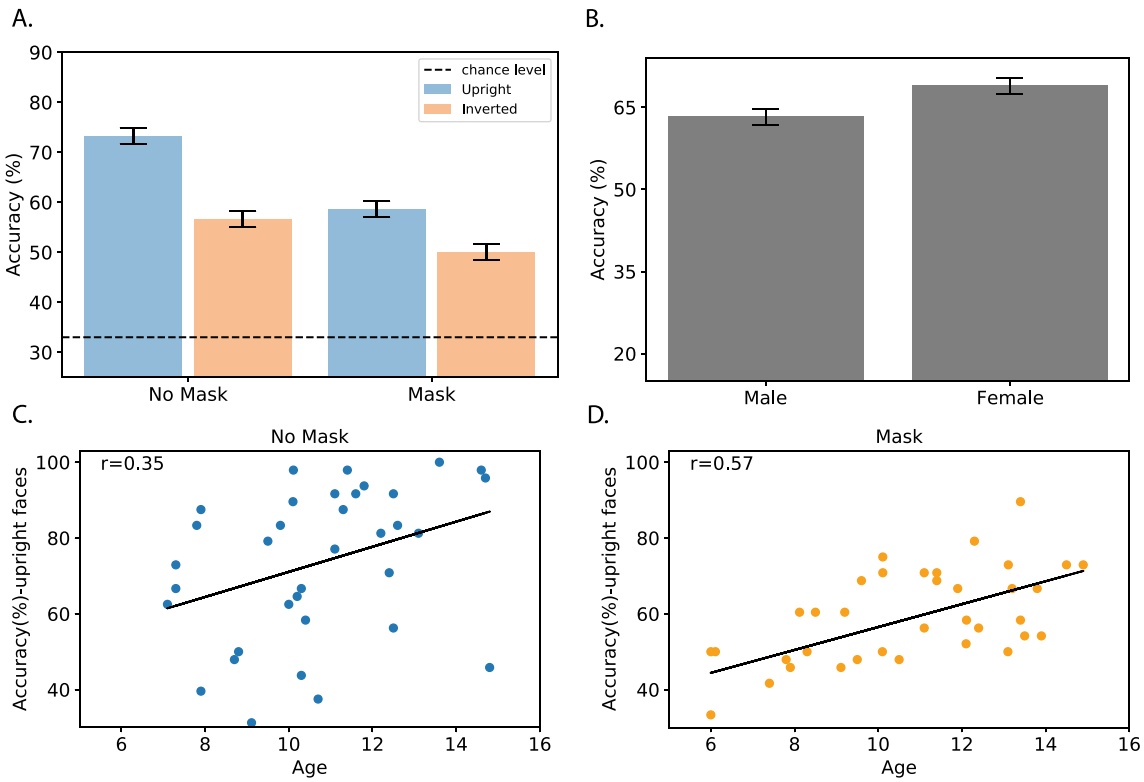


Fig. 2 **a** Results of the CFMT-K experiment for non-masked and masked faces across orientations. The dashed horizontal line represents chance level (33%). Performance was significantly impaired for masked faces. An inversion effect was found for masked and non-masked faces, but it was significantly reduced for masked faces. Error bars represent the 95% confidence interval for the main effect of group (mask/no mask). **b** Average performance of males and females on the CFMT-K. Females showed better face recognition abilities than males. Error bars represent the 95% confidence interval for the main effect of gender. (c) Correlation between age and CFMT-K % accuracy for upright non-masked and (d) masked faces. A positive correlation between age and face recognition abilities was found for both conditions, such that face recognition abilities improve with age

effect, as performance for inverted masked faces was well above chance level (average score for inverted mask faces = 50%, SD = 12; One-sample t-test against chance level (33%)—$t_{(36)} = 4.86$, $p < 0.001$, $\eta_p^2 = 0.79$).

An additional main effect of sex/gender was found, with females outperforming males [$F_{(1,68)} = 7.44$, $p < 0.01$, $\eta_p^2 = 0.09$; Fig. 2b]. This result is consistent with some of the previous literature (e.g., Rehnman & Herlitz, 2006; but see Grüsser et al. (1985) for different results). We further elaborate on this topic in the discussion.

Children's age and face recognition abilities

To explore whether face recognition abilities in children improve with age, a correlation between age and CFMT-K scores for masked and non-masked upright faces was calculated. In line with previous literature, face recognition abilities were positively correlated with age, such that older children performed better on the CFMT-K (masked faces: $r_{(35)} = 0.57$, $p < 0.001$) (Fig. 2c); non-masked faces: $r_{(33)} = 0.35$, $p = 0.03$) (Fig. 2d). Despite the numerical differences, these correlations were not statistically different [$Z = 1.15$, $p > 0.1$].

Notably, as mask type (mask/no mask) was manipulated as a between-subjects variable, we could not directly assess the correlation between age and the mask effect. Thus, we split the children into two age groups (11 years and younger and older than 11) and conducted an ANOVA with age group as an additional between-subjects variable. This analysis revealed a robust main effect of age-group with better performance for older children [$F_{(1,68)} = 21.07$, $p < 0.001$, $\eta_p^2 = 0.23$] and a two-way interaction between age-group and orientation [$F_{(1,68)} = 5.27$, $p = 0.025$, $\eta_p^2 = 0.072$], such that a greater inversion effect was found for older children. This finding might serve as an indication that holistic processing mechanisms are subject to a protracted developmental trajectory.

Importantly, however, we did not find any evidence [$F < 1$] for differences in the effect of mask across the two groups of children [young children—19.7%, older children—22.4% for upright faces]. This result suggests that

while face perception abilities are subject to a prolonged developmental trajectory, the mask effect is relatively stable during childhood.

Children's and adults' face recognition performance

Next, we compared children's face recognition abilities to that of adults. First, we compared children's performance to that of a group of 495 adults who completed the CFMT with adult upright and inverted masked and non-masked faces. Notably, the two tests are adjusted in terms of their difficulty to account for the differences across the age groups. Hence, the comparison between adults and children can uncover potential differences in the mask effect while controlling other variables.

A repeated measures ANOVA with age group (adult/child), mask type (mask/no mask) and orientation (upright/inverted) was conducted. First, we found that the overall accuracy rate was similar across the two age groups [$F_{(1,563)} < 1$], confirming that the difficulty level was adjusted across the two tests (i.e., CFMT/CFMT-K). Importantly, we found a modest two-way interaction between mask type and age group [$F_{(1,563)} = 4.82$, $p = 0.028$, $\eta_p^2 = 0.008$], reflecting a greater mask effect for children (20.1%, upright faces) compared to adults (13.6%, upright faces) (Fig. 3). This finding might suggest that children are more susceptible to the visual alterations embedded in masked faces. Finally, we found an additional two-way interaction between mask type and orientation [$F_{(1,563)} = 36.44$, $p < 0.001$, $\eta_p^2 = 0.06$], mirroring the greater inversion effect for non-masked faces. This effect was similar across the age groups, as the three-way interaction was not significant [$F < 1$], suggesting that in both groups holistic processing was disrupted by face masks to a similar extent (Fig. 3). Notably, these results were fully replicated when we used a bootstrap approach to equate the number of participants across the two groups (see Additional file 1: Fig. S1).

An additional challenge to the interpretation of face perception abilities across the two age groups is posed by the use of different versions of the CFMT task (CFMT-K vs. CFMT). Hence, we also tested a group of 72 adults who completed the CFMT-K, thus equalizing the sample size and ensuring that both children and adults are exposed to the same set of face stimuli.

We used a repeated measures ANOVA with gender, age group and mask type, and orientation as independent variables. As expected, we found main effects of gender [females > males; $F_{(1,136)} = 7.068$, $p < 0.01$, $\eta_p^2 = 0.049$], mask type [$F_{(1,136)} = 19.325$, $p < 0.001$, $\eta_p^2 = 0.124$], and orientation [$F_{(1,136)} = 198.7$, $p < 0.001$, $\eta_p^2 = 0.594$]. Since difficulty was no longer adjusted across age group, we also found a robust main effect of age group [$F_{(1,136)} = 33.98$, $p < 0.001$, $\eta_p^2 = 0.2$], demonstrating a clear advantage in face perception abilities for the adult group (Fig. 3).

In addition to these main effects, we also found a two-way interaction between orientation and mask type (i.e., reduced inversion for the mask condition; [$F_{(1,136)} = 17.99$, $p < 0.001$, $\eta_p^2 = 0.117$]). The masked faces condition elicited a smaller inversion effect in the adult group, but this reduction could not be attributed to a floor effect, as adults performed reasonably well even for masked inverted faces (~ 60%). We also found a two-way interaction between orientation and age group, such that adults exhibited a greater inversion effect [$F_{(1,136)} = 9.066$, $p < 0.01$, $\eta_p^2 = 0.062$] pointing to a greater degree of holistic processing for adults. The three-way interaction

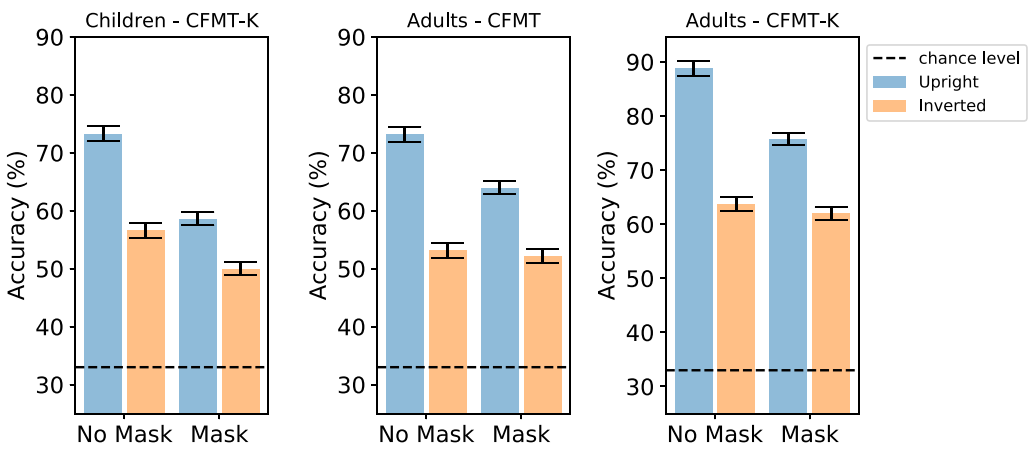


Fig. 3 Results of children's CFMT-K performance, adults' CFMT performance and adults CFMT-K performance for non-masked and masked faces across orientations. The mask effect found in children was larger than the effect documented in adults who completed the CFMT. Across groups, an inversion effect was found for masked and non-masked faces, but it was significantly reduced for masked faces. Error bars represent the 95% confidence interval for the main effect of group (mask/no mask)

between group, orientation, and mask type was not significant [$F_{(1,136)} < 1$], suggesting that the reduced inversion effect for masked faces was similar across age groups.

Finally, we did not find evidence for differences in the size of the mask effect between the two groups [$F_{(1,136)} < 1$]. The absence of this effect might be accounted for by the robust differences in the overall performance levels observed for the two age groups (i.e., adults = 72.5%; children = 59.5%). Another related explanation for the lack of interaction is a celling effect for the upright, non-masked faces for the adult group (accuracy ~ 90%, with 17 out of 36 participants with a performance level greater than 95%), further emphasizing the importance of adjusting performance difficulty between children and adults.

Discussion

Face masks have been accepted as an important tool to minimize the spread of COVID-19 and are thus prevalent in everyday social interactions. In the current study, we evaluated whether school-age children demonstrate a similar impairment in face perception abilities caused by face masks as previously found in adults (Carragher & Hancock, 2020; Freud et al., 2020). We have documented quantitative and qualitative changes in face processing abilities for masked faces in children. In particular, face masks led to a robust decrease in face processing abilities measured by the CFMT-K. This quantitative reduction was accompanied by a reduced inversion effect for masked faces, suggesting a qualitative change in the way masked faces are processed. The reduction of the FIE for masked faces was similar in younger and older children, implying that holistic face processing is similarly disrupted across ages.

The size of the mask effect was compared between children and two separate groups of adults. First, we compared the children to adults who completed the CFMT-K and the CFMT, thus equalizing the overall level of performance across the groups. Under this condition, children showed a greater mask effect (20.1% compared to 13.5% for adults), suggesting greater susceptibility to visual alterations caused by face masks. These findings were maintained when sample size between the adults and children groups was adjusted via a bootstrap analysis. Next, we compared the children to adults who completed the CFMT-K and found a similar mask effect for both groups. Notably, however, the adults outperformed children in their overall performance, and this robust difference (together with a plausible celling effect) might hinder our ability to identify any changes in the size of the mask effect. Taken together, we propose that (a) it is plausible that the effect of masks on face perception abilities might be slightly greater for children and (b) any comparison between perceptual abilities of children and adults needs to take into account the overall level of performance across age groups.

Reduced holistic processing for masked faces

The current experiment also provides evidence for a reduction of the face inversion effect for masked faces in children. Specifically, for non-masked faces we found a decrease of 23% in the CFMT-K score for inverted faces, while a smaller inversion effect of 15% was found for masked faces. Notably, this effect could not be attributed to a floor effect, because children were well above chance level even for the masked, inverted, condition. The inversion of a face makes it difficult to extract configural relationships between face features (Farah et al., 1995; Freire et al., 2000; Yin, 1969); therefore, the twofold smaller inversion effect for masked faces can be taken as evidence that holistic face processing is largely reduced, though not entirely abolished. Thus, the processing of masked faces relies more heavily on the available features rather than on configural or holistic information.

The inversion effect is typically suggested to reflect a reduction in holistic processing and greater reliance on sequential, spatially restricted processing of face features (Rossion, 2009). This view can account for the smaller inversion effect for masked faces. In particular, the upright masked faces are processed in a less holistic manner, resulting in reduced face perception abilities. Then, when the masked faces are inverted, the effect of the mask is less evident due to feature processing being spatially limited, thus leading to a reduced face inversion effect. A similar alteration of face perception and holistic processing has been documented within the context of the "other race effect" (ORE; Kuefner et al., 2010; Mondloch et al., 2007). Reduced face recognition performance in these studies was interpreted as evidence for reduced holistic processing of other-race faces. Together, these findings provide evidence for the co-occurrence of a reduction in face perception abilities and a disruption of holistic face processing.

Interestingly, the face inversion effect increased for older children, presumably reflecting a greater reliance on holistic processing in this group. Along similar lines, a greater inversion effect was found among the adults who completed the CFMT-K. Hence, if the mask effect solely reflects a disruption in holistic processing, a plausible prediction would be that younger children should exhibit a reduced mask effect. However, this was not the case, as the mask effect remained stable across children's ages. This pattern of results suggests that the mask effect is more likely to reflect a reduction in both holistic and featural processing. The relative contribution of each of

those components might change throughout development and requires further research.

Sex/gender differences in face perception abilities

An additional finding of the current study was better face recognition performance for female compared to male children. Superior face perception abilities in females has been extensively documented in adult participants (Bai et al., 2015; Bobak et al., 2016; Freud et al., 2020; McBain et al., 2009); however, findings in the developmental literature are less consistent. One study has reported a strong overall face recognition advantage for female children, with a magnified effect for own-sex faces (Rehnman & Herlitz, 2006); however, others have found only a minimal effect of sex/gender on face perception, with girls performing better on old/new and face inversion tasks (Zhu et al., 2010).

One limitation of the present study is the exclusive use of male faces in the CFMT-K. It is possible that greater sex/gender diversity in the face stimuli set would result in an even greater sex/gender difference between males and females than currently observed, given documented face recognition advantages for own-sex faces (Rehnman & Herlitz, 2006). On a similar note, it worth mentioning that the CFMT / CFMT-k suffers from the lack of ethnic diversity as only Caucasian faces were included. Hence, future studies should use the CFMT-K with a combination of male and female faces and ethnically diverse faces to explore possible sex/gender differences and the ORE in face recognition.

Conclusion

The current study provides evidence for quantitative and qualitative changes in the processing of masked faces in children. Changes in face recognition performance and alteration in the processing of partially occluded faces could have significant effects on children's social interactions with their peers and their ability to form relationships with educators. Previous research in adults has already demonstrated the detrimental effect of reduced face perception abilities on one's level of social confidence and quality of life (Lane et al., 2018). Given the recent increased uptake in mask-wearing due to the COVID-19 pandemic, future research should explore the social and psychological ramifications of wearing masks on children's performance.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41235-022-00360-2.

Additional file 1. Bootstrap analysis demonstrated that children show a larger mask effect even when sample size is taken into consideration.

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N/A.

Authors' contributions
All authors developed the study concept and contributed to study design. AS collected the data. AS and EF analyzed the data. AS drafted the first version of the manuscript. TG, RSR, GA and EF edited the manuscript. All authors read and approved the final manuscript

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Availability of data and materials
Data and analysis code are available on the Open-Source Framework (https://osf.io/yj38h/) under CC-By Attribution 4.0 International license.

Declarations

Ethics approval and consent to participate
All experiments were performed in accordance with relevant guidelines and regulations according to the protocol approved by the ethics review board. All participants provided informed consent.

Consent for publication
Child's picture was taken and published with permission from the child and their legal guardians.

Competing interests
The authors do not have any known conflicts of interest to disclose.

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A randomised clinical trial to evaluate the safety, fit, comfort of a novel N95 mask in children

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Children are more vulnerable to the risks of air pollution, including susceptibility to acquiring chronic diseases in their developing lungs. Despite these, there are no specific masks designed for and tested in children that are available to protect our young from the common particulate air pollutants today. We evaluated safety, fit and comfort of a specially designed paediatric N95 mask with an optional micro ventilator (micro fan, MF) in healthy children aged 7–14 years, in a randomized, two-period crossover design. The subjects' cardiorespiratory physiological measurements were assessed in different states of physical activity under different interventions (mask without and with MF). A total of 106 subjects were recruited between July-August 2016. The use of the mask without MF increased the End-Tidal CO_2 ($ETCO_2$) and Fractional concentration of Inspired CO_2 ($FICO_2$) at rest and on mild exertion, as expected. The use of the mask with MF brought $FICO_2$ levels comparably closer to baseline levels without the mask for both activities. The mask, with or without the MF, was found to be well fitting, comfortable and safe for use in children at rest and on mild exertion. The N95 mask tested offers a promising start for more studies in the paediatric population.

Air pollution, such as haze or smog, is an evolving and increasingly significant problem around the world. A wide range of hazards of chronic air pollution in children include nocturnal cough, asthma, poor performance in neurobehavioral function, negative impact in cognitive development and harmful effects on brain development[1–5]. In particular, children represent a vulnerable segment of any population. They carry more risks of long term exposure to pollution over the course of their lives and are susceptible to acquiring chronic diseases in their developing lungs[6–11]. Use of masks and respirators can offer protection against air pollutants. However, the commercially available disposable particulate respirators, typically certified for surgical (which may only offer some barrier against larger particles) and occupational use, are mainly designed for and studied in adults. The test standards are specified according to adult breathing conditions and fit. There are to date, no masks designed for and evaluated in children.

Several studies have investigated the effectiveness, safety, fit and comfort of different types of masks[12–15]. However these studies were done only in adult populations. Even alternatives such as cloth masks have been tested only in adult populations[16]. In another study, the facemasks for paediatric use (FPU, the masks that are not specifically designed for paediatric use but are the existing mask that may be used for children during emergency situation like that of airborne disease outbreaks) were tested mainly to evaluate the leakage associated with donning the FPU[17]. This study did show superiority of FPU in comparison to surgical masks in certain aspects, however, the study was not performed in children. One study was performed in children to evaluate the redesigned open system face mask. However, the objective of this study was to evaluate the mask for monitoring P_{ETCO2} during sedation in clinical practice and the children in this study donned the mask only for 30 sec.[18]. These and other similar studies merely point to the fact that there are no masks that are specifically designed and tested in children such that they can be prescribed for paediatric use in the setting of daily routine activities.

In our study, the N95 masks were specifically designed for use in children and they were evaluated in children under conditions of routine daily activities. They are the first to be paired with a micro ventilator (micro fan, MF), designed to reduce the accumulation of exhaled carbon dioxide (CO_2), heat and humidity in the dead space of

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the respirator by venting out the expired air. This is to enhance the comfort and experience in wearing the mask. This novel mask comprises a valved, disposable respirator which has the option of being paired with a reusable lithium battery powered MF.

This study was designed to evaluate the safety, fit and comfort of the novel disposable N95-class particulate respirator with and without MF, in healthy children aged 7 to 14 years without any underlying medical condition. The masks were specifically developed for the school going children aged 7 to 14 years since the children in this age group are largely school-going and would be involved in routine activities which would expose them to outdoor environment pollutants especially during seasonal or periodic haze. Children below 7 years of age are more likely to be confined to indoor environments while children above 14 years can use the masks certified for adult use.

Methods

Trial design. This was a randomised, two-period crossover study in which the subjects were randomly assigned to one of the two sequences of the interventions (Trial Registration: ClinicalTrials.gov, NCT03252574, August 17, 2017). The study was approved by the National Healthcare Group Domain Specific Review Board (NHG DSRB Reference: 2015/01059) and the informed consent was obtained from the parent or legal guardian as well as consent/assent as appropriate from children, prior to enrolment in the study for their study participation. All methods were performed in accordance with the relevant guidelines and regulations.

Randomization and blinding. Being a cross over study, each study subject served as their own control for comparison and received all interventions, eliminating the influence of selection bias. To avoid influence of the sequence in which the interventions were given, the study subjects were manually randomized to one of the two sequences of interventions and then crossed over. For example, the first eligible participant was asked to go to station A-B, the second B-A, the third A-B, the fourth B-A and so on.

Given the nature of the interventions used; without mask, with mask and, with mask and MF, it was not possible to blind the investigators. However, all the assessments were objectively measured by the sensors built in the device itself, thus avoiding the assessment bias associated with un-blinded investigators.

Participants. Children aged 7 to 14 years old, from two schools in Singapore, were invited to participate in the study by sending an invitation letter to the parents. The selection of the two schools was based on the availability of the participants within the desired age range (7 to 14 years) and the schools agreeing to participate in the study. These were regular schools in the community and would be fairly representative of the regular school-going child in Singapore. The subjects were randomly selected from the pool of eligible children meeting the inclusion-exclusion criteria listed below.

Inclusion criteria. The subjects meeting both inclusion criteria listed below were eligible to enrol in the study.

1. Aged between 7 and 14 years of age (inclusive).
2. The parents or legal guardians of the subjects must provide their consent to take part in the study.

Exclusion criteria. The subjects fulfilling any of the exclusion criteria listed below were excluded.

1. any known cardiorespiratory conditions (including but not limited to the following: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema)
2. any known medical conditions that may be exacerbated by strenuous physical activity, including but not limited to the following: exercise-induced asthma, lower respiratory infections (including pneumonia, bronchitis) in the past 2 weeks, anxiety disorders, diabetes, hypertension, or epilepsy/seizure disorders
3. any physical disability from medical, orthopaedic or neuromuscular disorders
4. have an acute upper respiratory tract infection or symptomatic rhinitis (i.e. blocked nasal passages, runny nose or significant sneezing) on the day of the study
5. may have conditions or abnormalities that may compromise the integrity of the mask fit (e.g. those with excessive facial hair or craniofacial abnormalities)

An on-site doctor and a nurse administered the screening questionnaire to assess the subjects' pre-investigation condition. Each participant underwent a mask fit test to determine the right mask size for the face, including testing for leakage. Participants were excluded if he/she was unable to be fitted with any of the mask sizes as determined by the mask fit and leak tests.

Mask fit test. The test involved performing the following exercises in sequence: normal breathing, deep breathing, turning head from side to side, up and down, speaking and bending exercise. The equipment used was the TSI Portacount 8038 respirator fit tester. A good or 'pass' fit was based on the fit factor as per the respirator certification EN 149:2001 + A1:2009 FFP2 standards.

Interventions. The mask and MF used in the study, as well as the experimental set up are depicted in Fig. 1. The subjects were randomly assigned by sequential allocation into one of two sequences, Sequence AB (No mask [Control], followed by AIR$^+$ Smart Mask only [A], then AIR$^+$ Smart Mask with MF [B]) or Sequence BA (No mask [Control], followed by AIR$^+$ Smart Mask with MF [B], then AIR$^+$ Smart Mask only [A]) (Fig. 2).

The impact on subjects' physiological measurements following different interventions (A and B) was assessed in different states of common physical activities such as at rest (reading) and on mild exertion (brisk-walking on the treadmill) to represent the daily routine activities for children such as reading in school or walking a short distance.

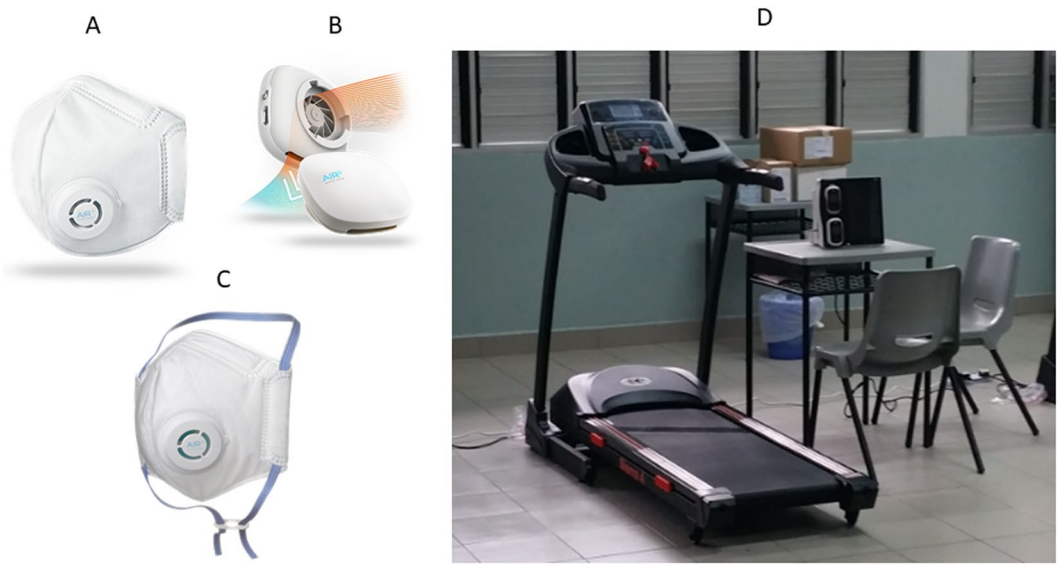


Figure 1. Illustration of the (**A**) disposable N95-class particulate respirator that is able to be paired with the (**B**) novel, reusable micro fan (**C**) AIR^{+} Smart Mask (**D**) Experimental set up.

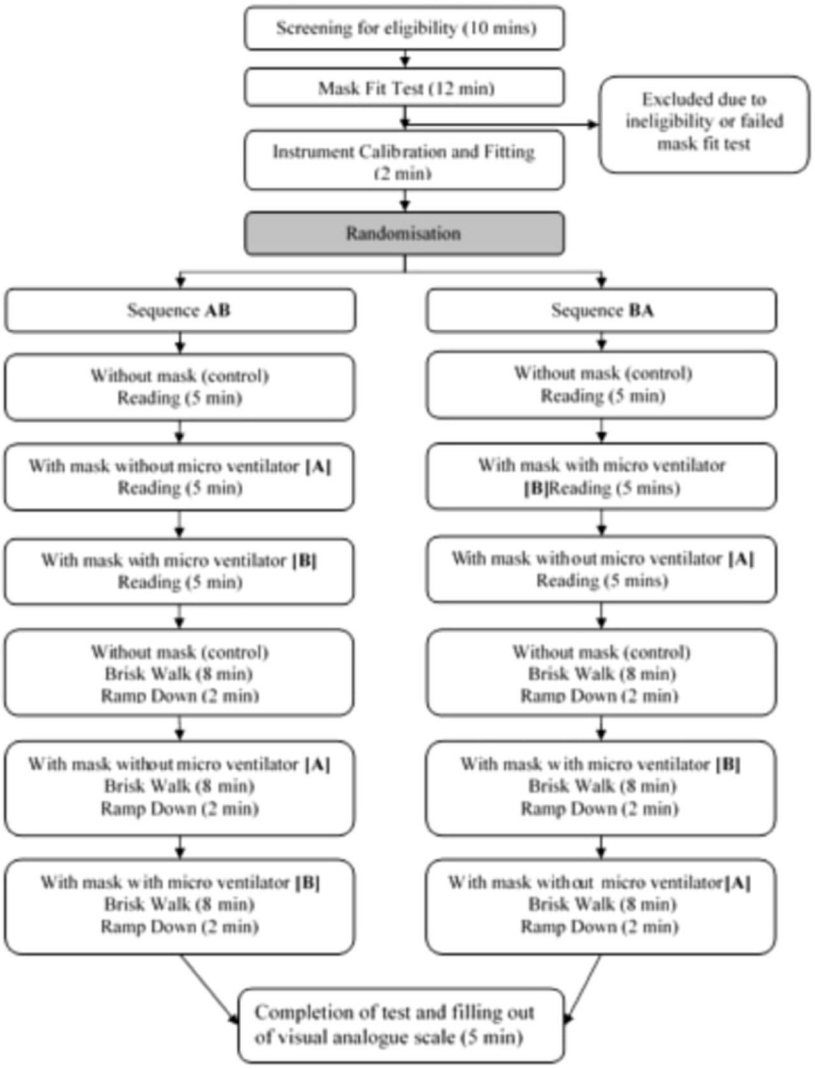


Figure 2. Process flow of the study design.

Briefly, each participant randomized to Sequence AB, was asked first to read, seated for 5 minutes during which baseline readings for all parameters were measured (Control). The participant then donned the mask without the MF for another 5 minutes. Finally, the MF was attached to the valve of the mask and the participant read for a final 5 minutes to complete the rest phase of the study.

The above procedure was repeated for the physical activity of mild exertion when the subjects performed brisk walking on the treadmill instead of reading. The brisk walk was targeted at reaching their target heart rate (HR) at mild exertion.

Mild exertion was achieved through the use of the treadmill at speeds that represent realistic activity levels during play. As the subjects were of varying ages and heights, with correspondingly different levels of physiological reserves, it may not be feasible to assign a specific treadmill speed that would indicate a uniform level of mild exertion. Based on the known normal resting HR of healthy children ages 7–14 years (70 to 100 beats per minute), this study aimed to keep the actual speed of the treadmill flexible and primarily target a heart rate zone of 50–60% of the subjects calculated maximum HR. The rationale for choosing this target is based on studies in adults where achieving a target HR zone of 50–60% of maximum HR would yield an exercise intensity of about 40% of maximal oxygen consumption (VO2max), which is a good indicator of aerobic endurance. For adults, the anaerobic threshold is about 50–60% of VO2max. There is no literature on VO2max for children, hence, to be conservative, we have referenced adult threshold and taken 40% of VO2max as children's normal anaerobic threshold. As such, to attain a stable ETCO2 during aerobic exercise and before the subject crosses the anaerobic threshold, we aim to keep to 50–60% of predicted maximal HR.

The most common method to estimate maximum HR within the exercise community is to use the 220 – age formula[19,20]. This study proposed a more conservative assumption of a maximum HR of 194 bpm, and a target HR zone to be achieved on the treadmill of between 100–120 bpm. As an additional safety measure, subjects were encouraged to talk comfortably while on the treadmill. This would indicate that the activity level is appropriate. The child was led to a target HR before 3 minutes of steady state data was taken. Given the physiological differences between different children, as well as their varying levels of fitness, different times were required to attain the requisite HR for the test.

Hence, in summary, we aimed at achieving mild physical activity comparable to a brisk walk and chose a target HR of approximately 50 to 60% of the calculated max HR as standardization of the level of physical activity.

At the end, the participants were asked to slow their walk to a leisurely pace on the treadmill for 2 minutes before the treadmill was stopped and their heart rates returned to the resting level. Two standard treadmills were used to achieve the target heart rates of between 100 to 120 bpm to simulate mild exertion[21]. The test was carried out in an open, naturally ventilated classroom in each of the two schools. The approximate ambient conditions in the classrooms were as follows: temperature range of 26 to 32 °C, relative humidity between 50–80%, and wind speed of <1.5 m/s (with a ceiling fan at medium speed).

For subjects randomized to Sequence BA, all of the above activities were repeated by reversing the sequence of MF use, B followed by A (Fig. 2).

Given the variability of physiological measurements between children, a randomised crossover design allowed for a more precise comparison of different interventions, and required a smaller number of subjects than a between-subjects study.

Outcomes and assessments. The primary outcome of the study was the end-tidal carbon dioxide ($ETCO_2$) levels to assess the safety of the mask in terms of potential carbon dioxide retention. The mask fit was assessed using the mask fit test. The comfort level of the masks worn was assessed on a visual analogue scale (VAS). Despite being a subjective assessment tool, it has the advantage of ease of rating specifically when used by children. In addition, the VAS has been shown to be a valid tool corroborating well with detailed questionnaires when used as a single question rating[22].

Single-use nasal cannulas were used in conjunction with Nomoline™ Adapters connected to a Masimo Root® Patient Monitoring System with an ISA™ CO_2 module to log the $ETCO_2$, fractional inspired carbon dioxide ($FICO_2$) and respiratory rate (RR) information.

M-LNC Pediatric adhesive sensors were worn by the subjects and the Masimo Radius-7™ was used to log oxygen saturation (SpO_2) and pulse rate (PR).

Sample size. It was anticipated that a child at rest will have a mean $ETCO_2$ of 40 mmHg with a standard deviation of approximately 8mmHg[23]. Based on the proposed safety threshold $ETCO_2$ level of below 50 mmHg[24,25], an increase of $\leq$10 mmHg after the subject wears the mask with or without the MF would indicate non-inferiority. We elected to adopt a more stringent tolerance level of less than 5 mmHg increase in $ETCO_2$ in this study.

Assuming a one-sided test size of 5% and one-sided power of 80%, at least 80 subjects were required. To account for the children who may withdraw during the study, a total of 100 children were proposed to be recruited, distributed across the age groups.

Statistical analysis. The 95% upper confidence limit of the increase in $ETCO_2$, the primary outcome of the study, after wearing a mask without or with MF was computed. The mean (SD) values of the primary outcome and other physiological parameters (RR, HR, SpO_2, $FICO_2$) obtained at rest and at mild exertion were presented descriptively. The % increase or decrease in the outcome variables over the control group values was computed to understand the physiological effect of wearing the mask with and without MF. The comfort of the mask from the VAS data was presented descriptively.

Physiological parameters (N = 106)	Without mask (Control)	With mask only (A)	With mask and with micro fan (B)
Mean (SD) $ETCO_2$, mmHg			
At rest (Reading)	30.9(3.37)	34.3(3.32)	32.2(3.27)
On mild exertion (Brisk walking)	28.2(2.8)	32.0(2.8)	30.6 (3.1)
Mean (SD) $FICO_2$, mmHg			
At rest (Reading)	8.2 (1.94)	10.7 (2.61)	7.8 (2.15)
On mild exertion (Brisk walking)	9.9 (1.69)	12.1 (2.47)	10.8 (2.33)
Mean (SD) RR, bpm			
At rest (Reading)	18.0 (3.21)	17.4 (3.57)	16.8 (3.33)
On mild exertion (Brisk walking)	23.5 (3.53)	23.2 (3.73)	23.2 (3.88)
Mean (SD) HR/bpm			
At rest (Reading)	89.6 (11.31)	90.7(11.37)	89.2 (11.27)
On mild exertion (Brisk walking)	108.4 (9.84)	110.2(7.73)	109.5 (7.78)
Mean (SD) SpO_2/%			
At rest (Reading)	99.6 (0.52)	99.5 (0.51)	99.6 (0.54)
On mild exertion (Brisk walking)	99.2 (0.81)	99.2 (0.65)	99.2 (0.78)

Table 1. Physiological parameters of the study subjects. $ETCO_2$ = end-tidal carbon dioxide, $FICO_2$ = fractional inspired carbon dioxide, RR = respiratory rate, SpO_2 = oxygen saturation, HR = Heart rate.

Ethics approval and consent to participate. The study was approved by the National Healthcare Group Domain Specific Review Board (NHG DSRB Reference: 2015/01059) and the consent was obtained from the parent or legal guardian prior to enrolment in the study.

Results

Participant demographics. A total of 106 subjects were recruited in the study between July and August 2016. There were 59 (55.6%) boys indicating equal distribution of the gender in the study population. The mean (SD) weight, height and BMI of the participants were, 41.4 (15.3) kg, 144.6 (17.4) cm and 19.1 (5.4) kg/m^2 respectively. The physiological parameters are summarized in Table 1. All subjects recruited were successfully fitted with the mask and all passed the mask fit test. No participants had to be rejected because of inability to fit a mask.

Outcomes and assessments. *Safety of the mask.* $ETCO_2$. All the children wearing the mask alone had $ETCO_2$ values below 50 mmHg. The highest $ETCO_2$ value recorded was 42 mmHg.

The mean $ETCO_2$ values at rest were 30.9 mmHg, 34.3 mmHg and 32.2 mmHg for the subjects without mask, with mask, and with mask and MF respectively. The corresponding mean values at mild exertion were 28.2 mmHg, 32.9 mmHg and 30.6 mmHg for the subjects without mask, with mask, and with mask and MF respectively. Whether at rest or on mild exertion, the $ETCO_2$ values were higher when the mask was worn but the values decreased, approaching the control values when the mask was worn with the MF.

The mean $ETCO_2$ values on mild exertion were observed to be consistently about 2 mmHg lower in comparison to when at rest. This is attributed to CO_2 levels being lower from increased minute ventilation as a result of exercise; as respiratory rate and tidal volume increased, resulting in the decrease in CO_2 levels (Fig. 3).

$FICO_2$. The mean $FICO_2$ values at rest were 8.2 mmHg, 10.7 mmHg and 7.8 mmHg for the participants without mask, with mask, and with mask and MF respectively. The corresponding mean values at mild exertion were 9.9 mmHg, 12.1 mmHg and 10.8 mmHg for the subjects without mask, with mask, and with mask and MF respectively.

Similar to $ETCO_2$, the $FICO_2$ values also appeared to increase when the mask was worn. However, when the MF was used, it decreased $FICO_2$ levels towards the control level, approximating to the baseline levels seen when not wearing a mask (Fig. 4).

Change in $ETCO_2$ and $FICO_2$ values. At rest, the % increase over control for $ETCO_2$ and $FICO_2$ when mask was worn was 13.9% and 23.9% respectively. However, this increase was minimal when the mask was worn with the MF, 8.8% and 9.5% for $ETCO_2$ and $FICO_2$ respectively (Fig. 5).

Similarly, at mild exertion, the % increase over control for $ETCO_2$ and $FICO_2$ when the mask was worn was 11.3% and 34.4% respectively. However, this increase was minimal or even better than control (i.e. not wearing a mask) when the mask was worn with the MF, 4.7% and −3.3% for $ETCO_2$ and $FICO_2$ respectively (Fig. 5).

The values of other physiological parameters (RR, HR, SpO_2) obtained in the study are presented in the Tables 1 and 2.

Mask fit. The masks used were found to fit all the children tested in the study.

Comfort of mask worn and physiological parameters for children rating mild breathing difficulty. The VAS showed that 93% of the children experienced no breathing difficulty when using the mask while 7% (4 males and 3 female subjects) indicated that they experienced mild breathing difficulty. The mean values of $ETCO_2$, $FICO_2$ and other physiological parameters for these 7% subjects were comparable to the rest of the study population and were well within acceptable ranges (Table 2) indicating that none of these subjects had any clinically significant respiratory compromise despite their reported subjective discomfort.

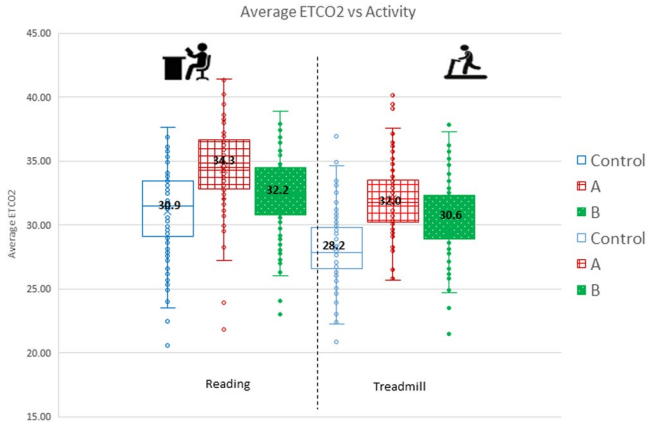


Figure 3. Mean $ETCO_2$ values at rest and on mild exertion for Control, Intervention (**A**) and Intervention (**B**).

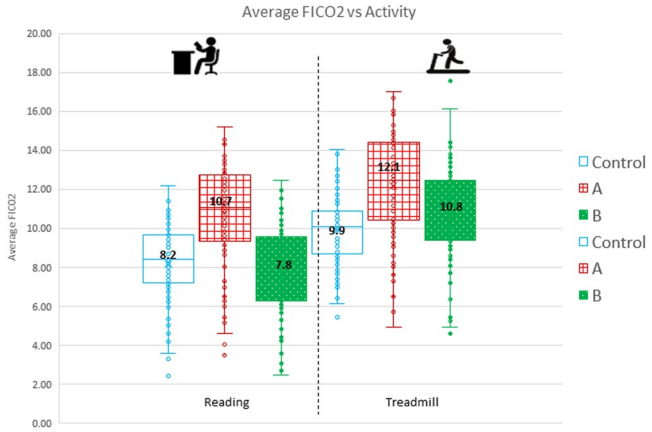


Figure 4. Mean $FICO_2$ values at rest and on mild exertion for Control, Intervention (**A**) and Intervention (**B**).

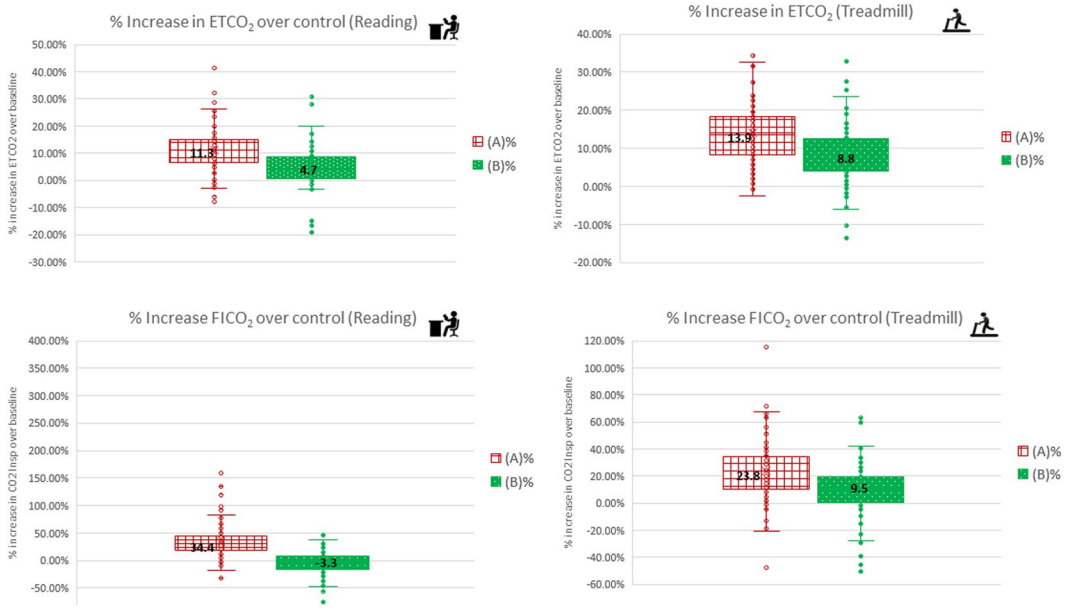


Figure 5. Percentage change in $ETCO_2$ and $FICO_2$ for Intervention (**A**) and Intervention (**B**).

Physiological parameters	Without mask (Control)		With mask only (A)		With mask and with micro fan (B)	
	7 subjects	99 subjects	7 subjects	99 subjects	7 subjects	99 subjects
Mean (SD) $ETCO_2$, mmHg						
At rest (Reading)	29.1 (2.89)	30.9(3.4)	32.9 (3.18)	34.3 (3.3)	30.1 (4.16)	32.2 (3.3)
On mild exertion (Brisk walking on treadmill)	27.1 (2.02)	28.2 (2.8)	31.2 (1.61)	32.0(2.8)	29.8 (1.27)	30.6 (3.1)
Mean (SD) $FICO_2$, mmHg						
At rest (Reading)	7.9 (2.11)	8.2 (1.9)	9.8 (2.58)	10.7 (2.6)	7.7 (1.52)	7.8 (2.1)
On mild exertion (Brisk walking on treadmill)	9.4 (1.46)	9.9 (1.7)	11.7 (2.05)	12.1 (2.5)	10.6 (2.41)	10.8 (2.3)
Mean (SD) RR, bpm						
At rest (Reading)	17.6 (3.15)	18.0 (3.2)	16.7 (3.67)	17.4 (3.6)	16.2 (3.47)	16.8 (3.3)
On mild exertion (Brisk walking on treadmill)	23.4(2.79)	23.5 (3.5)	23.5 (4.28)	23.2 (3.7)	23.4 (4.04)	23.2 (3.9)
Mean (SD) HR /bpm						
At rest (Reading)	91.8 (10.67)	89.6 (11.3)	92.3(11.91)	90.7 (11.4)	91.1(12.77)	89.2 (11.3)
On mild exertion (Brisk walking on treadmill)	108.7(11.66)	108.4 (9.8)	109.4(9.82)	110.2 (7.7)	110.5(7.63)	109.5 (7.8)
Mean (SD) SpO_2/%						
At rest (Reading)	99.1 (0.75)	99.6 (0.5)	99.0 (0.77)	99.5 (0.5)	99.1 (0.77)	99.6 (0.5)
On mild exertion (Brisk walking on treadmill)	99.0 (0.61)	99.2 (0.8)	99.1 (0.45)	99.2 (0.6)	99.1 (0.49)	99.2 (0.8)

Table 2. Comparison of the mean $ETCO_2$, $FICO_2$ and other physiological parameters for subjects indicating experiencing mild breathing difficulty on VAS (7) vs the rest of the participants (99). $ETCO_2$ = end-tidal carbon dioxide, $FICO_2$ = fractional inspired carbon dioxide, RR = respiratory rate, SpO_2 = oxygen saturation, HR = Heart rate.

Impact of the randomisation sequence: The readings were independent of the sequence of the intervention (Fig. 6).

Discussion

In our study, the physiological parameters; $ETCO_2$, $FICO_2$, RR, HR, SpO_2, were well within the acceptable range, the masks used were found to fit all the children tested in the study and majority of the children did not experience any difficulty in breathing while wearing the masks indicating good comfort. The two physical activities included in the study, reading and brisk walking on treadmill, represent the daily routine activities for children such as reading in school or walking a short distance (for example, walking to a bus stop to catch bus) indicating that the masks can be safely and effectively used during such routine activities without any respiratory compromise.

This is the first study done to assess the specially designed N95 mask for paediatric participants hence there is no comparable data to reference. Comparisons with studies in adult subjects would not be relevant in view of the different physiological setting and the aims of the studies would be different. Nevertheless, with the use of data from the control group included in the current study, the results are self-explanatory and provide evidence of the safety, fit and comfort of the mask designed for and applied in paediatric subjects.

Although safety and efficacy are clinically important, the fit and comfort determine the compliance to and efficacy of the mask. Masks with inadequate fit would not offer optimal protection in children against hazardous particulate matter (PM) including PM 2.5, the main air pollutant found in transboundary smoke and haze. Poor comfort is repeatedly brought up as the main hindrance for compliance in studies done in adult populations[26–29]. In adults, despite poor fit and comfort, compliance can still be achieved through the understanding of the benefits and need, but this may not be the case in children. Hence, the fit and comfort are essential determinants for the acceptance of the mask from the wearer's perspective and since they also contribute to its effectiveness, they are especially critical in children.

Although more comfortable, surgical masks (SM) and also medical masks (MM), tested in various studies have been shown to perform poorly as protection against airborne and particulate infection compared to N95 masks[30–34]. Hence the masks under evaluation in this study are N95 masks that are specifically designed for children.

Generally, when masks are worn, they increase the resistance of breathing resulting in increase in CO_2 in the dead space of the mask. As a result, the wearer encounters increased work of breathing needing more effort, causing discomfort and fatigue. The MF used in the study was found to effectively decrease $FICO_2$ levels, bring them closer to the control level, approximating to not wearing a mask consistent with the results in computational experiments[35].

The provision of the MF as an optional device for better air exchange and reducing heat and moisture build up, when needed, is also one of the recommendations of the Project BREATHE[28]. Earlier simulation experiments done in adult subjects have demonstrated that the introduction of the fan to the N95 mask is a feasible option to reduce the CO_2 accumulation in the dead space and also to control the temperature[36].

Vaccination and antiviral agents as preventive and therapeutic measures are important in disease control, however the prevention of disease transmission plays a vital part in preventive medicine and infectious disease control[37]. Studies have established the benefits of masks as a non-pharmaceutical modality that serves as a barrier between the virus and the subjects thus breaking the transmission of virus into human host[38,39]. In fact, during

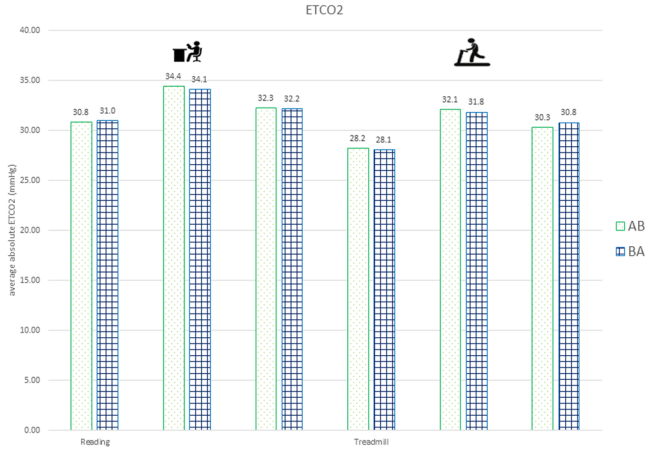


Figure 6. Sequence AB and BA did not have noticeable impact on $ETCO_2$ results.

pandemics or disease outbreaks, vaccines may not be available or able to effect its benefits immediately. In such situations, the use of effective masks to prevent the spread of pathogens remains the one and only useful intervention. Children are often a more vulnerable group to infectious disease complications. At the same time they may be more capable of spreading disease as they may shed viruses for longer periods of time compared to adults[40,41]. The use of effective masks can therefore be even more impactful in children and its effectiveness (including comfort and fit) are especially pertinent in children. Be it in disease outbreaks or environmental disasters, protecting self or protecting others from self, masks remain the mainstay of respiratory disease protection.

The study has a few limitations. In our study, the children wore the mask for short durations of time, just about 5 minutes. Since this was the first study done in children to evaluate the safety and efficacy of novel N95 masks, we kept it very simple with minimum evaluations and shorter exposure time to ascertain the compliance. We believe, the study still provides the basis for future studies that can be designed to evaluate the impact of wearing the mask or mask with MF, for longer durations. Although, assessing the mask fit in children from other geographic regions due to variability prevailing in the anthropometric characteristics may be suggested, given the ethnic mix of population residing in Singapore, as well the preliminary data available for the Sellion to Menton Measurements, we believe, the mask will reasonably fit children from other parts of the world too. The preliminary data on the facial screening and measurement for the Sellion to Menton Measurements of Singapore children aged 7 to 14 years (Mean [range] of 9.63 [7.43–15.96] cm) suggests that the measurements compared well with the data of children of similar age from US (Mean [range] 10.16 [7.59–12.29] cm)[42].

Multiple *in-vitro* and animal studies have already been undertaken to evaluate the biocompatibility of the mask used in the study. The results of these studies have shown no delayed hypersensitivity on the skin of the tested Guinea pigs, causing no intracutaneous irritation in New Zealand White Rabbit, showing no cytotoxic effect in terms of cell lysis or reduction of cell growth. The masks have shown the bacterial and viral filtration efficiency of >99% and synthetic blood penetration resistance test passing quality standards of Per ASTM F1862 and ISO 22609.

With the above data, the findings of this preliminary study done in healthy children opens up avenues for future research using the mask tested in this study. Use of these masks in children with cardiopulmonary disease including asthma, respiratory diseases, as well as testing and evaluating the masks in vulnerable children for quantitative risk assessment will have to be undertaken to understand and expand the potential use of the mask. Also, studies on extended mask use, as well as qualitative studies assessing the impact of mask use in children in different settings and activities will have to be undertaken.

In conclusion, the mask evaluated in this study (with or without MF) is safe for use in children 7 to 14 years old with no underlying medical conditions and in the setting of routine daily activities including brisk walking. The endpoint measure of $ETCO_2$ documented no significant rise and the highest $ETCO_2$ reading recorded for all subjects was 42 mmHg. It was observed that wearing a mask only marginally increased the $ETCO_2$ and $FICO_2$ when at rest and with brisk walking. The MF was observed to effectively bring the $FICO_2$ levels to a level comparable to that of not wearing a mask.

The current study demonstrates that the mask under study is suitably fit for use in children and the reported comfort level is likely reflective of a good acceptance of its use in the study population.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due to confidentiality reasons but are available from the corresponding author on reasonable request.

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Author contributions
D.Y.T. Goh conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. M.W.M. and W.L.J. Lee designed the data collection instruments, and coordinated and supervised data collection, carried out the initial analyses, and reviewed and revised the manuscript. O.H.T. designed the study, collected and interpreted the data, and reviewed and revised the manuscript. D.D.R. designed the study, interpreted the data, conducted the literature search and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Competing interests
Both, Mr. MWM and WLJL are staff of Innosparks Pte Ltd., Singapore, whose product was used in the study. The other authors have no competing interest relevant to this article to disclose.

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Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures

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There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

Influenza pandemics occur at irregular intervals when new strains of influenza A virus spread in humans (*1*). Influenza pandemics cause considerable health and social impact that exceeds that of typical seasonal (interpandemic) influenza epidemics. One of the characteristics of influenza pandemics is the high incidence of infections in all age groups because of the lack of population immunity. Although influenza vaccines are the cornerstone of seasonal influenza control, specific vaccines for a novel pandemic strain are not expected to be available for the first 5–6 months of the next pandemic. Antiviral drugs will be available in some locations to treat more severe infections but are unlikely to be available in the quantities that might be required to control transmission in the general community. Thus, efforts to control the next pandemic will rely largely on nonpharmaceutical interventions.

Most influenza virus infections cause mild and self-limiting disease; only a small fraction of case-patients require hospitalization. Therefore, influenza virus infections spread mainly in the community. Influenza virus is believed to be transmitted predominantly by respiratory droplets, but the size distribution of particles responsible for transmission remains unclear, and in particular, there is a lack of consensus on the role of fine particle aerosols in transmission (*2*,*3*). In healthcare settings, droplet precautions are recommended in addition to standard precautions for healthcare personnel when interacting with influenza patients and for all visitors during influenza seasons (*4*). Outside healthcare settings, hand hygiene is recommended in most national pandemic plans (*5*), and medical face masks were a common sight during the influenza pandemic in 2009. Hand hygiene has been proven to prevent many infectious diseases and might be considered a major component in influenza pandemic plans, whether or not it has proven effectiveness against influenza virus transmission, specifically because of its potential to reduce other infections and thereby reduce pressure on healthcare services.

In this article, we review the evidence base for personal protective measures and environmental hygiene measures, and specifically the evidence for the effectiveness of these measures in reducing transmission of laboratory-confirmed influenza in the community. We also discuss the implications of the evidence base for inclusion of these measures in pandemic plans.

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[1]These first authors contributed equally to this article.

Methods and Results

We conducted systematic reviews to evaluate the effectiveness of personal protective measures on influenza virus transmission, including hand hygiene, respiratory etiquette, and face masks, and a systematic review of surface and object cleaning as an environmental measure (Table 1). We searched 4 databases (Medline, PubMed, EMBASE, and CENTRAL) for literature in all languages. We aimed to identify randomized controlled trials (RCTs) of each measure for laboratory-confirmed influenza outcomes for each of the measures because RCTs provide the highest quality of evidence. For respiratory etiquette and surface and object cleaning, because of a lack of RCTs for laboratory-confirmed influenza, we also searched for RCTs reporting effects of these interventions on influenza-like illness (ILI) and respiratory illness outcomes and then for observational studies on laboratory-confirmed influenza, ILI, and respiratory illness outcomes. For each review, 2 authors (E.Y.C.S. and J.X.) screened titles and abstracts and reviewed full texts independently.

We performed meta-analysis for hand hygiene and face mask interventions and estimated the effect of these measures on laboratory-confirmed influenza prevention by risk ratios (RRs). We used a fixed-effects model to estimate the overall effect in a pooled analysis or subgroup analysis. No overall effect would be generated if there was considerable heterogeneity on the basis of I^2 statistic ≥75% (*6*). We performed quality assessment of evidence on hand hygiene and face mask interventions by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (*7*). We provide additional details of the search strategies, selection of articles, summaries of the selected articles, and quality assessment (Appendix, https://wwwnc.cdc.gov/EID/article/26/5/19-0994-App1.pdf).

Personal Protective Measures

Hand Hygiene

We identified a recent systematic review by Wong et al. on RCTs designed to assess the efficacy of hand hygiene interventions against transmission of laboratory-confirmed influenza (*8*). We used this review as a starting point and then searched for additional literature published after 2013; we found 3 additional eligible articles published during the search period of January 1, 2013–August 13, 2018. In total, we identified 12 articles (*9*–*20*), of which 3 articles were from the updated search and 9 articles from Wong et al. (*8*). Two articles relied on the same underlying dataset (*16*,*19*); therefore, we counted these 2 articles as 1 study, which resulted in 11 RCTs. We further selected 10 studies with >10,000 participants for inclusion in the meta-analysis (Figure 1). We excluded 1 study from the meta-analysis because it provided estimates of infection risks only at the household level, not the individual level (*20*). We did not generate an overall pooled effect of hand hygiene only or of hand hygiene with or without face mask because of high heterogeneity in individual estimates (I^2 87 and 82%, respectively). The effect of hand hygiene combined with face masks on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73–1.13; I^2 = 35%, p = 0.39). Some studies reported being underpowered because of limited sample size, and low adherence to hand hygiene interventions was observed in some studies.

We further analyzed the effect of hand hygiene by setting because transmission routes might vary

Table 1. Summary of literature searches for systematic review on personal and environmental nonpharmaceutical interventions for pandemic influenza*

Types of interventions	No. studies identified	Study designs included†	Main findings
Hand hygiene	12	RCT	The evidence from RCTs suggested that hand hygiene interventions do not have a substantial effect on influenza transmission.
Respiratory etiquette	0	NA	We did not identify research evaluating the effectiveness of respiratory etiquette on influenza transmission.
Face masks	10	RCT	The evidence from RCTs suggested that the use of face masks either by infected persons or by uninfected persons does not have a substantial effect on influenza transmission.
Surface and object cleaning	3	RCT, observational studies	There was a limited amount of evidence suggesting that surface and object cleaning does not have a substantial effect on influenza transmission.

*NA, not available; RCT randomized controlled trial.
†In these systematic reviews, we prioritized RCTs, and only considered observational studies if there were a small number of RCTs. Our rationale was that with evidence from a larger number of RCTs, additional evidence from observational studies would be unlikely to change overall conclusions.

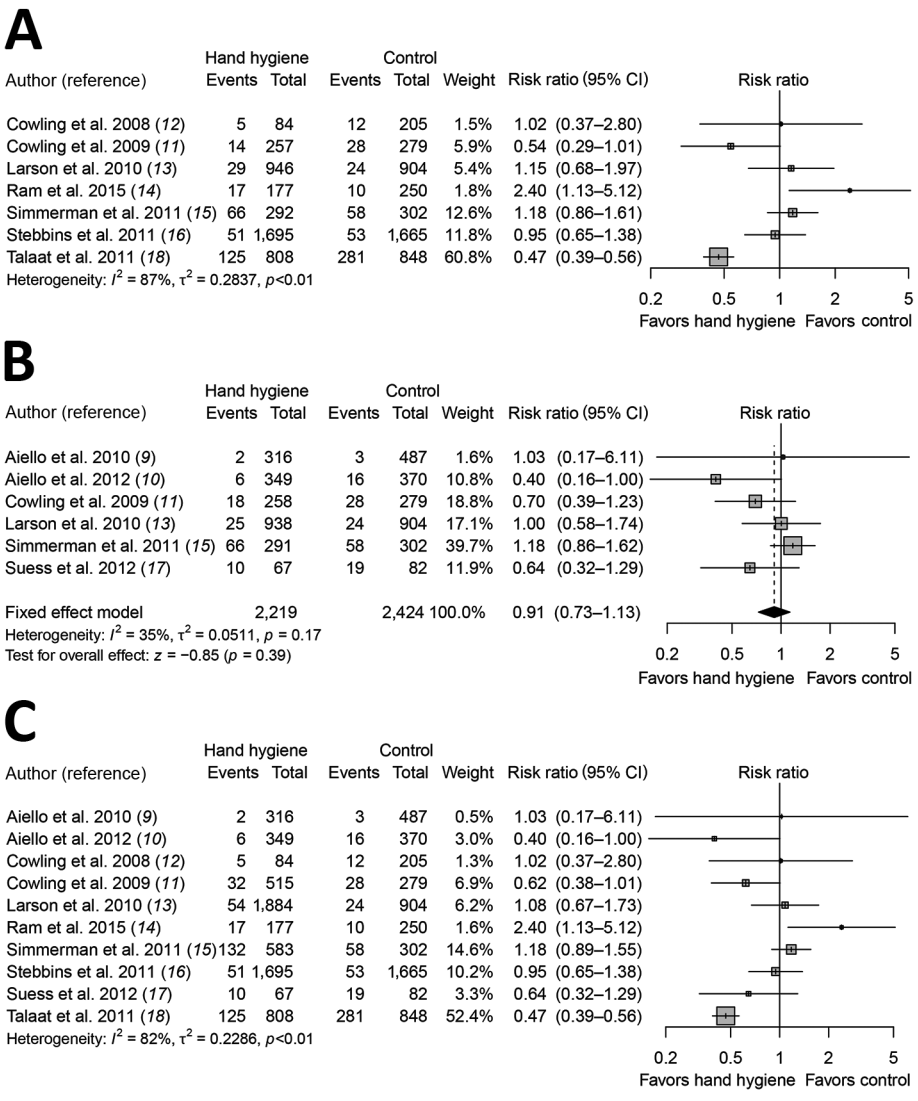


Figure 1. Meta-analysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza from 10 randomized controlled trials with >11,000 participants. A) Hand hygiene alone; B) hand hygiene and face mask; C) hand hygiene with or without face mask. Pooled estimates were not made if there was high heterogeneity (I^2 ≥75%). Squares indicate risk ratio for each of the included studies, horizontal line indicates 95% CIs, dashed vertical line indicates pooled estimation of risk ratio, and diamond indicates pooled estimation of risk ratio. Diamond width corresponds to the 95% CI.

in different settings. We found 6 studies in household settings examining the effect of hand hygiene with or without face masks, but the overall pooled effect was not statistically significant (RR 1.05, 95% CI 0.86–1.27; I^2 = 57%, p = 0.65) (Appendix Figure 4) (*11*–*15*,*17*). The findings of 2 studies in school settings were different (Appendix Figure 5). A study conducted in the United States (*16*) showed no major effect of hand hygiene, whereas a study in Egypt (*18*) reported that hand hygiene reduced the risk for influenza by >50%. A pooled analysis of 2 studies in university residential halls reported a marginally significant protective effect of a combination of hand hygiene plus face masks worn by all residents (RR 0.48, 95% CI 0.21–1.08; I^2 = 0%, p = 0.08) (Appendix Figure 6) (*9*,*10*).

In support of hand hygiene as an effective measure, experimental studies have reported that influenza virus could survive on human hands for a short time and could transmit between hands and contaminated surfaces (*2*,*21*). Some field studies reported that influenza A(H1N1)pdm09 and influenza A(H3N2) virus RNA and viable influenza virus could be detected on the hands of persons with laboratory-confirmed influenza (*22*,*23*), supporting the potential of direct and indirect contact transmission to play a role in the spread of influenza. Other experimental studies also demonstrated that hand hygiene could reduce or remove infectious influenza virus from human hands (*24*,*25*). However, results from our meta-analysis on RCTs did not provide evidence to support a protective effect of hand hygiene against transmission of laboratory-confirmed influenza. One study did report a major effect, but in this trial of hand hygiene in schools in Egypt, running water had to be installed and soap and hand-drying

material had to be introduced into the intervention schools as part of the project (*18*). Therefore, the impact of hand hygiene might also be a reflection of the introduction of soap and running water into primary schools in a lower-income setting. If one considers all of the evidence from RCTs together, it is useful to note that some studies might have underestimated the true effect of hand hygiene because of the complexity of implementing these intervention studies. For instance, the control group would not typically have zero knowledge or use of hand hygiene, and the intervention group might not adhere to optimal hand hygiene practices (*11*,*13*,*15*).

Hand hygiene is also effective in preventing other infectious diseases, including diarrheal diseases and some respiratory diseases (*8*,*26*). The need for hand hygiene in disease prevention is well recognized among most communities. Hand hygiene has been accepted as a personal protective measure in >50% of national preparedness plans for pandemic influenza (*5*). Hand hygiene practice is commonly performed with soap and water, alcohol-based hand rub, or other waterless hand disinfectants, all of which are easily accessible, available, affordable, and well accepted in most communities. However, resource limitations in some areas are a concern when clean running water or alcohol-based hand rub are not available. There are few adverse effects of hand hygiene except for skin irritation caused by some hand hygiene products (*27*). However, because of certain social or religious practices, alcohol-based hand sanitizers might not be permitted in some locations (*28*). Compliance with proper hand hygiene practice tends to be low because habitual behaviors are difficult to change (*29*). Therefore, hand hygiene promotion programs are needed to advocate and encourage proper and effective hand hygiene.

Respiratory Etiquette

Respiratory etiquette is defined as covering the nose and mouth with a tissue or a mask (but not a hand) when coughing or sneezing, followed by proper disposal of used tissues, and proper hand hygiene after contact with respiratory secretions (*30*). Other descriptions of this measure have included turning the head and covering the mouth when coughing and coughing or sneezing into a sleeve or elbow, rather than a hand. The rationale for not coughing into hands is to prevent subsequent contamination of other surfaces or objects (*31*). We conducted a search on November 6, 2018, and identified literature that was available in the databases during 1946–November 5, 2018. We did not identify any published research on the effectiveness of respiratory etiquette in reducing the risk for laboratory-confirmed influenza or ILI. One observational study reported a similar incidence rate of self-reported respiratory illness (defined by >1 symptoms: cough, congestion, sore throat, sneezing, or breathing problems) among US pilgrims with or without practicing respiratory etiquette during the Hajj (*32*). The authors did not specify the type of respiratory etiquette used by participants in the study. A laboratory-based study reported that common respiratory etiquette, including covering the mouth by hands, tissue, or sleeve/arm, was fairly ineffective in blocking the release and dispersion of droplets into the surrounding environment on the basis of measurement of emitted droplets with a laser diffraction system (*31*).

Respiratory etiquette is often listed as a preventive measure for respiratory infections. However, there is a lack of scientific evidence to support this measure. Whether respiratory etiquette is an effective nonpharmaceutical intervention in preventing influenza virus transmission remains questionable, and worthy of further research.

Face Masks

In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25) (Figure 2). One study evaluated the use of masks among pilgrims from Australia during the Hajj pilgrimage and reported no major difference in the risk for laboratory-confirmed influenza virus infection in the control or mask group (*33*). Two studies in university settings assessed the effectiveness of face masks for primary protection by monitoring the incidence of laboratory-confirmed influenza among student hall residents for 5 months (*9*,*10*). The overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies (*9*,*10*). Study designs in the 7 household studies were slightly different: 1 study provided face masks and P2 respirators for household contacts only (*34*), another study evaluated face mask use as a source control for infected persons only (*35*), and the remaining studies provided masks for the infected persons as well as their close contacts (*11*–*13*,*15*,*17*). None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face

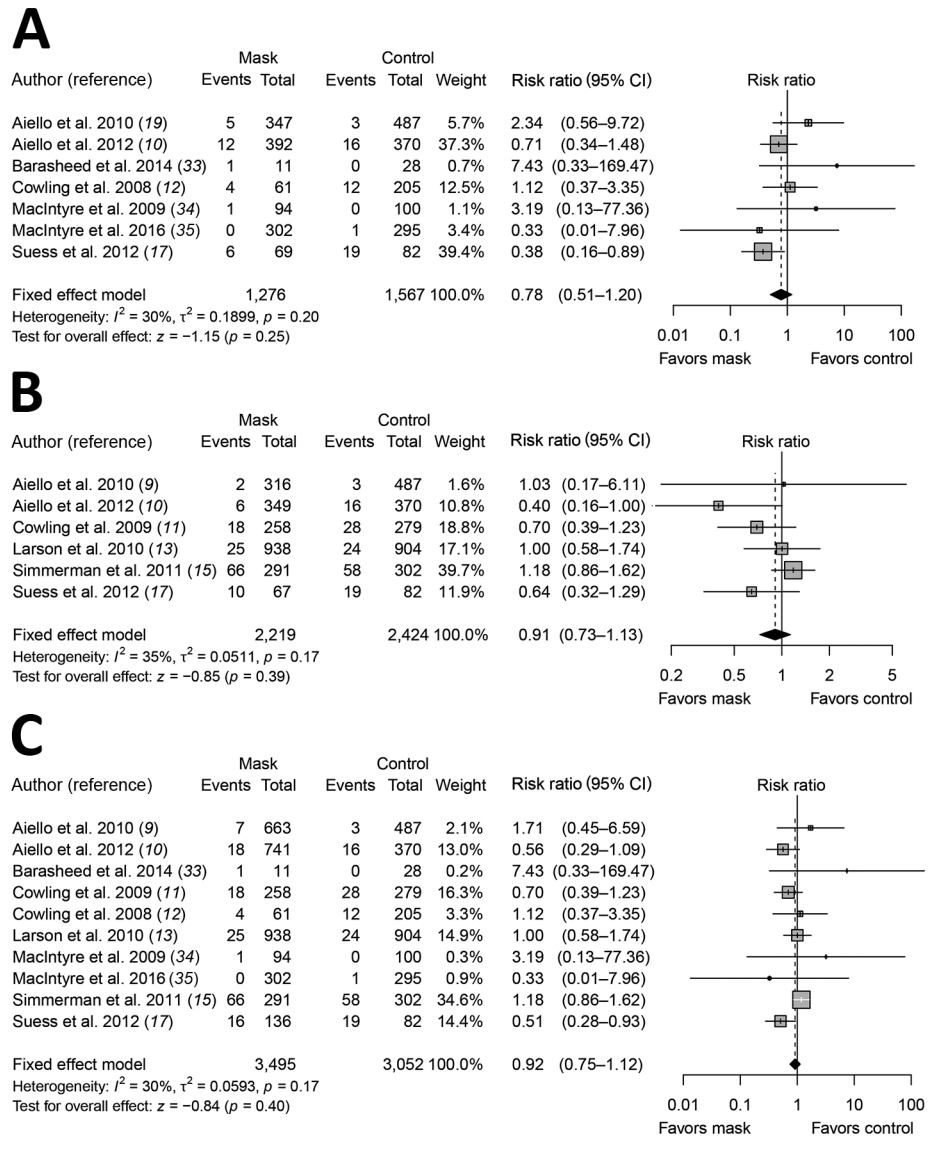


Figure 2. Meta-analysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza from 10 randomized controlled trials with >6,500 participants. A) Face mask use alone; B) face mask and hand hygiene; C) face mask with or without hand hygiene. Pooled estimates were not made if there was high heterogeneity (I^2 ≥75%). Squares indicate risk ratio for each of the included studies, horizontal lines indicate 95% CIs, dashed vertical lines indicate pooled estimation of risk ratio, and diamonds indicate pooled estimation of risk ratio. Diamond width corresponds to the 95% CI.

mask group (*11–13*,*15*,*17*,*34*,*35*). Most studies were underpowered because of limited sample size, and some studies also reported suboptimal adherence in the face mask group.

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids (*36*). There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory-confirmed influenza.

We did not consider the use of respirators in the community. Respirators are tight-fitting masks that can protect the wearer from fine particles (*37*) and should provide better protection against influenza virus exposures when properly worn because of higher filtration efficiency. However, respirators, such as N95 and P2 masks, work best when they are fit-tested, and these masks will be in limited supply during the next pandemic. These specialist devices should be reserved for use in healthcare settings or in special subpopulations such as immunocompromised persons in the community, first responders, and those performing other critical community functions, as supplies permit.

In lower-income settings, it is more likely that reusable cloth masks will be used rather than

disposable medical masks because of cost and availability (*38*). There are still few uncertainties in the practice of face mask use, such as who should wear the mask and how long it should be used for. In theory, transmission should be reduced the most if both infected members and other contacts wear masks, but compliance in uninfected close contacts could be a problem (*12*,*34*). Proper use of face masks is essential because improper use might increase the risk for transmission (*39*). Thus, education on the proper use and disposal of used face masks, including hand hygiene, is also needed.

Environmental Measures

Surface and Object Cleaning

For the search period from 1946 through October 14, 2018, we identified 2 RCTs and 1 observational study about surface and object cleaning measures for inclusion in our systematic review (*40*–*42*). One RCT conducted in day care nurseries found that biweekly cleaning and disinfection of toys and linen reduced the detection of multiple viruses, including adenovirus, rhinovirus, and respiratory syncytial virus in the environment, but this intervention was not significant in reducing detection of influenza virus, and it had no major protective effect on acute respiratory illness (*41*). Another RCT found that hand hygiene with hand sanitizer together with surface disinfection reduced absenteeism related to gastrointestinal illness in elementary schools, but there was no major reduction in absenteeism related to respiratory illness (*42*). A cross-sectional study found that passive contact with bleach was associated with a major increase in self-reported influenza (*40*).

Given that influenza virus can survive on some surfaces for prolonged periods (*43*), and that cleaning or disinfection procedures can effectively reduce or inactivate influenza virus from surfaces and objects in experimental studies (*44*), there is a theoretical basis to believe that environmental cleaning could reduce influenza transmission. As an illustration of this proposal, a modeling study estimated that cleaning of extensively touched surfaces could reduce influenza A infection by 2% (*45*). However, most studies of influenza virus in the environment are based on detection of virus RNA by PCR, and few studies reported detection of viable virus.

Although we found no evidence that surface and object cleaning could reduce influenza transmission, this measure does have an established impact on prevention of other infectious diseases (*42*). It should be feasible to implement this measure in most settings, subject to the availability of water and cleaning products. Although irritation caused by cleaning products is limited, safety remains a concern because some cleaning products can be toxic or cause allergies (*40*).

Discussion

In this review, we did not find evidence to support a protective effect of personal protective measures or environmental measures in reducing influenza transmission. Although these measures have mechanistic support based on our knowledge of how influenza is transmitted from person to person, randomized trials of hand hygiene and face masks have not demonstrated protection against laboratory-confirmed influenza, with 1 exception (*18*). We identified only 2 RCTs on environmental cleaning and no RCTs on cough etiquette.

Hand hygiene is a widely used intervention and has been shown to effectively reduce the transmission of gastrointestinal infections and respiratory infections (*26*). However, in our systematic review, updating the findings of Wong et al. (*8*), we did not find evidence of a major effect of hand hygiene on laboratory-confirmed influenza virus transmission (Figure 1). Nevertheless, hand hygiene might be included in influenza pandemic plans as part of general hygiene and infection prevention.

We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility (Figure 2). However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and therefore have value in an influenza pandemic when healthcare resources are stretched.

It is essential to note that the mechanisms of person-to-person transmission in the community have not been fully determined. Controversy remains over the role of transmission through fine-particle aerosols (*3*,*46*). Transmission by indirect contact requires transfer of viable virus from respiratory mucosa onto hands and other surfaces, survival on those surfaces, and successful inoculation into the respiratory mucosa of another person. All of these components of the transmission route have not been studied extensively. The impact of environmental factors, such as temperature and humidity, on influenza transmission is also uncertain (*47*). These uncertainties over basic transmission modes and mechanisms hinder the optimization of control measures.

Table 2. Knowledge gaps for personal protective and environmental nonpharmaceutical interventions for pandemic influenza*

Intervention	Knowledge gaps	Suggested studies
Hand hygiene	There are major gaps in our knowledge of the mechanisms of person-to-person transmission of influenza, including the role of direct and indirect contact, the degree of viral contamination on hands and various types of surfaces in different settings, and the potential for contact transmission to occur in different locations and under different environmental conditions. There is little information on whether greater reductions in transmission could be possible with combinations of personal intervention (e.g., isolation away from family members as much as possible, plus using face masks and enhancing hand hygiene).	Additional high-quality RCTs of efficacy of hand hygiene against laboratory-confirmed influenza in other nonhealthcare settings, except households and university residential halls, would be valuable. In particular, studies in school settings are needed to solve the discrepancy between the two studies from the United States and Egypt.
Respiratory etiquette	There is no evidence about the quantitative effectiveness of respiratory etiquette against influenza virus.	RCTs of interventions to demonstrate the effectiveness of respiratory etiquette in reducing influenza transmission would be valuable.
Face mask	There are major gaps in our knowledge of the mechanisms of person-to-person transmission of influenza, including the importance of transmission through droplets of different sizes including small particle aerosols, and the potential for droplet and aerosol transmission to occur in different locations and with environmental conditions.	Additional high-quality RCTs of efficacy of face masks against laboratory-confirmed influenza would be valuable. Effectiveness of face masks or respirator use to prevent influenza prevention in special subpopulation, such as immunocompromised persons, would be valuable.
Surface and object cleaning	The effectiveness of different cleaning products in preventing influenza transmission–in terms of cleaning frequency, cleaning dosage, cleaning time point, and cleaning targeted surface and object material–remains unknown.	RCTs of interventions to demonstrate the effectiveness of surface and object cleaning in reducing influenza transmission would be valuable. Studies that can demonstrate the reduction of environmental detection of influenza virus through cleaning of surfaces and objects would also be valuable.

*RCT, randomized control trial.

In this review, we focused on 3 personal protective measures and 1 environmental measure. Other potential environmental measures include humidification in dry environments (*48*), increasing ventilation (*49*), and use of upper-room UV light (*50*), but there is limited evidence to support these measures. Further investigations on the effectiveness of respiratory etiquette and surface cleaning through conducting RCTs would be helpful to provide evidence with higher quality; evaluation of the effectiveness of these measures targeting specific population groups, such as immunocompromised persons, would also be beneficial (Table 2). Future cost-effectiveness evaluations could provide more support for the potential use of these measures. Further research on transmission modes and alternative interventions to reduce influenza transmission would be valuable in improving pandemic preparedness. Finally, although our review focused on nonpharmaceutical measures to be taken during influenza pandemics, the findings could also apply to severe seasonal influenza epidemics. Evidence from RCTs of hand hygiene or face masks did not support a substantial effect on transmission of laboratory-confirmed influenza, and limited evidence was available on other environmental measures.

This study was conducted in preparation for the development of guidelines by the World Health Organization on the use of nonpharmaceutical interventions for pandemic influenza in nonmedical settings.

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Nonpharmaceutical Measures for Pandemic Influenza in Nonheathcare Settings—Personal Protective and Environmental Measures

Appendix

Hand Hygiene

Terminology

Relevant terminology relating to hand hygiene are shown as follows (Appendix Table 1):

Appendix Table 1. Definition of terms relevant to hand hygiene

Term	Definition
Hand hygiene practices	
Hand hygiene	"A general term referring to any action of hand cleansing" (e.g., handwashing, antiseptic handwash, antiseptic hand rub and surgical hand antisepsis) (*1,2*)
Hand cleansing	"Action of performing hand hygiene for the purpose of physically or mechanically removing dirt, organic material, and/or microorganisms" (*1*)
Handwashing	"Washing hands with plain or antimicrobial soap and water" (*1*)
Antiseptic handwashing	"Washing hands with soap and water, or other detergents containing an antiseptic agent" (*1*)
Antiseptic handrubbing (or handrubbing)	Applying an antiseptic handrub to all surfaces of the hands "to reduce or inhibit the growth of microorganisms without the need for an exogenous source of water and requiring no rinsing or drying with towels or other devices" (*1,2*)
Hand disinfection	"Hand disinfection is extensively used as a term in some parts of the world and can refer to antiseptic handwash, antiseptic handrubbing, hand antisepsis/decontamination/degerming, handwashing with an antimicrobial soap and water, hygienic hand antisepsis, or hygienic handrub" (*1*)
Hand hygiene products	
Alcohol-based (hand) rub (or hand sanitizer)	"An alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients with excipients, and humectants" (*1)*
Antimicrobial (medicated) soap	"Soap (detergent) containing an antiseptic agent at a concentration sufficient to inactivate microorganisms and/or temporarily suppress their growth. The detergent activity of such soaps may also dislodge transient microorganisms or other contaminants from the skin to facilitate their subsequent removal by water" (*1*)
Antiseptic hand wipe	"A piece of fabric or paper pre-wetted with an antiseptic used for wiping hands to inactivate and/or remove microbial contamination. They may be considered as an alternative to washing hands with non-antimicrobial soap and water but, because they are not as effective at reducing bacterial counts on HCWs' hands as alcohol-based handrubs or washing hands with an antimicrobial soap and water, they are not a substitute for using an alcohol-based handrub or antimicrobial soap" (*1*)
Plain soap	"Plain soap refers to detergents that do not contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives" (*2*)
Other	
Visibly soiled hands	"Hands showing visible dirt or visibly contaminated with proteinaceous material, blood, or other body fluids (e.g., fecal material or urine)" (2)

Search Strategy

We conducted a review of systematic review on 1 August 2018 using the following search terms (Appendix Table 2) to identify literatures that were available from 1946 through July 31, 2018. Four databases (PubMed, Medline, EMBASE, and CENTRAL) were searched. Review selection criteria are systematic reviews published within 5 years studying the effect of hand hygiene interventions on prevention of laboratory-confirmed influenza in community settings. We reviewed literatures of all languages.

Appendix Table 2. Search strategy for hand hygiene

Search terms	Search date	Reviewers
#1: "hand hygiene" OR "hand washing" OR "handwashing" OR "hand-washing" OR "hand-wash" OR "hand wash" OR "handwash" OR "hand sanitize" OR "hand sanitizers" OR "hand sanitizer" OR "hand rub" OR "handrub" OR "hand rubbing" OR "hand cleansing" OR "hand cleans" OR "hand cleanser" OR "hand disinfectant" OR "hand disinfectants" OR "hand disinfection" OR "hand soap" OR "hand wipe"	August 1, 2018 for review of systematic review and August 14, 2018 for additional search	J.X. E.S.
#2: "influenza" OR "flu"		
#3: #1 AND #2		

After identifying the most recent published systematic review, we conducted an additional literature search to capture articles of all languages that were not included in the review. The search was conducted on 14 August 2018 using the same search terms in 4 databases to identify literatures that were available during January 1, 2013–August 13, 2018. Study selection criteria are randomized control trials (RCTs) comparing the effect of hand hygiene interventions with that of no intervention in preventing laboratory-confirmed influenza infections in community settings. Study participants or clusters of participants were assigned prospectively into intervention and control groups using random allocation. A community setting was defined as an open setting without confinement or special care for patients. Articles describing any hand hygiene related interventions were included. Two reviewers (J.X. and E.S.) reviewed retrieved titles and subsequent relevant abstracts independently. Titles and abstract selected by any of the reviewers were included for subsequent screening. Both reviewers reviewed full-text and extracted data for selected studies independently. If a consensus was not reached, further discussion was held or opinion was obtained from a third reviewer.

With a substantial number of randomized controlled trials conducted on hand hygiene, we did not extend the search to observational studies, but we did note the findings from earlier systematic reviews of observational studies of hand hygiene (*4–6*).

Risk ratios (RRs) and their 95% confidence intervals (95% CIs) were calculated to estimate the effect of hand hygiene intervention on prevention of laboratory-confirmed influenza.

Heterogeneity of each pooled and subgroup analysis was assessed by I^2 statistics. The overall effect of each pooled and subgroup analysis was estimated by fixed-effect model. If the heterogeneity was high (I^2 ≥75%), we did not estimate an overall pooled effect.

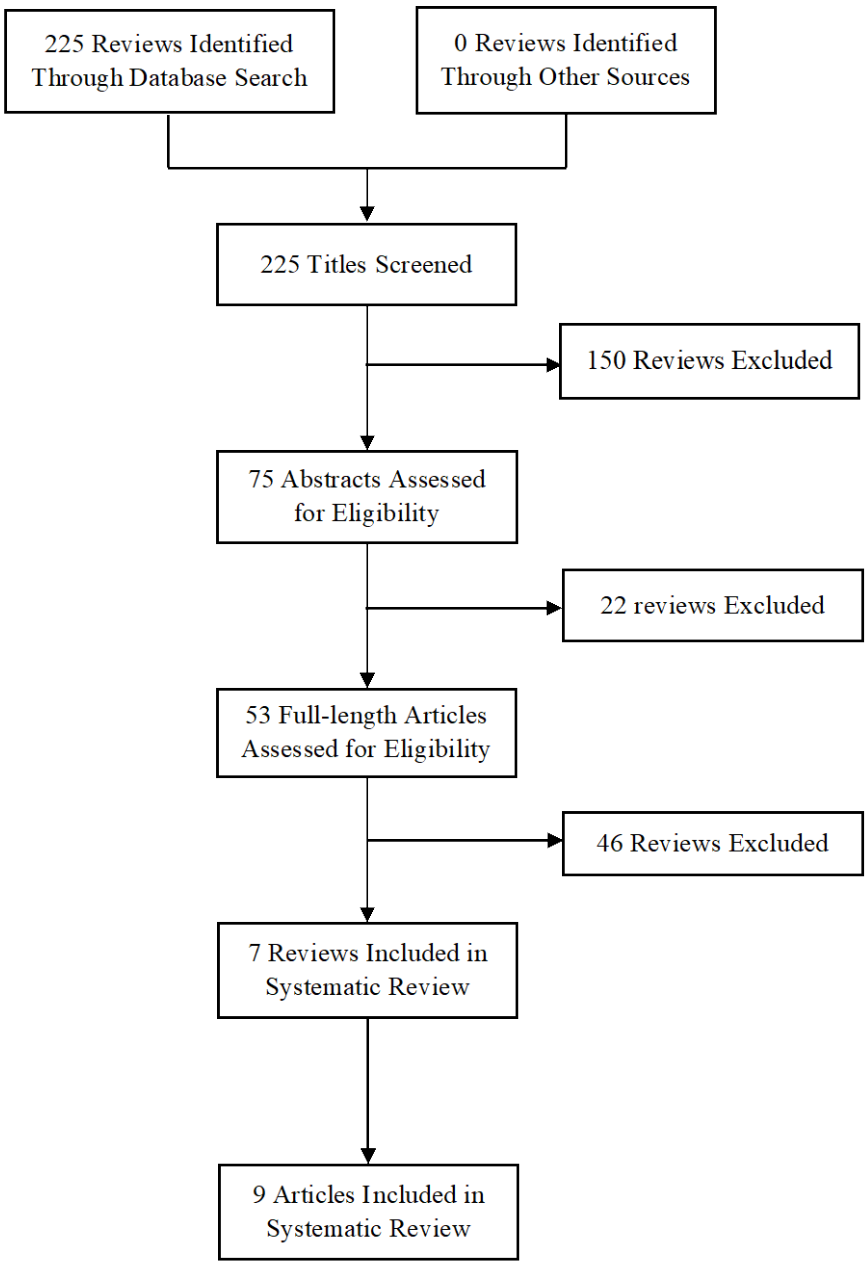
Findings

Appendix Table 3. Basic characteristics of included studies

Characteristic	No. of studies (%)
Country	
Industrialized	7 (64)
Developing	4 (36)
Setting	
Household	7 (64)
Elementary school	2 (18)
University residential hall	2 (18)
Transmission mode	
Primary	5 (45)
Secondary	6 (55)
Intervention evaluated*	
Hand sanitizer and education	3 (20)
Hand sanitizer, soap and education	1 (7)
Hand sanitizer and face mask	3 (20)
Hand sanitizer, face mask and education	2 (13)
Soap	3 (20)
Soap and education	1 (7)
Soap and face mask	2 (13)
Outcome assessed	
Laboratory-confirmed influenza	11 (100)

*More than one intervention for some studies.

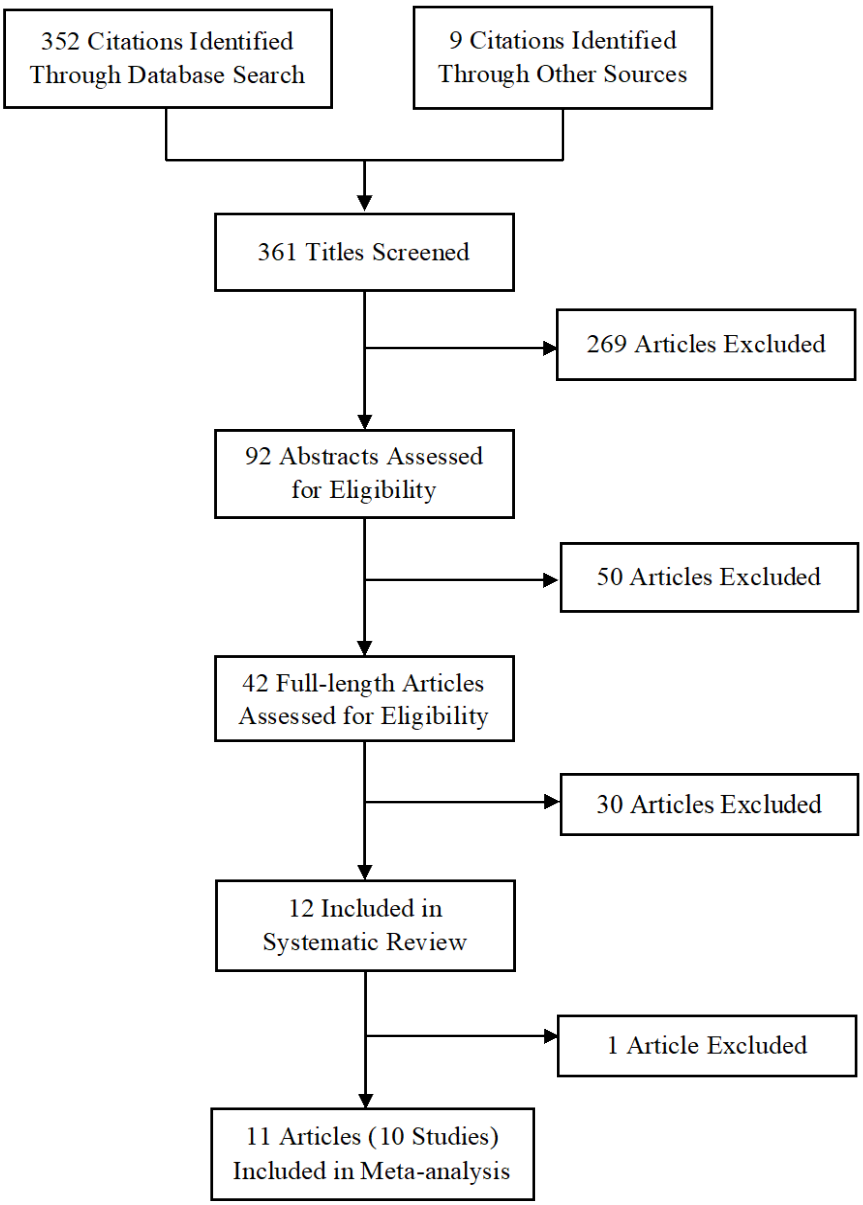
We identified 225 reviews through the search, of which 172 reviews were removed during title and abstract screening. We selected 7 reviews for our analysis after screening the full text. Reasons for exclusion included: reviews considered not systematic, reviews published outside the 5-year time frame, articles in reviews were not RCTs, and the reviews did not evaluate hand hygiene as a study intervention or laboratory-confirmed influenza infection as a study outcome. Among the 7 included reviews, we identified 9 relevant RCT studies, of which all 9 studies were included in a most recently published systematic review and metaanalysis conducted by Wong et al. (*7*). Therefore, we used this review as the reference base of our review of systematic review to evaluate the effect of hand hygiene in reducing the risk for laboratory-confirmed influenza virus infection. The flowchart is shown in Appendix Figure 1.



Appendix Figure 1. Flowchart of literature search and article selection for systematic reviews of the effectiveness of hand hygiene against laboratory-confirmed influenza.

Furthermore, we conducted an update search to capture literatures that were not included in the review by Wong et al. (*7*). We identified 352 articles from January 1, 2013 to August 13, 2018. We subsequently removed 319 articles during the title and abstract screening. Reasons for exclusion included: studies were not conducted in community settings, study design was not RCT and studies did not evaluate hand hygiene as a study intervention or laboratory-confirmed influenza infection as a study outcome. We identified 3 articles in this updated search, hence we included a total of 12 articles in our systematic review. Since two articles used the same dataset

to evaluate different research questions (*8*,*9*), we considered these articles as 1 study in our review. Moreover, one article only included secondary infection data in household level but not individual level (*9*), therefore we did not include this in the metaanalysis. To sum up, we included 12 articles in our systematic review and 11 articles in the metaanalysis. The flowchart is shown in Appendix Figure 2.



Appendix Figure 2. Flowchart of literature search and study selection for trials of the effectiveness of hand hygiene against laboratory-confirmed influenza.

Among the 11 studies included in the metaanalysis, 7 studies were in household settings (*10*–*16*), 2 studies in elementary school setting (*9*,*17*), and 2 studies in university residential hall

setting (*18*,*19*). Basic characteristics of the included studies are shown in Appendix Table 3, and detailed study description are shown in Appendix Table 4.

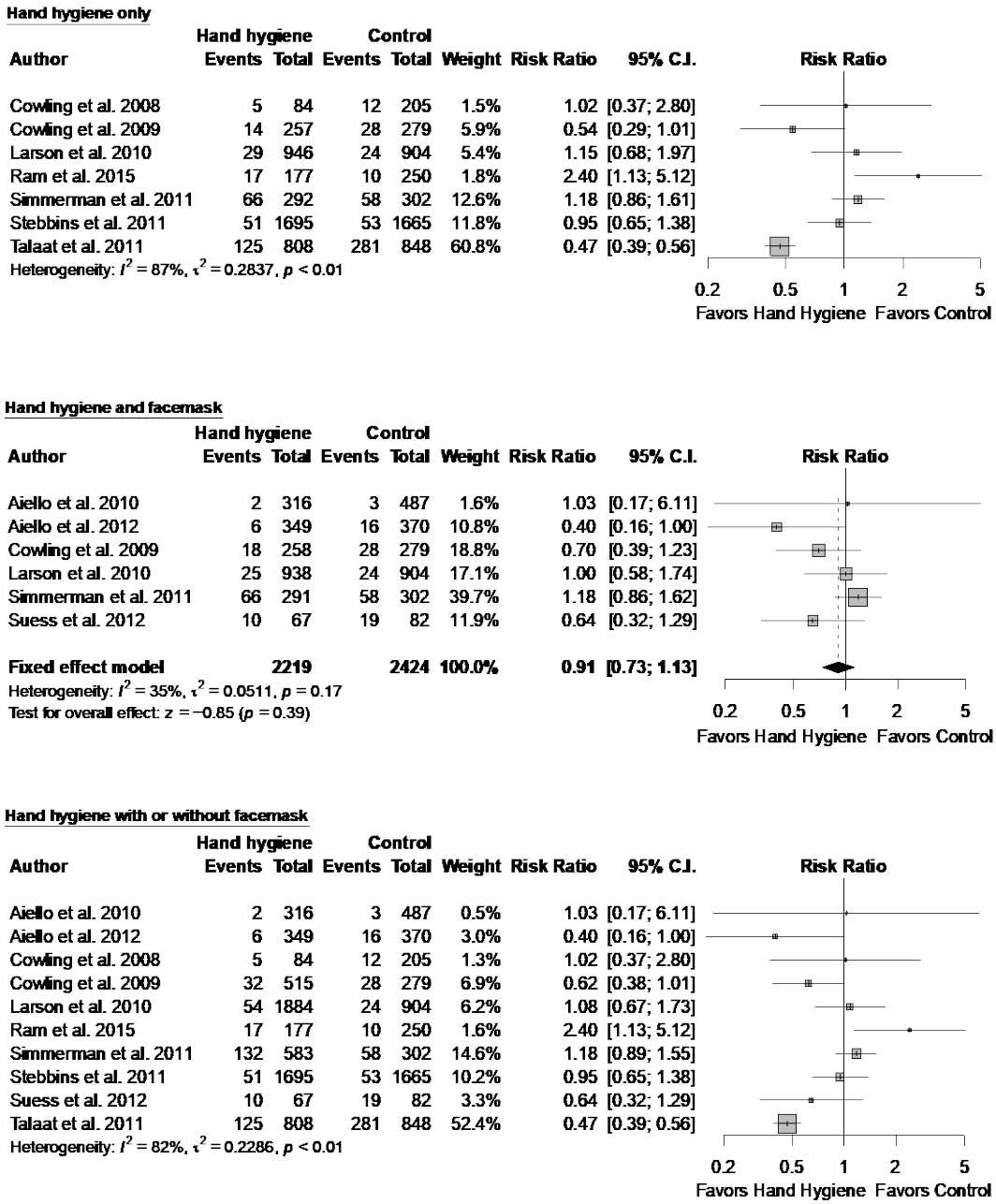
In the pooled analysis, hand hygiene with face mask (risk ratio [RR] 0.91, 95% CI 0.73–1.13; p = 0.39, I^2 = 35%) did not have a significant protective effect in community settings (Appendix Figure 3) (*11*,*13*,*15*,*16*,*18*,*19*). Some published studies noted that poor adherence to hand hygiene might lead to underestimation of the true effect of the intervention (*11*,*13*,*15*).

Because the relative importance of transmission modes of influenza might vary in different settings, we conducted subgroup analysis based on various settings. In household setting (*11–16*), the efficacy of hand hygiene with or without face mask was not significant (RR 1.05, 95% CI 0.86–1.27; p = 0.65, I^2 = 57%) (Appendix Figure 4). Although the pooled analysis did not identify an overall significant effect of hand hygiene, some household transmission studies reported that early implementation of hand hygiene in the index case after symptom onset might be more effective in preventing secondary infection in the household (*11*,*16*).

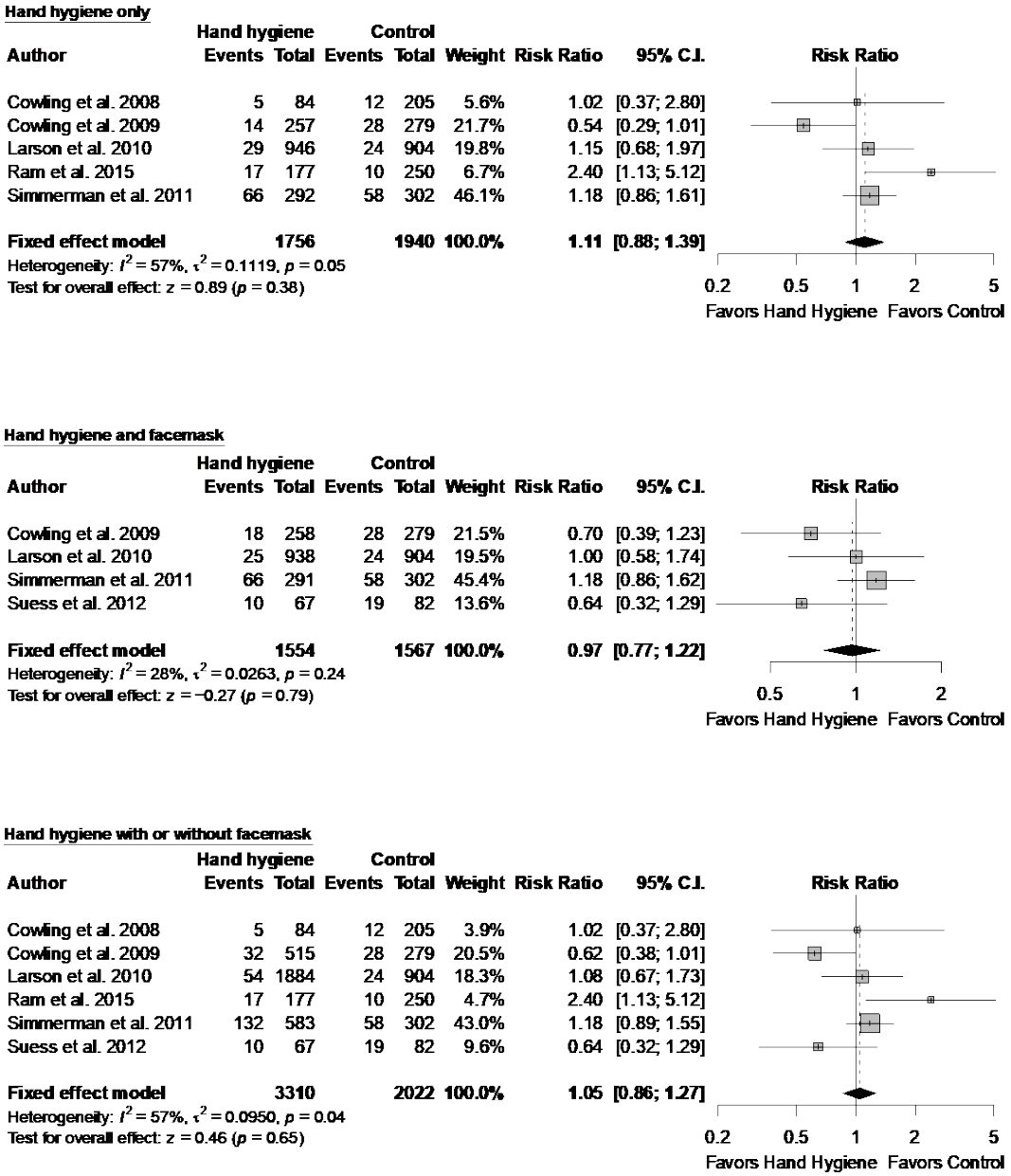
In school settings (*9*,*17*), total effect was not generated because of high heterogeneity (Appendix Figure 5). In a study in the United States (*9*), the effect of hand hygiene was not significant based on the point estimate of the RR close to 1, whereas a large trial in Egypt reported a reduction of >50% of influenza cases in the intervention group (*17*).

In university residential hall settings (*18*,*19*), hand hygiene with face mask intervention contributed to 52% RR reduction (RR = 0.48, 95% CI 0.21–1.08; p = 0.08, marginally significant, I^2 = 0%) of laboratory-confirmed influenza infection (Appendix Figure 6).

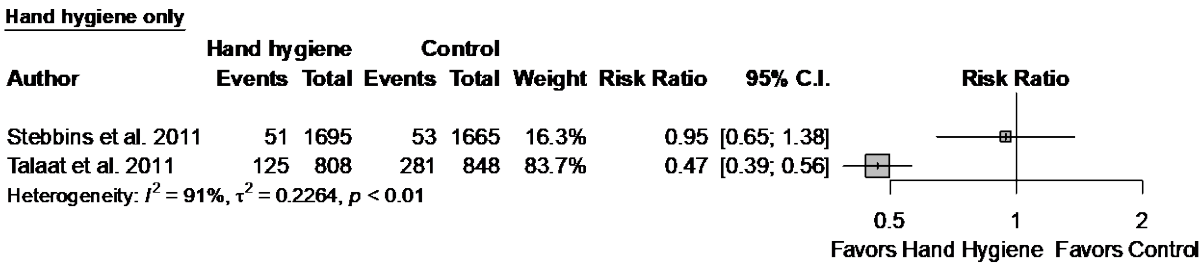
The results of quality assessment of evidence on hand hygiene intervention using GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach are shown in Appendix Table 5.

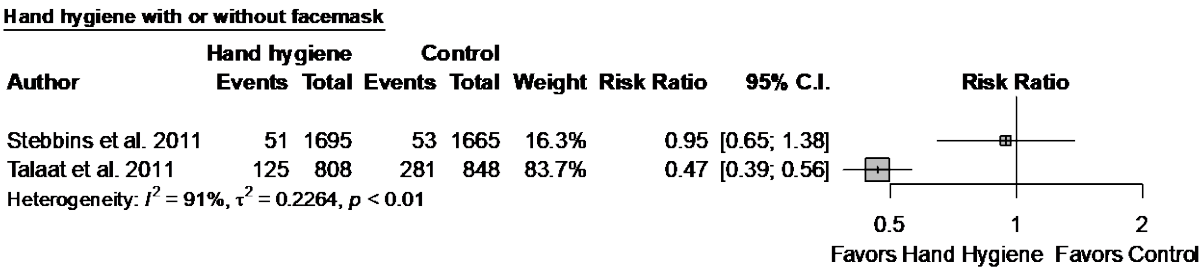


Appendix Figure 3. Metaanalysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza.

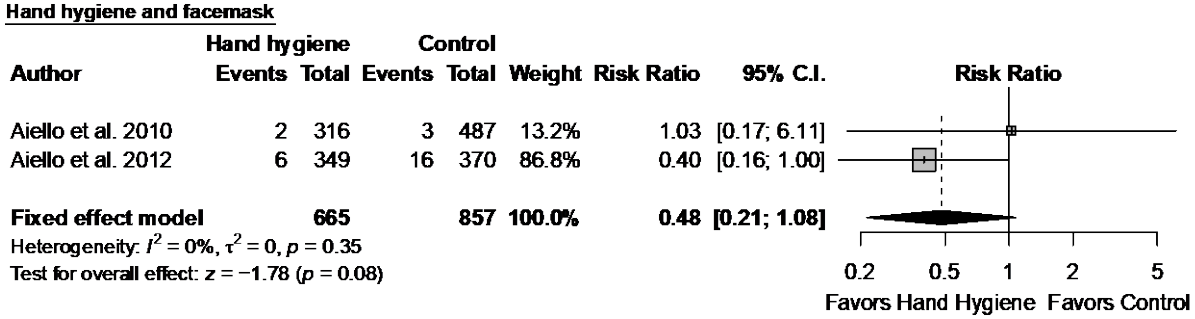


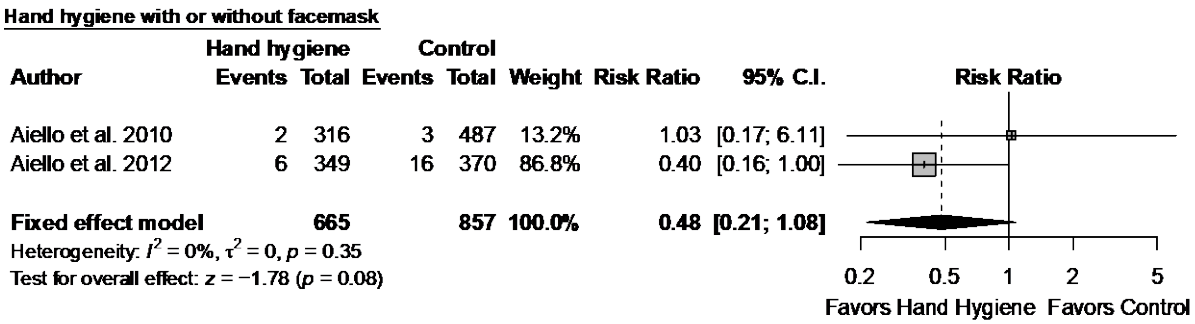
Appendix Figure 4. Metaanalysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza in household setting.





Appendix Figure 5. Metaanalysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza in elementary school setting.





Appendix Figure 6. Metaanalysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza in university residence hall setting.

Appendix Table 4. Summary of studies included in the review of hand hygiene

Study	Study design	Study period	Population and setting	Transmission mode	Intervention	Outcome and finding
Azman AS, 2013 (8)	Cluster-RCT School level	Nov 2007–Apr 2008	3,360 students recruited from 10 elementary schools (Pittsburgh, USA)	Primary and secondary	Hand sanitizer, soap and education; control: receive no hand hygiene training	Primary transmission outcome refers to Stebbins, S. 2011 (9); no significant difference in secondary influenza-like-illness (ILI) attack rate between intervention group and control group
Levy JW, 2014 (10)	Cluster-RCT Household level	Jun 2009–Nov 2010	191 households with index children recruited from a public pediatric hospital (Bangkok, Thailand)	Secondary	Handwashing; handwashing and face mask ; control: receive no intervention	Fewer secondary influenza infections in households in the intervention group than control group, but not statistically significant; handwashing reduces surface influenza RNA contamination
Ram PK, 2015 (14)	Cluster-RCT Household level	Jan 2009–Dec 2010	384 households with index case-patients recruited from a hospital, among them, 60 index cases were laboratory-confirmed influenza infection (Kishoregoni, Bangladesh)	Secondary	Handwashing with soap and education; control: standard practice, no handwashing education	Handwashing promotion did not effectively prevent secondary influenza infection in household setting
Aiello AE, 2010 (18)	Cluster-RCT University residence hall level	Nov 2006–Mar 2007	1,437 university hall residents from 7 halls recruited, 1,297 residents were further analyzed (Michigan, USA)	Primary	Hand sanitizer, face mask and education; face mask and education; control: receive same education, but no additional intervention	The protective effect of interventions in reducing laboratory-confirmed influenza is not significant, but the interventions may be effective in ILI reduction
Aiello AE, 2012 (19)	Cluster-RCT University residence hall level	Nov 2007–Mar 2008	1,178 university hall residents recruited from 5 halls, 1,111 residents were further analyzed (Michigan, USA)	Primary	Hand sanitizer, face mask and education; face mask and education; control: receive same education, but no additional intervention	Reductions in the rates of influenza in the intervention groups, but results were statistically insignificant; combined intervention showed significant reduction in the rates of ILI
Cowling BJ, 2008 (12)	Cluster-RCT Household level	Feb 2007–Sep 2007	198 laboratory-confirmed influenza cases and their household contacts recruited from outpatient clinics (Hong Kong, China)	Secondary	Hand sanitizer and education; face mask and education; control: received same education but no additional interventions	No significant difference between intervention groups and control group in laboratory-confirmed influenza and clinical secondary attack rate
Cowling BJ, 2009 (11)	Cluster-RCT Household level	Jan 2008–Sep 2008	407 laboratory-confirmed influenza cases recruited from outpatient clinics, 259 households which included 794 household contacts were further analyzed (Hong Kong, China)	Secondary	Hand sanitizer and education; hand sanitizer, face mask and education; control: received same education but no additional interventions	Interventions prevent influenza transmission, but results were not statistically significant; combined intervention significantly reduce influenza transmission if implement within 36 h of symptom onset among index cases
Larson EL, 2010 (13)	Cluster-RCT Household level	Nov 2006–Jul 2008	617 households recruited, 509 households were further analyzed (New York, USA)	Primary	Hand sanitizer and education; hand sanitizer, face mask and education; control: receive same education,	No significant protective effect was detected of hand hygiene, or hand hygiene and face mask interventions on influenza prevention

Study	Study design	Study period	Population and setting	Transmission mode	Intervention	Outcome and finding
					but no additional intervention	
Simmerman JM, 2011 (15)	Cluster-RCT Household level	Apr 2008–Aug 2009	465 households recruited from a public pediatric hospital, 442 households were further analyzed (Bangkok, Thailand)	Secondary	Handwashing; handwashing and face mask ; control: received education that was unrelated to personal protective measures, but no additional interventions	Hand hygiene and face mask interventions did not reduce influenza transmission
Stebbins S, 2011 (9)	Cluster-RCT School level	Nov 2007–Apr 2008	3360 students recruited from 10 elementary schools (Pittsburgh, USA)	Primary	Hand sanitizer, soap and education; control: receive no hand hygiene training	"WHACK the Flu" programme did not reduce laboratory-confirmed influenza infection, but reduction of absence episodes and laboratory-confirmed influenza A infection was observed
Suess T, 2011 (16)	Cluster-RCT Household level	Nov 2009–Jan 2010 and Jan 2011–Apr 2011	84 laboratory-confirmed influenza cases and 218 household contacts recruited by general practitioners or pediatricians (Berlin, Germany)	Secondary	Hand sanitizer, face mask and infection prevention material; face mask and infection prevention material; control: receive same infection prevention material, but no additional intervention	The interventions could reduce influenza transmission in household setting if implemented early and used properly
Talaat M, 2011 (17)	Cluster-RCT School level	Feb 2008–May 2008	44,451 students recruited from 60 elementary schools (Cairo, Egypt)	Primary	Handwashing; control: receive no intervention	Hand hygiene campaign effectively reduced different kinds of infectious diseases, including laboratory-confirmed influenza

Appendix Table 5. GRADE quality assessment for hand hygiene

Quality assessment							No. patients		Effect		
No. of studies	Design	Risk for bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hand hygiene with or without face mask versus control		Risk ratio	Quality	Importance
Effect of hand hygiene intervention on prevention of laboratory-confirmed influenza											
10	Randomized trial[1,2]	No serious risk for bias[3–7]	Serious inconsistency[8]	Serious indirectness[9]	No serious imprecision[10]	None	434/6478 (6.7%)	504/5392 (9.3%)	Risk ratio cannot be generated because of high heterogeneity	Low	Important

[1]All studies were randomized trials.
[2]All studies were cluster-RCTs: six studies at household level, two studies at school level and two studies at university residence level.
[3]Five studies reported blinding of study staff including clinical staff, laboratory staff or recruiting physicians. Subjects of all studies were not blinded due to the nature of the study design.
[4]Three studies used block randomization and seven studies used simple randomization.
[5]Allocation concealment was adequate in all trials. Nine studies described the baseline characteristics of participants in all intervention groups. No serious baseline imbalance was observed.
[6]All studies reported the number of loss to follow-up in all intervention groups. No serious differential loss to follow-up occurred for whole clusters or individuals in a cluster.
[7]All studies adjusted for clustering in their analysis.
[8]High heterogeneity was observed in the pooled analysis (I^2 > 50%).
[9]Studies evaluating the combined intervention were included.
[10]Total sample size is sufficient for a single adequately powered study.

Respiratory Etiquette

Terminology

Relevant terminology relating to respiratory etiquette is shown as follows (Appendix Table 6):

Appendix Table 6. Definition of terms relevant to respiratory etiquette

Term	Definition
Respiratory etiquette	Respiratory etiquette is also known as 'cough etiquette' (*20*). It is a simple hygiene practice to prevent person-to-person transmission of respiratory infections. Measures include (*21*): 1. Cover the mouth and nose with a tissue or mask when coughing or sneezing 2. Dispose the used tissue or mask in the nearest waste basket immediately 3. Proper hand hygiene after touching respiratory secretions and/or contaminated objects

Search Strategy

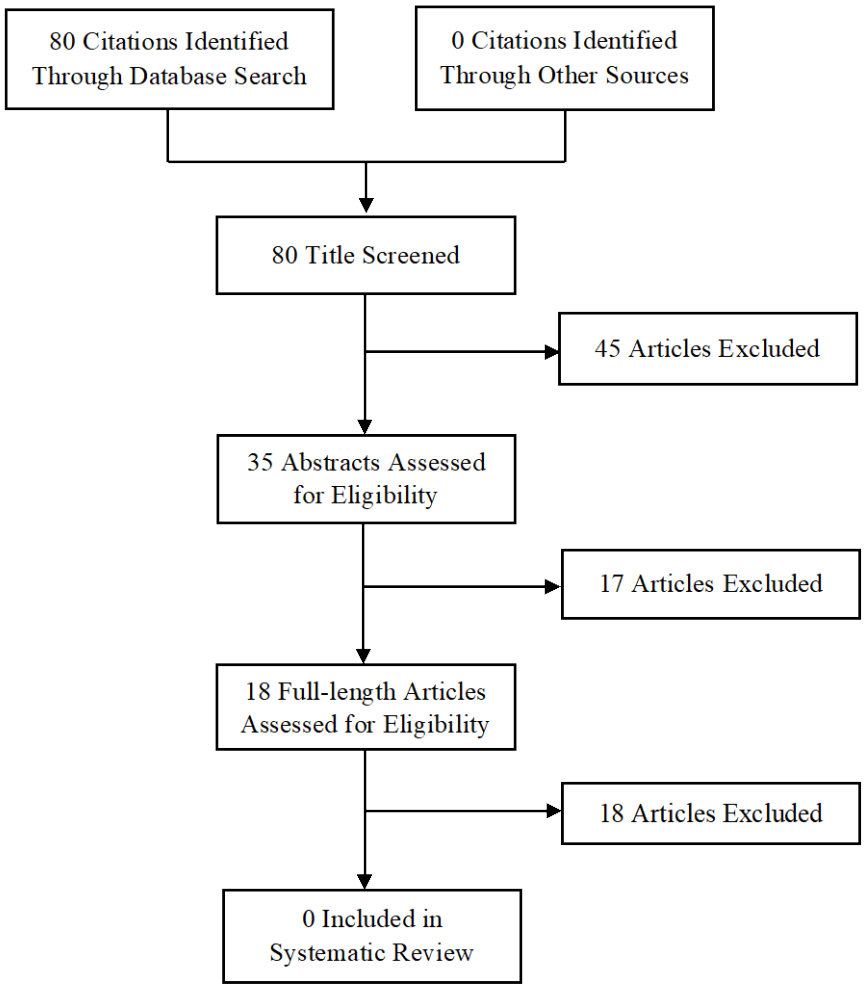
We conducted a literature search on 6 November 2018 using the following search terms (Appendix Table 7) in 4 databases (PubMed, Medline, EMBASE, and CENTRAL) to identify literatures that were available from 1946 through November 5, 2018. Studies were selected if they investigated specifically the use of respiratory/cough etiquette as the intervention along with the study outcome of laboratory-confirmed influenza virus infection. Studies that reported use of face mask as part of the respiratory etiquette were excluded because they will be covered in the next section. We reviewed literatures of all languages. Two reviewers (E.S. and S.G.) reviewed retrieved titles and subsequent relevant abstracts independently. Titles and abstract selected by any of the reviewers were included for subsequent screening. Both reviewers reviewed full-text and extracted data for selected studies independently. If a consensus was not reached, further discussion was held or opinion was obtained from a third reviewer.

Appendix Table 7. Search strategy for respiratory etiquette

Search terms	Search date	Reviewers
#1: "respiratory hygiene" OR "cough etiquette" OR "respiratory etiquette" #2: "influenza" OR "flu" #3: #1 AND #2	November 6, 2018	E.S., H.G.

Findings

Eighty articles were retrieved from 4 electronic databases after removing duplicate publications. A total of 35 abstracts were selected for screening and 18 full-text articles were assessed for eligibility. No studies were identified for this review to quantify the efficacy of respiratory etiquette with the outcome of laboratory-confirmed influenza. The flowchart is shown in Appendix Figure 7.



Appendix Figure 7. Flowchart of literature search and study selection for respiratory etiquette.

Face Masks

Terminology

Relevant terminology relating to face masks are shown as follows (Appendix Table 8):

Appendix Table 8. Definition of terms relevant to face masks

Types of masks	Terminology
Clothing, scarf, or rags tied over the nose and mouth	These are referred as alternative barriers to face mask s, but there is insufficient information available on their effectiveness on disease prevention (*22*).
Cloth mask	Cloth masks can be referred to "reusable masks made of cloth or any other fabric, including cotton, silk or muslin" (*23*). Filtration capacity is determined by the fitness of fabric and number of layers of a cloth mask (*23*). Cloth masks should be cleaned with household detergent thoroughly between each use (*24*).
Face mask	A face mask , also known as surgical, isolation, dental or medical procedure masks, is a loose-fitting, single-use disposable device that covers the mouth and nose of the user, and helps block large-particle droplets, splashes, sprays or splatter that may contain infectious agents (*25*). Face mask s may also help reduce exposure of user's saliva and respiratory secretions to others (*25*). They are not designed to protect against breathing in small-particle aerosols that may contain viruses.
Respirator	Respirator, also known as filtering facepiece respirator (FFR), is a personal protective device that covers the nose and mouth of the user, and helps reduce the risk for inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors on the user (*26*).

Types of masks	Terminology
	The National Institute for Occupational Safety and Health (NIOSH) in the United States certifies N, R and P series particulate filtering respirator types 95, 99 and 100 with minimum filtration efficiencies of 95, 99 and 99.97%, respectively. This certification is recognized by countries such as Canada, Mexico, and Chile. In Europe, respirators marked with 'Conformité Européen' (CE) such as FFP1 (class P1), FFP2 (class P2) and FFP3 (class P3) types meet minimum filtration efficiencies of 80, 94 and 99%, respectively (*27*).

Search Strategy

We conducted a literature search on July 28, 2018 by using the following search terms (Appendix Table 9) in 4 databases (PubMed, Medline, EMBASE, and CENTRAL) to identify literatures that were available from 1946 through July 26, 2018. Studies were selected if they were conducted in randomized controlled trial in community settings, such as households and schools, evaluated the use of face masks with or without the combination of other intervention as 1 intervention and included the incidence of laboratory-confirmed influenza case as a study outcome. We reviewed literatures of all languages. Two reviewers (E.S. and J.X.) reviewed retrieved titles and subsequent relevant abstracts independently. Titles and abstract selected by any of the reviewers were included for subsequent screening. Both reviewers reviewed full-text and extracted data for selected studies independently. If a consensus was not reached, further discussion was held or opinion was obtained from a third reviewer.

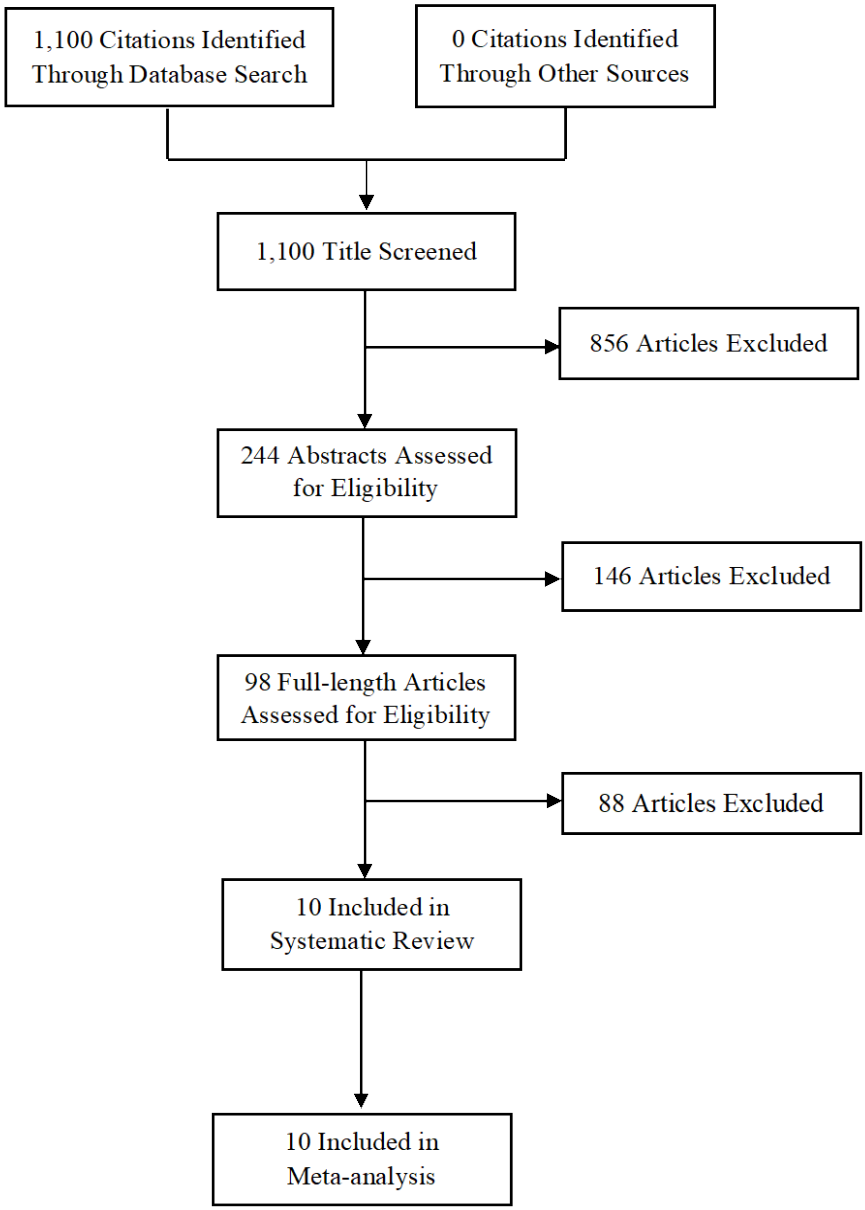
Appendix Table 9. Search strategy for face masks

Search terms	Search date	Reviewers
#1: "face mask " OR "face masks" OR "mask" OR "masks" OR "respirator" OR "respirators" #2: "influenza" OR "flu" #3: #1 AND 2	July 28, 2018	E.S., J.X.

Findings

A total of 1,100 articles were retrieved from four electronic databases after removing duplicate records. Ten relevant studies were identified for this review and metaanalysis to quantify the efficacy of community-based use of face mask s after excluding 89 articles by full-text assessment (Appendix Table 10). The flowchart is shown in Appendix Figure 8.

A total of 7/10 studies were conducted in household settings (*11–13*,*15*,*16*,*28*,*29*), with 2 studies conducted in university residential halls (*18*,*19*), and 1 study was conducted in Hajj pilgrims (*28*). Nearly half of the studies evaluated the effect of face mask use with the practice of hand hygiene, therefore results were analyzed in 2 groups *1*) comparison of control group with intervention group of face mask use only, and *2*) comparison of control group with intervention group of face mask use with or without hand hygiene (Appendix Figure 9).



Appendix Figure 8. Flowchart of literature search and study selection for face masks.

Among the 10 selected studies, two studies by MacIntyre et al. had a slightly different study design. One study enrolled families in which one person had laboratory-confirmed influenza, and only required the household contacts to wear face masks or P2 masks (equivalent to a N95 respirator) (*28*), whereas another study required only the ill members to wear face masks to evaluate the protective effect of face mask if worn by the ill individual (i.e., source control) (*29*). In the remaining 8 studies, every participant in the face mask intervention group was supposed to wear a face mask.

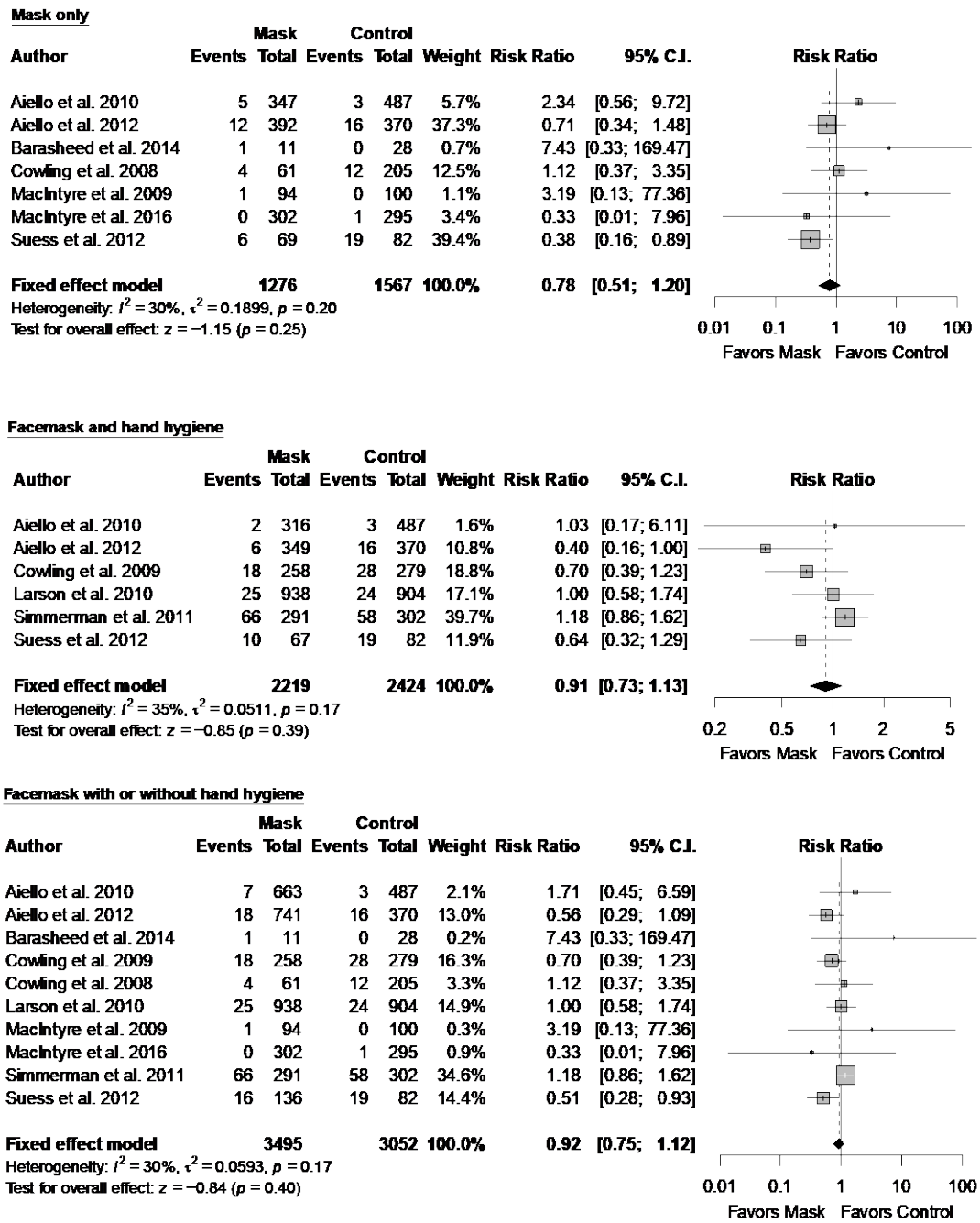
MacIntyre et al. compared the protective effect of face mask and P2 mask but they found no significant difference in ILI and laboratory-confirmed respiratory infections (influenza A and B virus, RSV, hMPV, adenovirus, PIV, coronavirus, rhinovirus, enterovirus, picornovirus); however, they reported a significant reduction in ILI if the mask was worn with good compliance in a secondary analysis (*28*).

Two studies by Aiello et al. were conducted in residential hall settings evaluating the effectiveness of face masks as a primary protection (*18,19*). They randomized university residents by cluster (each residential hall forming a cluster unit) to face masks, enhanced hand hygiene, or both. They then measured the incidence of laboratory-confirmed influenza in students in each hall. They reported no significant difference in ILI and laboratory-confirmed influenza in these three randomized groups; however, they observed a significant reduction in ILI in the combined face mask and hand hygiene intervention group during the latter half of the study period in a secondary analysis.

Seven studies were conducted in household settings where a person with laboratory-confirmed influenza was recruited as a household index case and the rate of secondary infections in the education group (control), mask group or hand hygiene group was monitored for illnesses and infections (*11–13,15,16,28,29*). All studies found no significant differences in the rate of laboratory-confirmed influenza virus infections in contacts in the face mask arms, and some studies reported that low compliance of the use of NPIs could affect the results (*13*). One study reported a significant reduction in laboratory-confirmed influenza virus infections in contacts in the face mask and hand hygiene group in the subset of households where the intervention was applied within 36 hours of symptom onset in the index case (*16*).

Ten studies were pooled to conduct a metaanalysis to quantify the efficacy of community-based use of face masks in the reduction of laboratory-confirmed influenza virus infection (*11–13,15–19,28–30*). In the pooled analysis, there was a nonsignificant RR reduction of 22% (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25) in the face mask group and 8% in the face mask group regardless of the enhanced hand hygiene (RR 0.92, 95% CI 0.75–1.12; I^2 = 30%, p = 0.40) (Appendix Figure 9).

Appendix Table 11 shows the results of quality assessment of evidence on face mask intervention by using the GRADE approach.



Appendix Figure 9. Metaanalysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza.

Appendix Table 10. Summary of studies included in the review of face masks

Study	Study design	Study period	Population and setting	Intervention	Outcome and finding
Aiello AE, 2010 (18)	Cluster-RCT University residence hall level	Nov 2006–Mar 2007	1437 university hall residents recruited, 1297 residents were further analyzed (Michigan, USA)	Hand sanitizer and face mask and education; face mask and education; control received the same education because all intervention groups but no additional interventions were given	Significant reduction in ILI in the latter half of the study period in mask and hand hygiene group compared with the control but no significant reduction in ILI in mask and hand group or mask-only group or control
Aiello AE, 2012(19)	Cluster-RCT University residence hall level	Nov 2007–Mar 2008	1,178 university hall residents recruited from 5 halls, 1,111 residents were further analyzed (Michigan, USA)	Hand sanitizer and face mask and education; face mask and education; control received the same education because all intervention groups but no additional interventions were given	No significant reduction in rates of laboratory-confirmed influenza in mask and hand group or mask-only group or control group
Barasheed O, 2014 (30)	Cluster-RCT Hajj pilgrimage	Nov 2011–Nov 2011	164 Australian pilgrims recruited from 2011 Hajj (Saudi Arabia)	Face mask; control were not provided with face mask s during the study period	No significant difference in laboratory-confirmed influenza between control and mask-only group but protective effect was observed against syndromic ILI in mask-only group compared with the control (31% vs. 53%, p = 0.04)
Cowling BJ, 2008 (12)	Cluster-RCT Household level	Feb 2007–Sep 2007	198 laboratory-confirmed influenza cases and their household contacts recruited from outpatient clinics (Hong Kong, China)	Hand sanitizer and education; face mask and education; control received same education because all intervention groups but no additional interventions were given	No significant reduction in the secondary influenza attack rate in control, mask or hand group
Cowling BJ, 2009 (11)	Cluster-RCT Household level	Jan 2008–Sep 2008	407 laboratory-confirmed influenza cases recruited from outpatient clinics, 259 households which included 794 household contacts were further analyzed (Hong Kong, China)	Hand sanitizer and education; hand sanitizer, face mask and education; control received same education because all intervention groups but no additional interventions were given	No significant difference in rates of laboratory-confirmed influenza in control, hand-only or mask and hand group
Larson EL, 2010 (13)	Cluster-RCT Household level	Nov 2006–Jul 2008	617 households recruited, 509 households were further analyzed (New York, NY, USA)	Hand sanitizer and education; hand sanitizer, face mask and education; control received same education because all intervention groups but no additional interventions were given	No significant reduction in rates of laboratory-confirmed nfluenza in control, hand-only, mask or hand group
MacIntyre CR, 2009 (28)	Cluster-RCT Household level	Aug 2006–Oct 2006 and Jun 2007–Oct 2007	145 laboratory-confirmed influenza cases and their adult household contacts recruited from a pediatric health service (Sydney, Australia)	Surgical mask; P2 mask; control were not provided with any masks during the study period	No significant difference in rate of laboratory confirmed influenza in control, face mask-only or P2 mask-only group
MacIntyre CR, 2016 (29)	Cluster-RCT Household level	Nov 2013–Jan 2014	245 ILI cases and 597 household contacts recruited from fever clinics	Face mask; control were not provided with any masks during the study period	Clinical respiratory illness, ILI and laboratory-confirmed viral infections were lower in the mask-only group

Study	Study design	Study period	Population and setting	Intervention	Outcome and finding
			(Beijing, China)		compared with the control group, but results were not statistically significant
Simmerman JM, 2011) (15)	Cluster-RCT Household level	Apr 2008–Aug 2009	465 households recruited from a public pediatric hospital, 442 households were further analyzed (Bangkok, Thailand)	Handwashing; handwashing and face mask; control received education that was unrelated to personal protective measures and no additional interventions were given	No significant reduction in rate of secondary influenza infection in control, hand-only, mask or hand group
Suess (2012) (16)	Cluster-RCT Household level	Nov 2009–Jan 2010 and Jan 2011–Apr 2011	84 laboratory-confirmed influenza cases and 218 household contacts recruited by general practitioners or pediatricians (Berlin, Germany)	Hand sanitizer and face mask; face mask; control were not provided with any face masks nor hand-rub during the study period	No significant difference in rate of laboratory confirmed influenza in control, mask-only, mask or hand group

Appendix Table 11. GRADE quality assessment for face masks

Quality assessment							No. of patients		Effect		
No. studies	Design	Risk for bias	Inconsistency	Indirectness	Imprecision	Other considerations	Face mask with or without hand hygiene	versus control	Risk ratio (95% CI)	Quality	Importance
Effect of face mask intervention on prevention of laboratory-confirmed influenza											
10	Randomized trial[1,2]	No serious risk for bias[3–7]	Serious inconsistency[8]	Serious indirectness[9]	No serious imprecision[10]	None	156/3495	161/3052	0.92 (0.75–1.12)	Low	Important

[1]All studies were randomized trials.
[2]All studies were cluster-RCTs: two studies at university residence level, seven studies at household level and one study randomized by sleeping tent during Hajj pilgrim.
[3]Eight studies reported blinding of study staffs including clinical staff, laboratory staff or recruiting physicians. Subjects of all studies were not blinded.
[4]Three studies used block randomization; six studies used computer program to generate the randomization order and one study used ticket-picking for selection.
[5]Allocation concealment was adequate in all trials. Eight studies described the baseline characteristics of participants in all intervention groups. No serious baseline imbalance was observed.
[6]All study reported the number of loss to follow-up in all intervention groups. No serious differential loss to follow-up occurred for whole clusters or persons in a cluster.
[7]Seven studies adjusted for clustering in their analysis.
[8]Moderate heterogeneity was observed in the pooled analysis.
[9]Studies evaluating the combined intervention were included.
[10]Total sample size is insufficient in the pooled analysis.

Surface and Object Cleaning

Terminology

Relevant terminology relating to surface and object cleaning is shown as follows (Appendix Table 12):

Appendix Table 12. Definition of terms relevant to surface and object cleaning

Term	Definition
Surface and object cleaning	Routine cleaning of frequently used surfaces and objects to reduce influenza transmission.

Search Strategy

We conducted a literature search on October 15, 2018 by using the following search terms (Appendix Table 13) in 4 databases (PubMed, Medline, EMBASE, and CENTRAL) to identify literature that was available from 1946 through October 14, 2018. Study selection criteria are studies reporting the effect of surface and object cleaning intervention compared with no intervention in preventing influenza virus infections in community settings. There were no limitations on the types of cleaning techniques. Randomized controlled trials and other types of epidemiologic studies were included if they evaluated the effect of surface and object cleaning on laboratory-confirmed influenza, ILI or respiratory illness. Simulation studies, recommendations, and commentaries/editorials were excluded. We reviewed literatures of all languages. Two reviewers (J.X. and E.S.) reviewed retrieved titles and subsequent relevant abstracts independently. Titles and abstract selected by any of the reviewers were included for subsequent screening. Both reviewers reviewed full-text and extracted data for selected studies independently. If a consensus was not reached, further discussion was held or opinion was obtained from a third reviewer.

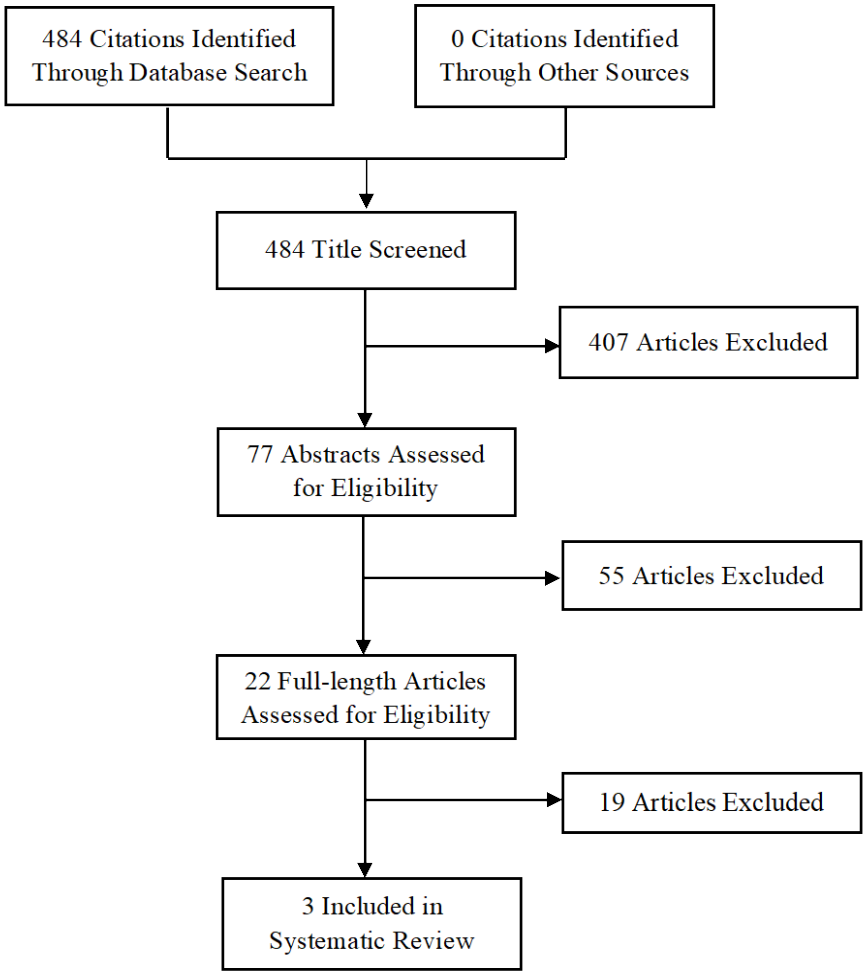
Appendix Table 13. Search strategy for surface and object cleaning

Search terms	Search date	Reviewers
#1: “surface” OR “surfaces” OR “object” OR “objects” OR “fomite” OR “fomites” OR “environment” OR “environmental”	October 15, 2018	J.X., E.S.
#2: “clean” OR “cleans” OR “cleaning” OR “cleanse” OR “cleansing” OR “disinfect” OR “disinfects” OR “disinfection” OR “disinfecting” OR “wipe” OR “wipes” OR “sanitize” OR “sanitizes” OR “sanitizing” OR “sanitation” OR “sterilize” OR “sterilizes” OR “sterilizing” OR “sterilization” OR “sterilise” OR “sterilises” OR “sterilising” OR “sterilisation” OR “decontaminate” OR “decontaminates” OR “decontaminating” OR “decontamination”		
#3: “influenza” OR “flu”		
#4: #1 AND #2 AND #3		

Findings

We identified 484 reviews through the search, of which 462 reviews were removed during title and abstract screening. We further excluded 19 articles after full text assessment because

they did not specify the surface or object cleaning as the study intervention or respiratory infections as the study outcome. Three articles were included in the systematic review to study the effectiveness of surface and object cleaning to prevent influenza infection. The flowchart is shown in Appendix Figure 10.



Appendix Figure 10. Flowchart of literature search and study selection for surface and object cleaning.

A cross-sectional study showed that bleach use in households was associated with a statistically significant increase in self-reported influenza based on self-administered questionnaires. The authors, however, did not specify the definition of influenza illness and they also hypothesized that the increase of cases might be due to the immunosuppressive properties of bleach (*31*). A randomized controlled trial with disinfection of toys and linen in day care nurseries reported a reduction in the detections of viruses in the environment, but no significant

reduction was observed on influenza-related and other acute respiratory-related illnesses among children (*32*). Another randomized controlled trial conducted in elementary schools demonstrated that hand hygiene with alcohol-based hand sanitizer and surface disinfection with quaternary ammonium wipes intervention could reduce gastrointestinal illness absenteeism, but not respiratory illness absenteeism (*32*). Detailed study description is shown in Appendix Table 14.

Appendix Table 14. Summary of studies included in the review of surface and object cleaning

Study	Study design	Study period	Population and setting	Intervention	Outcome measures	Main findings
Casas L, 2015 (30)	Cross-sectional study	Apr 2008–Dec 2010	9,102 students from schools (Spain, Netherlands and Finland)	Not intervention. Environment cleaning with bleach versus no use of bleach	Self-reported influenza	Passive contact with cleaning bleach in the household might increase the risk for respiratory and other infections in children, which might have an adverse effect on school-age children's health
Ibfelt T, 2015 (31)	Cluster-RCT	Autumn 2012–Apr 2013	12 d-care nurseries caring for 587 children (Copenhagen, Denmark)	Disinfection of toys; control: receive no intervention	Respiratory infections and surface sample influenza virus detection	Frequent disinfection of toys could reduce the presence of environmental microbial, but not significantly reduce respiratory illness of nursery children
Sandora TJ, 2008 (32)	Cluster-RCT	Mar 2006–May 2006	285 students from elementary schools (Ohio, USA)	Hand hygiene and surface cleaning; control: usual baseline practice, no additional intervention	Respiratory illness	Surface disinfection could reduce gastrointestinal-related absenteeism among school-age children, but not respiratory-related illness

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RESEARCH ARTICLE

Effect of distributing locally produced cloth facemasks on COVID-19-like illness and all-cause mortality–a cluster-randomised controlled trial in urban Guinea-Bissau

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Abstract

Facemasks have been employed to mitigate the spread of SARS-CoV-2. The community effect of providing cloth facemasks on COVID-19 morbidity and mortality is unknown. In a cluster randomised trial in urban Bissau, Guinea-Bissau, clusters (geographical areas with an average of 19 houses), were randomised to an intervention or control arm using computer-generated random numbers. Between 20 July 2020 and 22 January 2021, trial participants (aged 10+ years) living in intervention clusters (n = 90) received two 2-layer cloth facemasks, while facemasks were only distributed later in control clusters (n = 91). All participants received information on COVID-19 prevention. Trial participants were followed through a telephone interview for COVID-19-like illness (3+ symptoms), care seeking, and mortality for 4 months. End-of-study home visits ensured full mortality information and distribution of facemasks to the control group. Individual level information on outcomes by trial arm was compared in logistic regression models with generalised estimating equation-based correction for cluster. Facemasks use was mandated. Facemask use in public areas was assessed by direct observation. We enrolled 39,574 trial participants among whom 95% reported exposure to groups of >20 persons and 99% reported facemasks use, with no difference between trial arms. Observed use was substantially lower (~40%) with a 3%, 95%CI: 0–6% absolute difference between control and intervention clusters. Half of those wearing a facemask wore it correctly. Few participants (532, 1.6%) reported COVID-19-like illness; proportions did not differ by trial arm: Odds Ratio (OR) = 0.81, 95%CI: 0.57–1.15. 177 (0.6%) participants reported consultations and COVID-19-like illness (OR = 0.83, 95%CI: 0.56–1.24); 89 participants (0.2%) died (OR = 1.34, 95%CI: 0.89–2.02). Hence, though trial participants were exposed to many people, facemasks were mostly not worn or not worn correctly. Providing facemasks and messages about correct use did not substantially increase their use and had limited impact on morbidity and mortality.

Trial registration: clinicaltrials.gov: NCT04471766.

of Public Health (INASA) and the Bandim Health Project, access to data will granted when covered by an ethical permission and approved the data access committee consisting of the director of INASA, the steering board of the Bandim Health Project and key researchers involved in the study. The Guinean Ethics Committee (Comité Nacional de Ética em Pesquisa na Saúde) can be contacted at nabangna.julho2009@gmail.com or djicoblama@gmail.com.

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Introduction

Facemasks have been one of the tools employed in the attempt to mitigate the spreading of SARS-CoV-2, based on the assumption that they would a) prevent transmission of the infection to others and b) protect the wearer against becoming infected [1]. Furthermore, it has been proposed that facemasks could reduce the inhaled viral load, and thereby reduce disease severity [2]. The use of facemasks is not a stand-alone intervention but has been advised and used in addition to other interventions, such as physical distancing, improved hygiene, and later vaccines.

The guidelines for facemask use have differed across settings and situations. In April 2020, WHO did not recommend the use of facemasks outside health care settings for the general public [3], by June 2020 the WHO guidelines included information on settings where the public could be recommended to wear a non-medical facemasks [4], and by December 2020, the WHO guidelines recommended wearing facemasks indoor, and in settings where physical distancing could not be sustained [5].

During the early phases of the pandemic, a global shortage of medical facemasks limited their availability [6]. Production of reusable facemasks using more readily available materials, such as fabric, was therefore widespread and in many settings recommended [7].

There was little empirical evidence for the effectiveness of medical facemasks or cloth facemasks in community settings. Ten trials that have assessed the effect of facemasks on preventing influenza infections yielded variable results [8] and only observational studies had assessed the effects of facemasks against COVID-19 and other corona viruses [9]. These studies suggested a potential beneficial effect of wearing facemasks in clinical settings, and to a lesser extent, and based on fewer studies, also in a community setting [9]. Thus, in the absence of data from trials, recommendations on facemasks were based on precautionary principles [1] and on extrapolation from efficacy studies.

The permeability of the different facemask materials has been studied [10,11], but the ability of the facemask to protect the wearer and surroundings also depends on the fit of the facemask [12]. Important to the effectiveness is also whether the use of a facemask alters the behaviour of the wearer and the surroundings: It has been hypothesised both that the use of facemasks could affect the behaviour of carriers and their surroundings making them more careful [13] or take more risks [14], and that facemask use would increase or decrease the risk of transmitting virus via fomites due to increased/decreased touching of the face [15].

Reusable cloth facemasks constitute a low-cost and sustainable preventive measure, which could potentially help mitigate the impact of COVID-19, especially in resource constrained settings where physical distancing is particularly difficult. However, so far, no studies have assessed the effect of facemask use on preventing infectious transmission in an African setting. We conducted a cluster-randomised trial to assess the impact of providing two 2-layer cloth facemasks and messages on preventive measures versus messages only for all individuals over the age of 10 years in an urban African setting during the COVID-19-pandemic. The outcomes were self-reported COVID-19-like illness, health care contacts for COVID-19-like illness and all-cause mortality during 4 months of follow-up.

Materials and methods

Setting

The facemask trial was conducted using the Bandim Health Project's (BHP) urban Health and Demographic Surveillance System (HDSS) in Guinea-Bissau. Since 1978, the BHP has monitored the health and survival of the population in suburbs of the Guinean capital, Bissau.

Today the urban BHP HDSS covers six districts with 37 zones and 324 geographically defined clusters (mean number of houses/cluster: 19) and a population of approximately 100,000 individuals of whom 73,500 are over 10 years of age (Fig A in S1 Text).

The first case of SARS-CoV2 infection in Guinea-Bissau was registered on March 25, 2020. When we initiated the trial in July 2020, a total of 1949 cases had been detected by PCR-test which were the only tests available. During the period of enrolment, the number increased to 2510 and 4 months later it was 3751 [16]. However, only a small proportion of the SARS-CoV-2 infections were likely detected: among 140 staff at BHP who were tested for antibodies in November 2020, 18% were IgG positive, but only 3 of the 25 persons with serological evidence of prior SARS-CoV2 infection reported having had a PCR test performed [17]. Facemask-use was mandated in Guinea-Bissau throughout the trial starting from May 11, 2020 [18] with the police intermittently enforcing the use on streets and in market areas [19,20]. Curfews were implemented and enforced to different extents from March 2020 until 26 June 2020 [21] and had thus ceased before trial start. COVID-19 vaccination in Guinea-Bissau started in April 2021 [22].

Study design and randomisation

The facemask trial was conducted in 20 zones with 182 clusters in three of the BHP districts: Cuntum-II, Bandim-I and Bandim-II. Clusters were randomised 1:1 to the intervention or the control group stratified by zone, using a computer algorithm to draw a random combination of clusters. To ensure balanced groups regarding key co-variates (population size, age distribution and households with functioning electricity), we used covariate-constrained randomisation (Supplementary Methods in S1 Text). The trial was unblinded.

All households in the included study area were visited during the day. A list of all residents $\geq$10 years of age was extracted from the BHP database. Field assistants verified and updated the list with new residents, migrations, and deaths. All household members aged $\geq$10 years in the study areas were eligible for enrolment. Provided oral consent, household members were enrolled and the enrolling field assistant documented consent on the enrolment form. If any household member $\geq$10 years of age was temporarily absent, a relative could accept enrolment on their behalf. For individuals under 18 years of age, we asked for a guardian's oral consent. The oral consent was used to maintain physical distance and described in the study protocol submitted for ethics evaluation.

During the visit, we updated the information on the socioeconomic variables related to household characteristics (type of roof, porch, source of water supply) and collected up to two telephone numbers for each household member in both the intervention and control group. In addition, we updated the information on sleeping arrangements (room and bed for each person) and whether the household had an indoor ceiling presumed to be a risk factors for infection in multi-family houses [23].

Intervention

Intervention and control households were provided with the key messages given in the country for prevention of COVID-19. These messages included frequent hand washing with soap, sanitizer or bleach solution, physical distancing (1 m apart), and avoiding crowds, hand shaking and kissing. The messages were short and communicated with pictures (Fig C in S1 Text).

Upon enrolment, each study participant in the intervention households received two cloth facemasks. The field assistant instructed the participants to use them each time they went out or when they were in close contact with many individuals not from the household. Furthermore, intervention group participants were instructed to wash the facemask with warm water

and soap before every use, and not to touch the facemask (Fig C in S1 Text). No facemasks were provided to participants in the control group at enrolment; they received one cloth facemask at the end of the study (Fig D in S1 Text). Group allocation was not concealed at enrolment.

The facemasks were locally produced in four sizes (small, medium, large, extra-large) based on a model developed at the University of Southern Denmark (Supplementary Methods in S1 Text). The facemasks had two layers of woven cotton fabric and a metal wire at the nose bridge to maintain a close fit. They were held in place by two horizontal elastic straps, one worn across the back of the head and the other across the back of the neck. When worn correctly, the facemask covered the lower half of the face from the nasal root to under the chin and jaw (Fig E in S1 Text) and provided a close fit even during movement. Based on laboratory measurements, the facemask cloth fabric was found to filter 19% of 0.4 μm particles (salt) and 11% of 0.6 μm particles (paraffin oil). It should be noted that the size of aerosols of a sneeze containing SARS-CoV-2 is larger [10] (~3 μm; Supplementary Methods in S1 Text).

Assessment of outcomes. Participants were followed up through telephone calls 4 months after enrolment. We had intended more frequent follow-up calls (every 2 months) but were unable to implement this for all participants for logistical reasons (Supplementary Methods in S1 Text).

During the telephone follow-up calls, individual-level information was collected on the four prespecified primary outcomes; self-reported COVID-19-like illness (defined as three or more of the following symptoms of COVID-19: fever, cough, fatigue, shortness of breath, loss of sense of smell/taste) and/or reported positive test (PCR-test performed by health personnel), consultation with COVID-19-like illness, severe COVID-19-like illness (defined as hospitalisation or death), and all-cause mortality. Information on these outcomes was obtained by asking the participant or guardian (for children <18 years of age), whether the participant, since enrolment, had experienced any episodes of illness, including any of the listed COVID-19 symptoms and/or other symptoms and had sought consultation, been hospitalised, or died. If the participant was absent, relatives in the same compound or neighbours were interviewed. Except for self-reported COVID-19-like illness, for which we had not collected information on date of the episode, only events occurring within 4 months (121 days) of enrolment were included in the analyses.

Information about potential exposure to SARS-CoV-2 was collected at the telephone interviews by asking whether participants attended any event(s) with 20 or more people not living with the participant or had been in contact with a person with COVID-19. Information on past exposure was not collected for individuals who had died. For the compliance sub-study, a field assistant was stationed in different clusters (outside, 2 hours of observation per session) to observe facemask use by counting the number of people in the vicinity and among those, the number of people wearing a facemask (Supplementary Methods in S1 Text).

All participants received a home visit after the telephone call after 4 months of follow-up to ensure that we had complete information on vital status for all enrolled participants, and to distribute facemasks to participants in the control group (Fig D in S1 Text).

Sample size

With an anticipated 90% acceptance rate, we expected to be able to enrol around 19,290 in each randomisation group in the study area. Based on the estimated number of enrolments within each cluster and assuming a baseline mortality risk of 1%, and a uniform mortality distribution of 0.5–1.5%, we estimated an 80% power to demonstrate an effect of the intervention if the true mortality reduction by the intervention was 27% (alpha = 0.05). For more frequent

outcomes we would have power to show smaller effects: for example, for illness (anticipated baseline rate 10%, uniform variation 5–15%), we estimated an 80% power to show a reduction if the real effect was a 10% reduction.

Statistical analyses

Primary analysis. Analyses were based on individual level data. We compared the proportion of individuals reporting a study outcome by group allocation using logistic regression models with generalised estimating equation (GEE)-based correction for cluster, robust standard error, and an exchangeable correlation matrix. We adjusted the estimates for zone (as the randomisation was stratified by zone) and the balancing variables: number of people living in the cluster, proportion of individuals aged ≥50 years and proportion of households with functioning electricity (Supplementary Methods in S1 Text). No adjustment was made for multiple testing. All analyses were made on the study population receiving facemasks according to their randomisation arm. Observations with missing information on the outcome were excluded from the analyses.

Secondary analyses. We investigated whether the effect of facemask distribution varied by potential effect modifiers identified as important for the severity of COVID-19, exposure to SARS-CoV-2 or for the effect of facemasks in prior studies; sex [24,25], age [26], and having an indoor ceiling (yes/no), attending events with ≥20 persons, reported contact with a person with COVID-19, number of children <10 years registered in household, and number of people sleeping in the same room. We compared self-reported and observed facemask compliance by group.

Sensitivity analyses. For the morbidity outcomes (COVID-19-like illness and consultation), we investigated whether the proportions differed for participants who received two telephone follow-up interviews (at both 2 and 4 months after enrolment) and those who received only one follow-up call. We did so by including an 'intensity of follow-up'-variable as a potential effect modifier.

Furthermore, due to delays in implementing the follow-up visits, we investigated whether extending the period of follow-up from 4 months to the date of the telephone interview/home visit affected the conclusions. During 2020 and 2021, Guinea-Bissau experienced three waves of COVD-19 infections during which the risk of COVID-19 was higher (Fig D in S1 Text); 1) before 1 October 2020, 2) 1 January—1 April 2021, and 3) after 1 July 2021. We generated a continuous measure of the proportion of follow-up time within these high-exposure periods and explored whether the effect varied by exposure.

In explorative analyses, we assessed whether conclusions differed when the morbidity analyses were limited to the observations where a) the participant provided information themselves, b) the participant was present at enrolment, and c) the participant was registered in the HDSS before enrolment. Furthermore, for reported morbidity outcomes, we assessed the impact of adjusting for time elapsed between enrolment and first successful follow-up call (number of days after 6 weeks). Finally, to compare mortality registered during the trial with the pre-trial mortality, we estimated the crude annual mortality rate among persons aged 10 + years under surveillance in the same zones in 2013–2019.

Ethics

Our trial protocol was approved by the Guinean National Ethics Committee (Comité Nacional de Ética na Saúde, reference: 79/CNES/INASA/2020). The explanations to participants included information on social distancing and hygiene and it was stressed that wearing a facemask, was complementary to other measures of protection. BHP field assistant used individual

protection (facemask, hand sanitizer) and maintained physical distance. Enrolment was initiated in parallel with the production of facemasks; the production pace was the limiting factor for enrolment and facemask distribution.

Role of the funding source

The funders had no role in study design, data collection, analysis, writing of the report or decision to submit the paper for publication.

Results

Between 20 July 2020 and 22 January 2021, we enrolled 39,688 trial participants among 39,721 eligible residents in the study area (Fig 1). In total, 8712 households in 181 of the eligible 182 clusters took part in the trial; 90 clusters in intervention arm and 91 in in the control arm. Enrolment in intervention and control clusters took place in parallel (Fig G in S1 Text). The median age at enrolment was 27 years. Most enrolled people shared a bedroom with at least one other trial participant. Though some of the background factors differed statistically significantly between the trial arms, the absolute differences were small (Table 1). However, more new residents were registered at the enrolment visit in the intervention arm (2126) than in the control arm (1447) (Fig 1, Supplementary Results in S1 Text).

114 persons were excluded due to protocol violations (control group receiving facemask: 92, intervention group not receiving facemask: 22) retaining 39,574 persons to be followed (Fig 1). We made 60,677 telephone calls and succeeded in obtaining information through telephone calls for 33,306 persons (84%; intervention: 16,779 (84%), control: 16,527 (84%) (Fig 1, Table A in S1 Text)). The median time elapsed between enrolment and the first successful call was 227 days, interquartile range (IQR): 104–246 with slightly shorter intervals in the intervention (210 days, IQR: 85–241) than control arm (231 days, IQR: 150–250). For 37% of the successful calls, the trial participants provided information for themselves (intervention: 39%, control 36%; $p<0.001$) (Table A in S1 Text). Among the trial participants with successful follow-up calls, 5% (1518/33,306) reported to have had a COVID-19 test performed, but only 24 of these tests (1.6%) were reported positive.

All individuals were also visited at home to ensure full information on survival and to confirm deaths registered through the telephone interviews. Ninety-seven percent (intervention 97%; control 98%) were still registered to be living in the study area 121 days after enrolment and 7 people (intervention: 3; control: 4) were lost to follow-up (Fig 1).

Most participants (95%) reported exposure to large groups of people (events with $\geq$ 20 people from outside their household) and the majority (90%) reported the events as frequent/recurring, such as attending school, going to the marked or going to work. The absolute differences between the intervention and control groups were small (Table A in S1 Text).

In both groups, 92% reported to use a facemask whenever leaving home. An additional 7% reported facemask use sometimes. The type of facemask used differed by study arm: 55% of the intervention group (63% among those providing information on facemask type) reported wearing cloth facemasks, while this was 22% (33%) in the control group. In contrast, the use of a medical facemasks was more common in the control group, 44% (among those with information on type: 67%) than in the intervention group 36% (37%) (Fig 2 and Table A in S1 Text). In the compliance sub-study, the observed facemask use was much lower than reported through the telephone follow-up: only 40% of individuals were observed to wear a facemask with little difference between observations made in the intervention and control areas (Fig 3). Adjusting for calendar time, an additional 3%, 95%CI: 0–6% of people observed in the intervention zones wore facemasks (Supplementary Results in S1 Text). Only half of the facemask

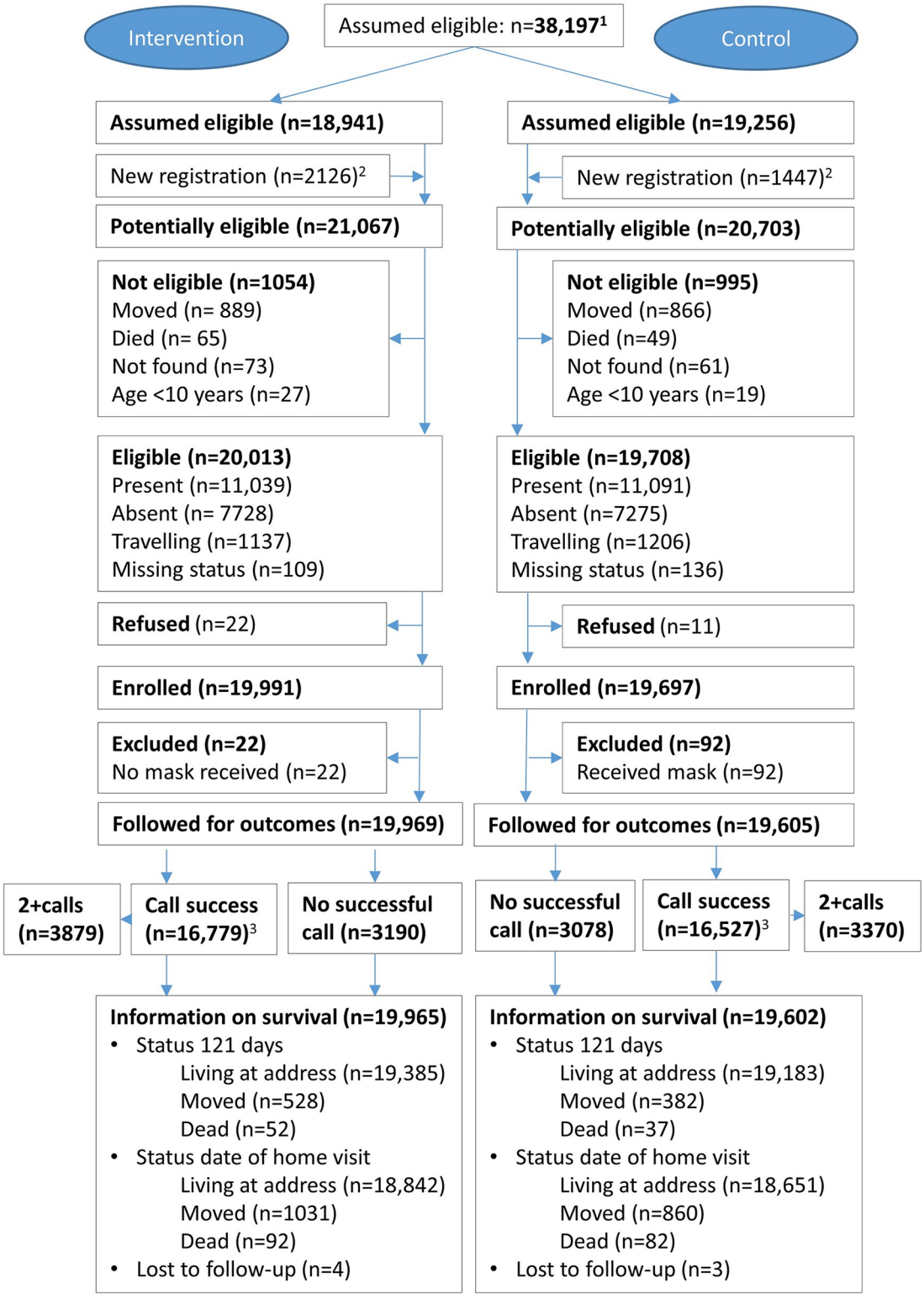


Fig 1. Participant flow in the Guinea-Bissau Face Mask trial. Notes: 1: Registered in the Bandim Health and Demographic Surveillance System before visit to enrol; 2: Added to population list during enrolment visit; 3: Participants with successful telephone calls contributing to the analysis for the main outcome "COVID-19-like-illness".

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Table 1. Baseline characteristics according to group allocation.

	Intervention [n, (%)]	Control [n, (%)]	P-value, test of same distribution[a]
Number	19969 (50)	19605 (50)	
Number of households	4428 (51)	4284 (49)	
Males	9384 (47)	9224 (47)	0.91
Age (years), median (IQR)[b]	27 (19–38)	27 (19–39)	0.44
District			0.01
Bandim-I	10477 (52)	10465 (53)	
Bandim-II	4794 (24)	4452 (23)	
Cuntum-II	4698 (24)	4688 (24)	
Number of people sleeping in same room, median (IQR)	2 (2–3)	2 (2–3)	0.001
Socio-economic factors (compared on household level)			
Type of roof[c]			0.08
Straw	14 (0)	18 (0)	
Zink	4221 (98)	4128 (98)	
Tiles	58 (1)	36 (1)	
Cement	10 (0)	17 (0)	
Other	1 (0)	0 (0)	
Type of veranda[c]			0.31
Mosaic	466 (11)	447 (11)	
Cement	3636 (85)	3595 (86)	
Stamped soil	184 (4)	154 (4)	
Has ceiling[d]	1478 (35)	1437 (35)	0.77
Type of water source[c]			<0.001
Tap inside	773 (18)	699 (17)	
Tap outside	2723 (64)	2841 (68)	
Small private well	431 (10)	308 (7)	
Public well	331 (8)	311 (7)	
Functioning electricity in household (family-level)[e]	629 (61)	670 (63)	0.25
Intention to use mask[c]			
Yes	11,400 (58)		
No	9 (0)		
Don't know	8380 (42)		
Intention of when to use mask[c]			
When leaving house	8775 (78)		
Often	2426 (22)		
Reason for mask use refusal[c]			
Not able to wear a mask	2 (29)		
Prefers medical mask	4 (57)		
Can't explain why	1 (14)		

a: Test of same distribution using chi2 for categorical variables and rank-sum tests for continuous variables

b: One person (control) with missing information on age

c: Numbers do not add up due to some having missing information

d: No information on ceiling for 305 households (189 intervention, 126 control)

e: Accessed for households with a registered birth in the last 5 years, thus missing information for 6619 households (3394 intervention; 3225 control).

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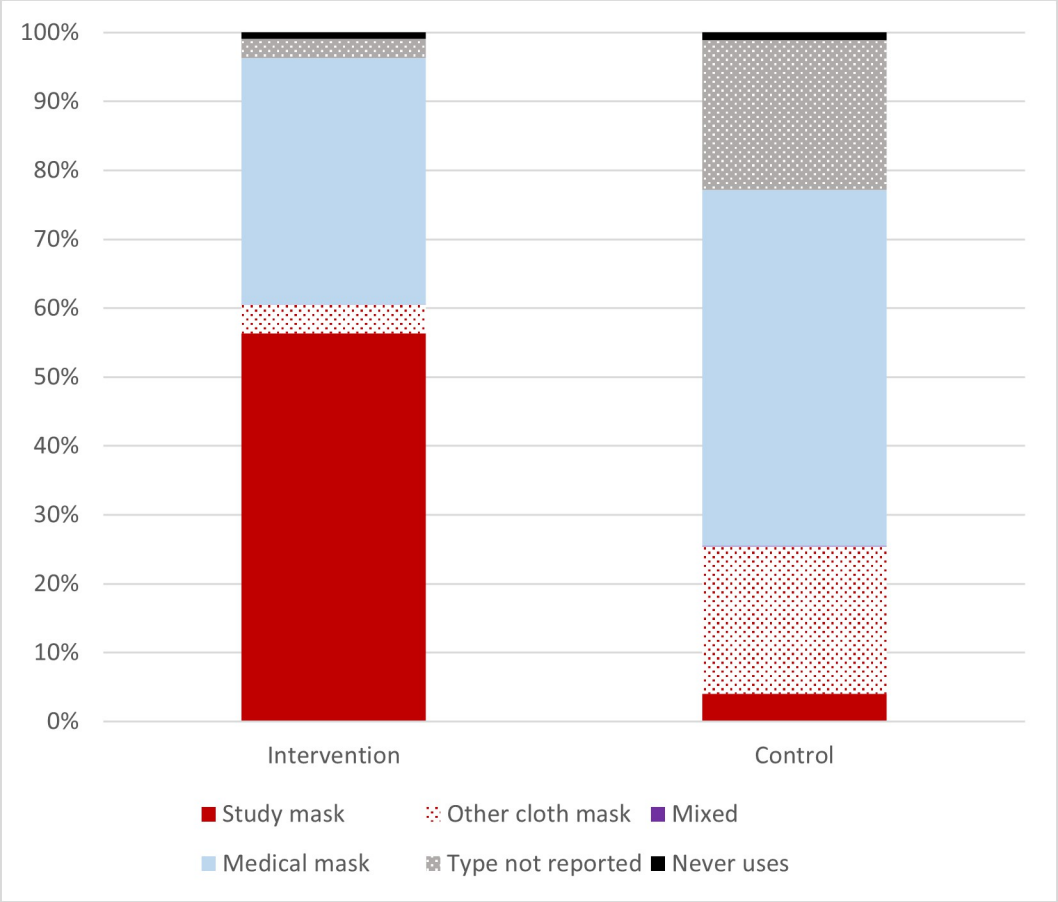


Fig 2. Mask use reported through telephone follow-up.

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wearers wore facemasks which covered both nose and mouth (Supplementary Results and Fig H in S1 Text).

Among the 33,406 participants followed-up through the telephone interviews there were a total of 532 episodes of COVID-19-like illness (intervention: 244 (1.45%); control: 288 (1.74%)). There was no statistically significant difference by group: OR: 0.81, 95%CI: 0.57–1.15 (Fig 4 and Table 2). Every third episode of COVID-19-like illness (intervention: 82 (0.51%); control: 95 (0.60%)) was accompanied by a consultation within the 4 months of follow-up, with no difference between the trial arms resulting in an OR of 0.83, 95%CI: 0.56–1.24 (Fig 4 and Table 2). We registered only 11 hospital admission within 4 months of follow-up among participants with COVID-19-like illness (intervention: 8, control: 3; OR = 3.21, 95%CI: 1.10–9.39). Only one of the admissions (intervention) was reported to have been diagnosed as COVID-19 (Supplementary Results in S1 Text). There were 89 deaths during the 4 months of follow-up, 52 (0.26%) in the intervention group and 37 in the control group (0.19%), OR = 1.34, 95%CI: 0.89–2.02 (Fig 4 and Table 2).

The analyses of the investigated effect modifiers did not indicate that a potential effect varied significantly by sex or age (Table 2, Fig 4 and Table B in S1 Text). Nor did the effect differ by factors potentially associated with COVID-19 exposure and there was no consistent pattern across the different indicators of exposure (Table B in S1 Text).

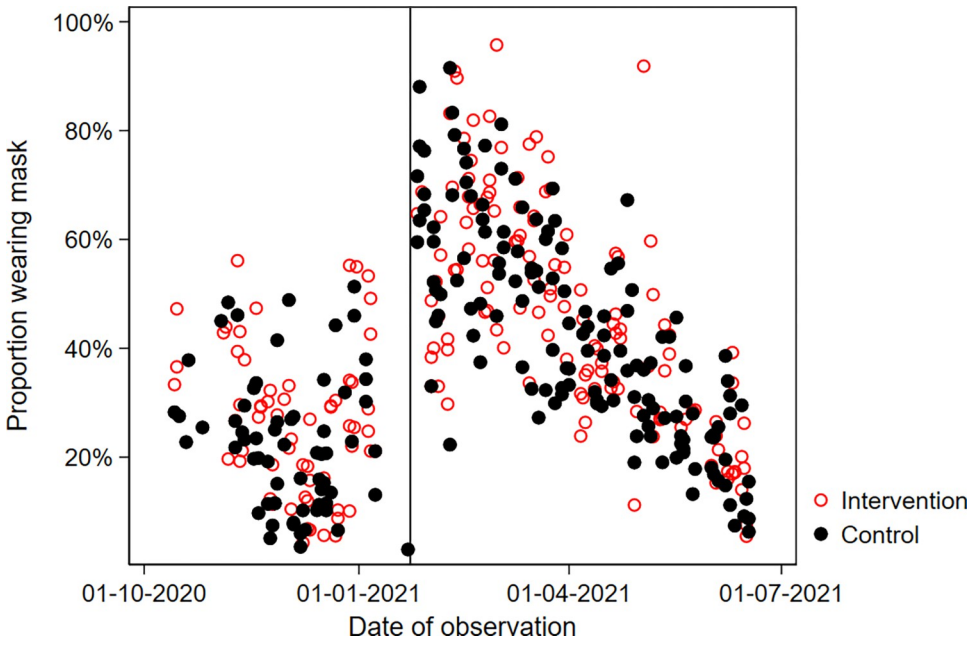


Fig 3. Direct observations. Proportion of individuals observed wearing a face mask during each 2-hour observation session. Note: Vertical line indicates January 22, 2021, when a sudden change in observed facemask use occurred.

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Extending the follow-up period for consultations with COVID-19-like symptoms to the time of the telephone interview, half the reported episodes with COVID-19-like illness led to consultation. The OR was 0.84, 95%CI: 0.56–1.25 overall, 0.97, 95%CI: 0.61–1.56 for men and 0.70, 95%CI: 0.43–1.13 for women (Table C in S1 Text). Extending the mortality analysis to

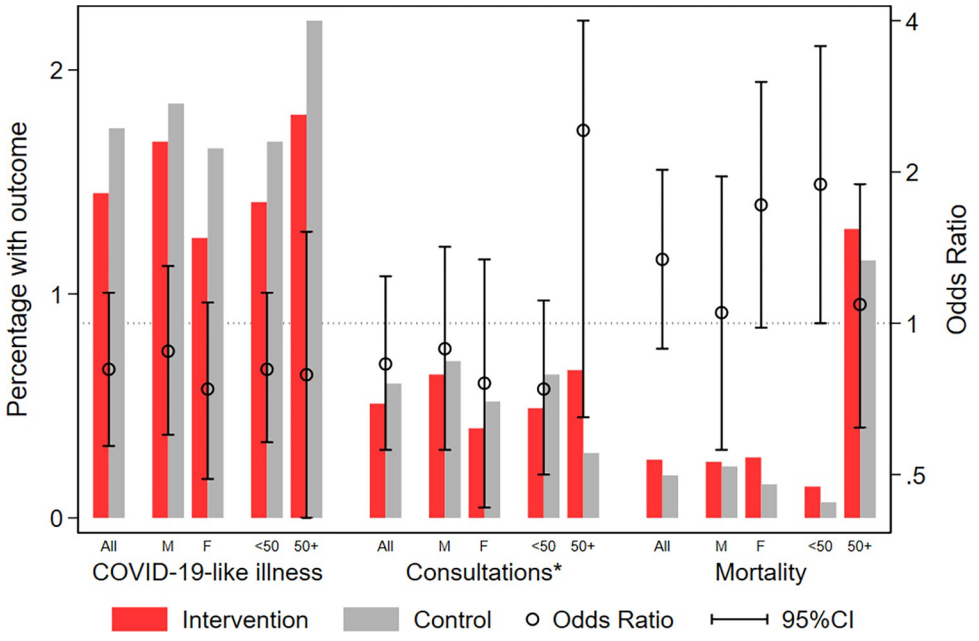


Fig 4. Effect of providing cloth face masks on self-reported COVID-19-like illness, consultations and mortality. Note: *Concurrent report of consultations and COVID-19-like illness.

https://doi.org/10.1371/journal.pgph.0002901.g004

Table 2. Effect of providing cloth face masks on self-reported Covid-19-like illness, consultations and mortality.

		Intervention [% (events/n)]	Control [% (events/n)]	OR (95%CI)[a]	P-value test of same effect across strata
Self-reported COVID-19-like illness					
Overall		1.45 (244/16779)	1.74 (288/16527)	0.81 (0.57–1.15)	
Sex	Male	1.68 (132/7837)	1.85 (143/7748)	0.88 (0.60–1.30)	0.34
	Female	1.25 (112/8942)	1.65 (145/8779)	0.74 (0.49–1.10)	
Age	<50 years	1.41 (213/15056)	1.68 (248/14724)	0.81 (0.58–1.15)	0.90
	> = 50 years	1.80 (31/1723)	2.22 (40/1803)	0.79 (0.41–1.52)	
Health centre/outpatient consultations for COVID-19-like illness during 4 months of follow-up					
Overall		0.51 (82/16009)	0.60 (95/15764)	0.83 (0.56–1.24)	
Sex	Male	0.64 (48/7507)	0.70 (52/7439)	0.89 (0.56–1.42)	0.63
	Female	0.40 (34/8502)	0.52 (43/8325)	0.76 (0.43–1.34)	
Age	<50 years	0.49 (71/14354)	0.64 (90/14041)	0.74 (0.50–1.11)	0.08
	> = 50 years	0.66 (11/1655)	0.29 (5/1723)	2.42 (0.65–9.02)	
All-cause mortality during 4 months of follow-up					
Overall		0.26 (52/19965)	0.19 (37/19602)	1.34 (0.89–2.02)	
Sex	Male	0.25 (23/9382)	0.23 (21/9224)	1.05 (0.56–1.96)	0.26
	Female	0.27 (29/10583)	0.15 (16/10378)	1.72 (0.98–3.02)	
Age	<50 years	0.14 (26/17957)	0.07 (13/17523)	1.89 (1.00–3.56)	0.20
	> = 50 years	1.29 (26/2008)	1.15 (24/2079)	1.09 (0.62–1.89)	

a: Estimated in logistic regression models with generalised estimating equation-based correction for cluster. Adjusted for zone and the cluster balancing variables: number of people, proportion aged ≥50 years and proportion of households with functioning electricity.

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the date of the home visit, there were 92 deaths in the intervention arm and 82 in the control arm, the OR for the intervention/control groups being 1.09, 95%CI: 0.83–1.43 overall, 0.86, 95%CI: 0.58–1.26 for men and 1.43, 95%CI: 0.93–2.18 for women (Table C in S1 Text).

The proportions reporting COVID-19-like illness and consultations were substantially higher for participants who were called two or more times, than for participants called only once during the follow-up period: COVID-19-like illness: ~5 times as high; consultations: 4–10 times as high dependent on period of assessment (Table D in S1 Text). The effects of face-mask distribution did not differ by follow-up intensity, and we observed the same tendency of a beneficial effect for women but not for men (Table D in S1 Text).

The 37% percent of trial participants who provided information on their own behalf during the telephone follow-up, reported 79% (418/532) of the episodes with COVID-19-like illness and 75% (132/177) of the consultations within 4 months of enrolment. However, limiting the morbidity analyses to this group meant little for the estimated effects overall or by sex (Table E in S1 Text).

The proportion of follow-up time during the higher SARS-CoV2-transmission periods varied from 24–74% during the period of enrolment (Fig J in S1 Text). The effect did not markedly differ by whether more or less than 50% of follow-up time was in high transmission periods (Table F in S1 Text).

The explorative analyses limiting the analysis to participants who were registered in the HDSS prior to the enrolment visit and to participants who were present on the date of enrolment did not alter conclusions (Table G in S1 Text). Adjusting for time elapsed between enrolment and first successful follow-up call gave very similar results: COVID-19-like illness, OR = 0.81, 95%CI: 0.57–1.16; consultation: OR = 0.84, 95%CI: 0.56–1.25.

The crude pre-trial mortality in the same zones and age group was 7.50 per 1000 person years (Supplementary Results in S1 Text).

Discussion

In this first trial of the effect of facemask distribution in an African setting, we found no statistically significant effect on the proportion reporting COVID-19-like illness, seeking consultations for illness or mortality. However, we also found that distributing facemasks and providing information on their use was insufficient to ensure high facemask use. The proportions reporting COVID-19-like morbidity and consultations were much lower than anticipated, and we found indications that we have substantially underestimated the morbidity burden. Nevertheless, even for mortality, where we are confident that we have obtained full information, the rates were much lower than anticipated, potentially indicating that the impact of COVID-19 on the population was less than feared.

By performing the trial in the context of the BHP HDSS, we ensured that we could follow participants after enrolment, limiting the loss to follow-up. Measuring several outcomes does however increase the risk of detecting spurious associations. By cluster-randomising, we aimed to be able to measure the effect on a population level. However, clusters were very close to each other (Fig A in S1 Text), and even if distributing facemasks had greatly reduced the risk of transmission, that effect would also affect the neighbouring clusters. Indeed, in the direct observations performed at public spaces situated in or at the edges of the clusters, we observed little difference between the use of trial facemasks. Thus, people observed passing through the areas were likely from a mix of intervention and control clusters, and hence measuring a potential differential use becomes problematic. Furthermore, in contrast to when we planned the trial, facemask use was mandated in Guinea-Bissau throughout the trial period. Thus, the information on use obtained through the telephone follow-up is likely influenced by social desirability bias. Nevertheless, the facemask mandates likely increased the mask-use in both the intervention and control group and may have meant that we have been comparing an intervention group who (at times) used the provided cloth facemasks, with a control group who were more likely to use medical facemasks. However, it should be noted that medical facemasks were not worn as single-use facemasks but often reused, presumably due to the high cost [27].

While we have high quality and complete information on mortality, we detected very few cases of COVID-19-like illness, with only 1.5% of participants reporting an episode. Our analyses showed higher proportions of events when called with a shorter recall period, hence the recall periods were clearly too long to provide a full picture. Furthermore, a poorer recall on behalf of other household members (~5 times lower proportion), was also evident. Nevertheless, as the conclusions did not change when restricting the analyses to information being provided by the participant or adjusting for recall period, this should not affect the relative comparison.

COVID-19-like illness was based on symptoms compatible with SARS-CoV2 infection, but the symptoms overlap with other infections. Hence, in addition to the low sensitivity described above, the specificity is not likely to be high: In Bangladesh, approximately 26% of persons with recent symptoms of COVID-19-like illness had serological evidence of past infection [26]. Nevertheless, a large proportion of the Guinean population has likely had COVID-19 [17].

Two other randomised trials have now assessed the effects of wearing facemasks. In Denmark, an individually randomised trial, hence not designed to assess the effect of facemasks on transmission, showed no overall effect of facemasks on the proportion having a SARS-CoV-2 infection during 1 month of follow-up (OR = 0.82, 95%CI: 0.54–1.23) [28]. However, a potential beneficial effect may have been present for women (OR = 0.65, 95%CI: 0.38–1.12) but not for men (OR = 1.12, 95%CI: 0.59–2.12) [28]. Self-reported mask-use (predominantly or fully as recommended) in the intervention group was 93%, but there was no observation of actual use [28]. In Bangladesh, 600 villages with a population of 342,183 were randomised to an

intervention or control group. In the intervention group, facemasks (surgical or cloth) were distributed and interventions to increase facemask use during the 8-week follow-up period were implemented. The combined intervention increased observed facemask wearing from 13% to 42% while facemask use was promoted but it dropped to baseline levels 3 months after the facemask use promoting activities stopped [26]. There was an 11.6%, 95%CI: 6.6–16.6% lower incidence of COVID-19-like illness during follow-up and during the end of trial survey, 9.5%, 95%CI: 0.5–18.5% fewer participants in the intervention group (0.68%) reported episodes of COVID-19-like illness and had COVID-19 antibodies than in the control group (0.76%) [26]. The Bangladeshi trial reports stronger benefits for medical facemasks than for cloth facemasks, however facemask type appeared to be less important for women (who also wore facemasks more frequently) than for men. Thus, the Bangladeshi trial showed a COVID-19-protective effect of facemasks at the community level.

Mortality was not assessed in the trial in Bangladesh [26]. Though mortality in our trial tended to be higher in the intervention than in control group (OR = 1.34, 95%CI: 0.89–2.02 with 4 months of follow-up and OR = 1.09, 95%CI: 0.83–1.43 with the extended follow-up), it should be noted that mortality registered at the enrolment visits also tended to be higher in the intervention than in the control group (Fig 1 and Supplementary Results in S1 Text). Nevertheless, the overall mortality was not higher than during the prior years. The 89 deaths among the 39,657 participants translates to approximately 6.7 per 1000 person years, while annual mortality among individuals in the same area in 2013–19 was 7.5 per 1000 person years. There is little empirical data on all-cause mortality in Africa during the pandemic [29]. Hence most African mortality estimates are based on models [29,30].

Substantially higher reported than observed facemask use also been seen in Kenya [31] and in Bangladesh [26], limiting the usefulness of information on reported use.

Providing free cloth facemasks to the study population in a context with mandated facemask use did not increase the reported or observed facemask wearing substantially. While our results are compatible with reductions in COVID-19-like illness, the confidence intervals are wide. As indicated by the secondary and explorative analyses, our results are also compatible with a potential benefit on mask distribution on morbidity for females. It could be speculated that women are more compliant with facemask use recommendations, have different exposure intensities or that different infectious doses are necessary to cause illness. However, the under-reporting impairs our ability to measure a potential effect. Furthermore, according to the information reported during the follow-up calls, the control group was more likely to wear a medical facemask, which may have provided better protection against COVID-19 [26]. If anything, the indicators of severe morbidity, the hospitalisation and mortality data, indicated that the risk was higher in the intervention group.

The facemask trial was conducted prior to vaccines being available in Guinea-Bissau and the preventive measures included physical distancing, avoiding large groups of people and improved hygiene. As indicated by the follow-up calls, compliance with the advised avoidance of crowds was low. Such recommendations are difficult to follow in a setting where at least one household member must go to the market every day and working from home is not possible. Thus, participants were presumably widely exposed to SARS-CoV-2. However, as interactions take place outside buildings, people are exposed to lower virus doses. This supports that the partial protection from wearing a facemask could be clinically important [32].

There is still very limited empirical data on overall mortality during the pandemic based on community data from Africa. Though our trial covers only a narrow time window, it suggests that the impact of COVID-19 on the overall mortality may have been less severe than feared. Hence, as also shown in other African HDSS sites [33,34], the lower death toll in some African settings cannot be fully explained by lack of data.

Conclusions

Providing free facemasks and messages about their correct use did not substantially increase facemask use in the context of mandated use in urban Guinea-Bissau. While the point estimates for COVID-19-like illness are similar to prior trials, the facemask distribution had no statistically significant effect on the risk of COVID-19-like-illness, consultations or mortality.

Supporting information

S1 Text. Supplementary Methods, Supplementary Results, Fig A-J, Tables A-G.
(DOCX)

S1 Protocol.
(PDF)

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PLOS ONE

RESEARCH ARTICLE

Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial

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Abstract

Background

In this large-scale cluster-randomized controlled trial (cRCT) we sought to assess the effectiveness of facemasks against viral respiratory infections.

Methods and results

Over three consecutive Hajj seasons (2013, 2014, 2015) pilgrims' tents in Makkah were allocated to 'facemask' or 'no facemask' group. Fifty facemasks were offered to participants in intervention tents, to be worn over four days, and none were offered to participants in control tents. All participants recorded facemask use and respiratory symptoms in health diaries. Nasal swabs were collected from the symptomatic for virus detection by reverse transcription polymerase chain reaction. Clinical symptoms and laboratory results were analyzed by 'intention- to-treat' and 'per-protocol'. A total of 7687 adult participants from 318 tents were randomized: 3864 from 149 tents to the intervention group, and 3823 from 169 tents to the control group. Participants were aged 18 to 95 (median 34, mean 37) years, with a male to

analysis, decision to publish, or preparation of the manuscript.

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female ratio of 1:1.2. Overall, respiratory viruses were detected in 277 of 650 (43%) nasal/pharyngeal swabs collected from symptomatic pilgrims. Common viruses were rhinovirus (35.1%), influenza (4.5%) and parainfluenza (1.7%). In the intervention arm, respectively 954 (24.7%) and 1842 (47.7%) participants used facemasks daily and intermittently, while in the control arm, respectively 546 (14.3%) and 1334 (34.9%) used facemasks daily and intermittently. By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections (odds ratio [OR], 1.4; 95% confidence interval [CI], 0.9 to 2.1, p = 0.18) nor against clinical respiratory infection (OR, 1.1; 95% CI, 0.9 to 1.4, p = 0.40). Similarly, in a per-protocol analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections (OR 1.2, 95% CI 0.9–1.7, p = 0.26) nor against clinical respiratory infection (OR 1.3, 95% CI 1.0–1.8, p = 0.06).

Conclusion

This trial was unable to provide conclusive evidence on facemask efficacy against viral respiratory infections most likely due to poor adherence to protocol.

Introduction

Viral respiratory infections are a major public health burden, causing serious disease especially in vulnerable populations. Influenza-associated lower respiratory tract disease alone causes over 54 million infections per year, eight million cases of severe illness, and 145,000 deaths across all age groups [1]. Ever-increasing and faster international travel intensifies the transmission of respiratory infections, especially in the setting of mass gatherings such as Hajj pilgrimage in Makkah [2]. The rites of Hajj are performed over five or six days, beginning on the eighth day and ending on the thirteenth day of the last month of the Islamic calendar. Coming from over 180 countries pilgrims converge on Makkah to join a procession of two to three million people who perform a series of physically demanding rituals. Such religious and other mass gatherings amplify the transmission of respiratory viruses by up to eight times [3] and may even accelerate the progression of a pandemic as occurred during the 2009 influenza A (H1N1) pandemic following the Iztapalapa Passion Play mass gathering in Mexico in April 2009 [4]. The current outbreak of coronavirus disease 2019 (COVID-19) is an example of how travel accelerates the spread of respiratory viral infection [5].

Non-pharmacological interventions, such as facemask use, and hand washing have been used to complement pharmacological measures in the prevention and control of viral respiratory infections at mass gatherings with no documented efficacy [6]. There is clinical and experimental evidence that surgical masks and respirators reduce transmission of drug-resistant tuberculosis and influenza from infected patients [7, 8], but randomized trials examining the effectiveness of facemasks against viral respiratory infections in household, community or healthcare settings have been either conflicting or inconclusive [9–15], though at least one randomized controlled trial has suggested protection against influenza by facemasks and hand washing, if applied early after exposure [13].

Inadequate sample size is thought to be an important cause of this discrepancy [16–18]. Therefore we designed a large cluster-randomized controlled trial (cRCT) over three years among pilgrims at Hajj to evaluate the efficacy of facemasks against laboratory-confirmed viral

respiratory infections. The rationale of the cluster design was to increase administrative efficiency.

Methods

Trial design

Our study was an open label cRCT conducted during Hajj in Mina, Greater Makkah, Saudi Arabia among pilgrims from Saudi Arabia, Australia and Qatar over three Hajj seasons, 2013 to 2015. Mina is an uninhabited valley at the outskirts of Makkah and has about 30,000 tents to accommodate pilgrims for up to five days as part of Hajj rituals. Generally, 50 to 150 pilgrims occupy each large tent, allocated by gender and country of origin, but tents with a much smaller number also exist. Pilgrims in each tent sleep close to each other, head-to-head, have meals and perform rites together hence are considered a cluster. A pilot trial was conducted among Australian pilgrims in 2011 to examine the feasibility of such a study and inform power calculations [19]. Following the Consolidated Standards of Reporting Trials (CONSORT) guidelines (S1 Checklist) for cRCTs participants in respective tents were allocated to intervention or control group as per the trial protocol (S2 Appendix) [20, 21]. Our null hypothesis was that facemask use, according to protocol, does not protect from viral respiratory diseases.

Ethical approval for this study was obtained in Saudi Arabia from the Institutional Review Board of King Abdullah Medical City, Makkah, (IRB Ref. No.: 15–205), in Australia from the Hunter New England Human Research Ethics Committee (Reference No: 13/07/17/3.04), and in Qatar from the Joint Institutional Review Board of Hamad Medical Corporation/Weill Cornell Medical College (Ref: 13–00039).

Procedure

Hajj pilgrims aged $\geq$18 years from participating countries, staying in allocated tents and able to provide signed informed consent were included. Pilgrims aged $<$18 years, or $\geq$18 who had a known contraindication to mask use, had participated in another randomized trial investigating a medical intervention, refused or were unable to sign the consent were excluded.

Agreement was secured from 318 Hajj tour group leaders for 346 tents, occupied by pilgrims from Saudi Arabia, Qatar and Australia to facilitate the study. The randomization unit of this trial was the accommodation tent. We planned to stratify the randomization by country and gender. Although per protocol computer-generated random number allocation by an offsite research coordinator had been planned, this proved impractical in this field study due to poor internet/mobile phone network at the study sites. Because real-time, effective and smooth communication with the offsite research coordinator responsible for random allocation generation was not possible, coin-tossing by an individual who was not a member of the research team (i.e., a fellow pilgrim who was not a participant in the trial, a tour operator or a medical volunteer at Hajj who was not a study team member) was used. As the intervention of wearing a facemask was visible to participants and investigators, the trial could not be blinded; laboratory staff could be, and were blinded to the intervention.

Trained research team members approached adult pilgrims aged 18 years or older in their assigned tents and explained the study in detail on the first day of each Hajj (October 13th 2013, October 2nd 2014 and September 22nd 2015). Individual research team members were assigned about 15 participants from the first day of Hajj. The researchers gave pilgrims an information sheet and answered their queries. Written informed consent was obtained from pilgrims who agreed to participate in the study. As per the study design, no minor, i.e., person under 18 years of age, was recruited in this study. All participants were asked to complete a baseline questionnaire and were provided with a health diary (S1 Appendix) in their preferred

language (Arabic or English) which they were to fill out daily during the trial. Each participant was identified with a unique barcode number on their consent form, baseline questionnaire, health diary and any clinical specimens taken. A post-Hajj diary (S1 Appendix) for an additional three days was planned but a negligible return rate prevented this information being included in the analysis.

The consent forms and the baseline questionnaires were collected on day one, whereas participants retained diaries for completion over the next four days of Hajj rituals while they were being actively followed (Fig 1).

Each participant in the intervention group was provided with 50 surgical facemasks (3M™ Standard Tie-On surgical mask, Cat No: 1816) as well as verbal and printed instructions and demonstration of appropriate facemask usage (S1 Appendix). Pilgrims in the control group were not provided with facemasks and instructions but could use their own masks if they chose to do so. All pilgrims in both study arms were asked to record their facemask usage (including number of masks used and hours worn each study day) in their health diary daily for four consecutive days. Although facemasks were to be worn for 24 hours daily per protocol if possible, for the analysis, pilgrims who used at least one facemask each day during Hajj were considered to have used a facemask during that day, counter to the planned design.

Measures

As the primary objectives of our trial were to assess the role of facemasks in preventing the acquisition of laboratory-confirmed viral respiratory infections and symptomatic respiratory infection, first primary endpoint was the efficacy of facemasks against laboratory-confirmed viral respiratory infections, and the second primary endpoint was the efficacy of facemasks against clinical respiratory infections in participants.

A total of 464 volunteer researchers were trained by the principal investigators before the study period. Training activities included how to approach pilgrims, the trial processes, explanation and demonstration of facemask use, data collection, follow-up, and sample collection and storage. Study team members were oriented to good clinical practice guidance for the conduct of clinical trials according to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

The research team visited the study tents twice daily during the study period to ask if the participants developed respiratory or systemic symptoms and collected a nasal swab (FLOQSwabs™; COPAN Diagnostics Inc., Murrieta, CA) from those who developed subjective fever together with one respiratory symptom, or two or more respiratory symptoms without fever. Swabs were placed it into UTM™ (COPAN) viral transport media. Swabs labelled with the participant's unique barcode number were stored in an icebox at –20˚C before being re-stored by day's end in a –80˚C freezer at the laboratory of the Hajj Research Center at Umm Al-Qura University, Makkah. After Hajj, these swabs were shipped in refrigerated or cold containers to the Centre for Infectious Disease and Microbiology Laboratory Services, Westmead Hospital, NSW, Australia. There, nucleic acid was extracted with the Qiagen bioROBOT EZ instrument (Qiagen, Valencia, CA), and amplification was performed using the Roche LC 480 (Roche Diagnostics GmbH, Mannheim, Germany) instrument. Respiratory viruses were detected using a real-time, multiplex reverse transcription polymerase chain reaction assay targeting human coronaviruses (OC43, 229E and NL63), influenza A and B viruses, respiratory syncytial virus (RSV), parainfluenza viruses 1–3, human metapneumovirus, rhinovirus, enterovirus and adenovirus as described elsewhere [22, 23]. Middle East respiratory syndrome coronavirus

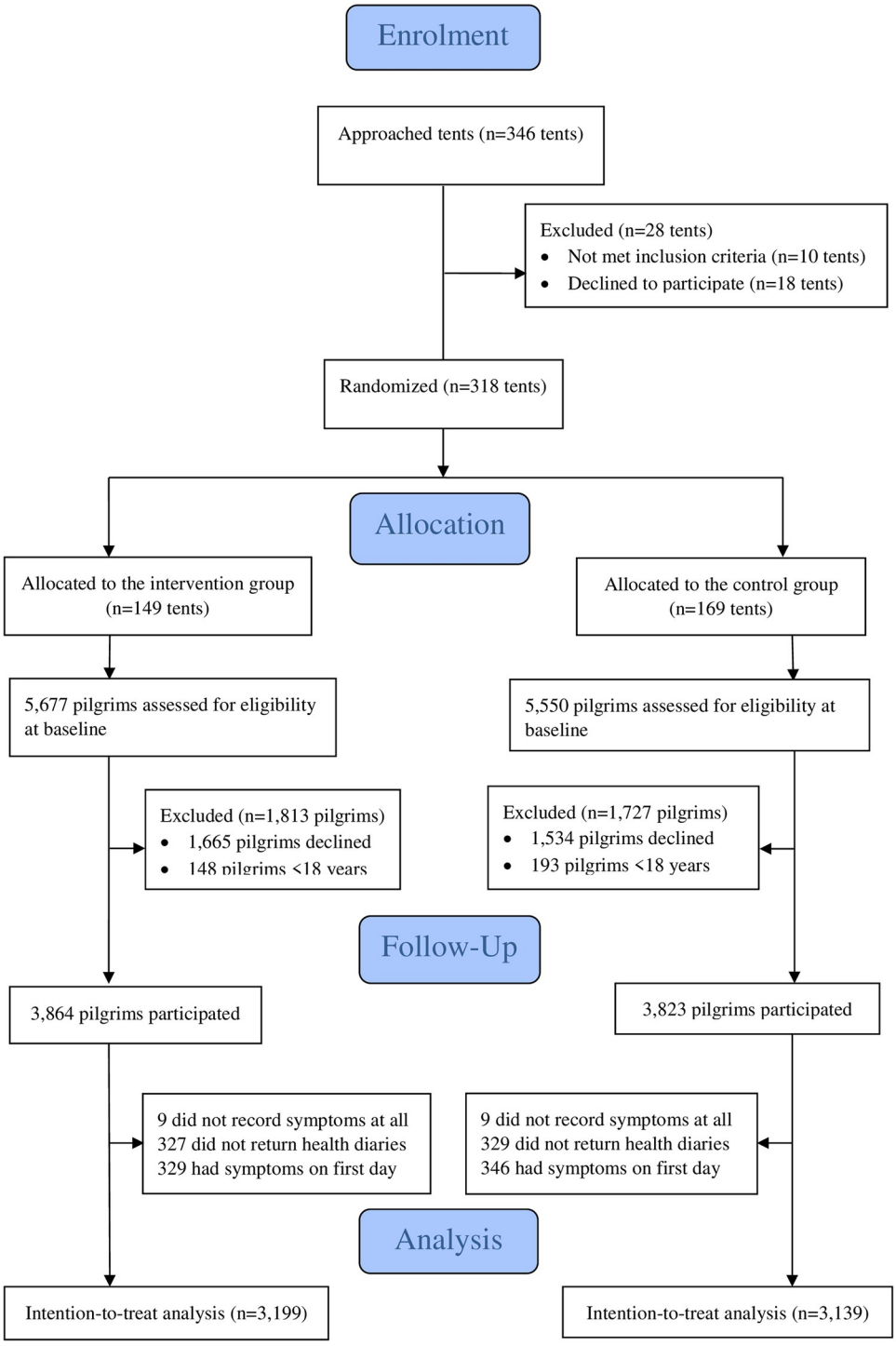


Fig 1. Overall trial flow.

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(MERS-CoV) assay targeting the upstream region of the E gene (upE) was also performed as described previously [24].

Symptomatic pilgrims were given generic medications for fever and pain, usually acetaminophen.

Statistical analysis and power calculation

Data from baseline questionnaires and health diaries were entered by trained research staff into customized web-based forms (WUFOO®, https://www.wufoo.com), and extracted into Excel sheets. Data checking against paper records was undertaken by four dedicated researchers (M.A., O.B., A.-M.B., M.T).

Statistical analysis was performed using the SPSS Statistics® v25 (IBM, Chicago, IL, USA) and checked by a statistician using SAS V.9.3.

Assuming that the prevalence of symptomatic viral respiratory infections is 30% in controls and the prevalence of laboratory-confirmed viral respiratory infections in controls is approximately 12%, the intervention was considered clinically worthwhile if it reduced the prevalence of clinical respiratory infection or laboratory-confirmed viral respiratory infections by 50%.

Assuming a moderate intra-cluster correlation of 0.1 and a mean of 75 participants per cluster (tent), and inflating the sample by a design effect of 8.4 to account for clustering [25], the sample size required for a cRCT to detect a reduction from 12% to 6% with 80% power at 5% significance is 2976 per arm. An additional inflation factor of 1.2 was included to allow for up to 15% loss to follow-up or incomplete outcome data. This resulted in a sample size of approximately 3500 participants per arm, making a total of 7000.

A descriptive analysis compared the characteristics of participants in the two arms (intervention and control), both at tent level and at individual participant level, as appropriate. Categorical variables were described using frequencies and percentages, and were compared, where appropriate, by using the Chi-squared test. Continuous data were described using the mean and standard deviation, and were compared by the Student's t-test. The number or proportion of participants with missing data were reported for all variables, but comparisons between groups only included known values, except where otherwise specified. P values and 95% confidence intervals (CIs) were presented without adjustment.

The first and second primary endpoints were analyzed by intention-to-treat analysis according to the participants' randomized treatment group regardless of treatment actually received. Outcomes were analyzed using a generalized estimating equation statistical model that accounted for the binary distribution of the data and the correlation between participants in the same tent, assuming an exchangeable correlation structure.

Exploratory multivariable analyses examined the effect of randomized treatment on outcomes in models adjusted for demographic factors, facemask usage and compliance with treatment. Subgroup analyses were conducted to compare the effect of treatment between groups of participants: male vs. female, those with known risk factors vs. those without risk factors or risk status unknown for viral respiratory infections, vaccinated against influenza vs. unvaccinated (or vaccination status reported as unknown), smoker vs. non-smoker, compliance with daily facemask use vs. non-compliance, and by pilgrim's country of origin.

Subgroup analyses used the same statistical model as the primary outcomes and included an interaction term between randomized treatment and subgroup. If the p value for the interaction term was < 0.05, the effect of treatment was described separately within each subgroup. Primary analysis included all participants who reported symptoms at any time during the study period. Eighteen participants who failed to report symptoms were excluded, but those (n = 675) who reported symptoms only at baseline (i.e., on day one) were included. A per-protocol analysis was undertaken amongst participants who were compliant with instructions and reported symptoms daily after the baseline time point. An analysis was performed on participants who were symptom-free at baseline and who completed symptom reports at least once after baseline (i.e., on day one).

For the primary analysis, pilgrims who did not report symptoms daily were assumed to have no change in their symptoms compared to the most recent reporting day. Those who reported no symptom on any study day were assumed to have never developed symptoms while those who reported symptoms on any day were considered symptomatic.

Results

Participants

A total of 318 tents that housed 11,227 pilgrims were recruited in both study arms on the first day of each Hajj over three years (13th October in 2013, 2nd October in 2014 and 22nd September in 2015) and followed for the next four days. The number of occupants in each tent varied according to the size of the tent, ranging from 6 to 150 pilgrims per tent. The total number of participants across all study years was 7,687 with an average participation rate of 68.5% (7687 of 11,227) (ranged from 10 to 100%). Of the total 7687 participants, 3864 from 149 tents were assigned to the intervention and 3,823 from 169 tents were assigned to the control group, with an overall participation rate of respectively 68% (3864 of 5686) and 69% (3823 of 5541). Their age ranged from 18 to 95 years (median, 34; mean, 37; standard deviation, 12.3 years), with 53.9% female. Of all participants, 6998 (91%) were from Saudi Arabia and Qatar, and the rest were from Australia. A large proportion of pilgrims 57.6% (4428 of 7687) were recruited in the third year, 2015. The baseline characteristics are shown in Table 1.

Overall facemask use was low, even in the intervention tents, with only 24.7% of participants using facemasks daily. Conversely, in the control tents 14.3% participants used facemasks daily. More participants in the intervention group had used a facemask anytime in the weeks before the actual Hajj compared to those assigned in the control group (27.4% vs. 24.2%, $p < 0.01$).

Slightly more pilgrims in the intervention group than in the control group reported frequent hand washing during Hajj, including their ritual ablutions (69.1% vs. 65.9%, $p < 0.01$).

The proportion of pilgrims who participated in the study and used facemasks ranged between 0 and 50% per tent and the proportion of pilgrims who reported developing clinical respiratory infection in each tent ranged between 0 and 46%. However, in the intervention group, the number by subgroup of recorded time of daily facemask use for at least 4 hours was consistently greater than in the control group (Fig 2).

The most common side effects of using facemask were difficulty in breathing (26.2%) and discomfort (22%); a small minority (3%) reported feeling hot, sweating, a bad smell or blurred vision with eyeglasses (Fig 3).

A total of 650 nasal swabs were collected from symptomatic pilgrims in both groups. Overall, one or more respiratory viruses were detected in 277 (42.6%) of samples tested. The most prevalent viruses were rhinovirus (35.1%), influenza, including A/H1N1 and A/H3N2 (4.5%), and parainfluenza (1.7%), and 2% had dual infections (Table 2).

In the intention-to-treat analysis, allocation to facemask use was not associated with reduced laboratory-confirmed viral respiratory infections (odds ratio [OR], 1.4; 95% CI, 0.9 to 2.1; p = 0.18) or clinical respiratory infection (OR, 1.1; 95% CI 0.9 to 1.4; p = 0.40) (Table 3).

In a per-protocol analysis (including only participants allocated to the intervention group who used facemasks daily, and participants allocated to the control group who never used any facemasks) there was no benefit of facemask in preventing laboratory-confirmed viral respiratory infections (OR, 1.2; 95% CI 0.9 to 1.7; p = 0.26) or clinical respiratory infection (OR, 1.3; 95% CI 1.0 to 1.8; p = 0.06) (Table 4).

Table 1. Baseline characteristics of participants and their compliance with facemask and hand hygiene across the study arms.

	Intervention n (%)	Control n (%)
Tents		
Total number of recruited tents	149	169
Gulf	137 (91.9)	151 (89.3)
Australia	12 (8.1)	18 (10.7)
2013	26 (17.4)	22 (13)
2014	46 (30.9)	55 (32.5)
2015	77 (51.7)	92 (54.4)
Male tent	71 (47.7)	72 (42.6)
Participants		
Total number of participants	3,864	3,823
Gulf countries	3,575 (92.5)	3,423 (89.5)
Australia	289 (7.5)	400 (10.5)
2013	551 (14.3)	474 (12.4)
2014	1,106 (28.6)	1,128 (29.5)
2015	2,207 (57.1)	2,221 (58.1)
Male	1,891 (48.9)	1,651 (43.2)
Mean (standard deviation) age	36.9 (12.1)	37.2 (12.5)
Median (range) age	34 (18–95)	35 (18–95)
With any risk factor	741 (19.2)	715 (18.7)
Smoking as the single risk factor	401 (10.4)	355 (9.3)
Pregnant among women	32 (1.6)	31 (1.4)
Influenza vaccine uptake	1,929 (49.9)	1,887 (49.4)
Facemask use before recruitment	1,057 (27.4)	924 (24.2)
Daily use of facemask	954 (24.7)	545 (14.3)
Intermittent usage	1,842 (47.7)	1,333 (34.9)
Did not use facemask	808 (20.9)	1,672 (43.7)
Used antiseptic/hand rub	1,818 (47)	1,720 (45)
Washed hands frequently (>2 times a day)	2670 (69.1)	2520 (65.9)
Rarely washed hands (1–2 times a day)	578 (15)	619 (16.2)
Never washed their hands	140 (3.6)	178 (4.5)

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Discussion

This randomized trial, like other smaller trials [9–15], failed to provide conclusive evidence on facemask efficacy against laboratory-confirmed or clinical respiratory infections. Inconclusiveness of this and previous studies might be attributed in part to respiratory pathogens having multiple routes of transmission including contact with contaminated surface [26, 27] and fecal-oral transmission of some respiratory viruses [28].

The large sample size in our cRCT enabled the comparison of a much larger number of clinical infections (intervention: control = 354: 322) and many more laboratory-confirmed infections (intervention: control = 96: 60) with higher power than the other randomized trials combined. Although unvaccinated pilgrims in the intervention group had a higher rate of clinical respiratory infection than their counterpart in the control group (13% vs. 10%, p = 0.03), this difference is unexplained. However, in previous studies, the prevalence of influenza-like illness among Hajj pilgrims was inversely proportional to their influenza vaccination uptake [29], and vaccinated Hajj pilgrims had 43% reduction in the probability of proven influenza

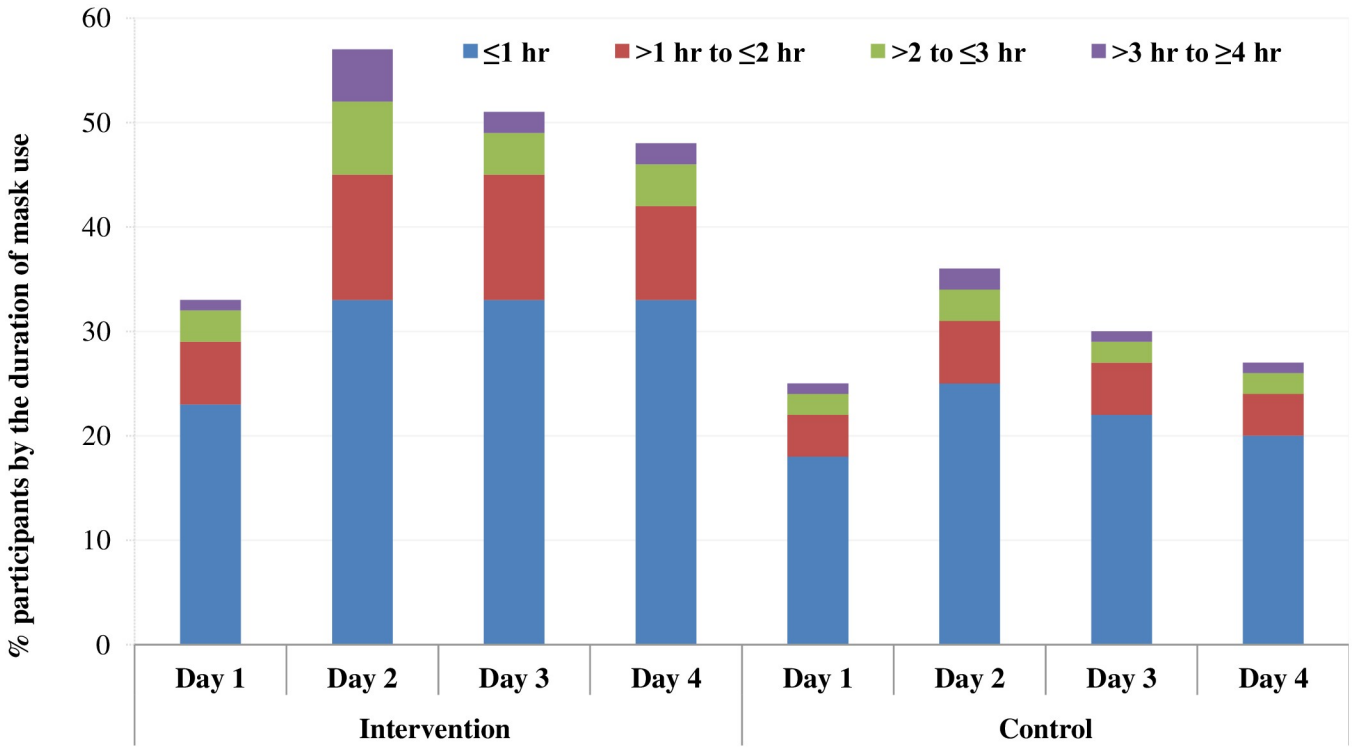


Fig 2. Proportion of facemask using participants by the duration of mask use across the study arms. (This stacked bar chart shows the proportion by subgroup of recorded time of daily facemask use in the intervention group was consistently greater than in the control group).

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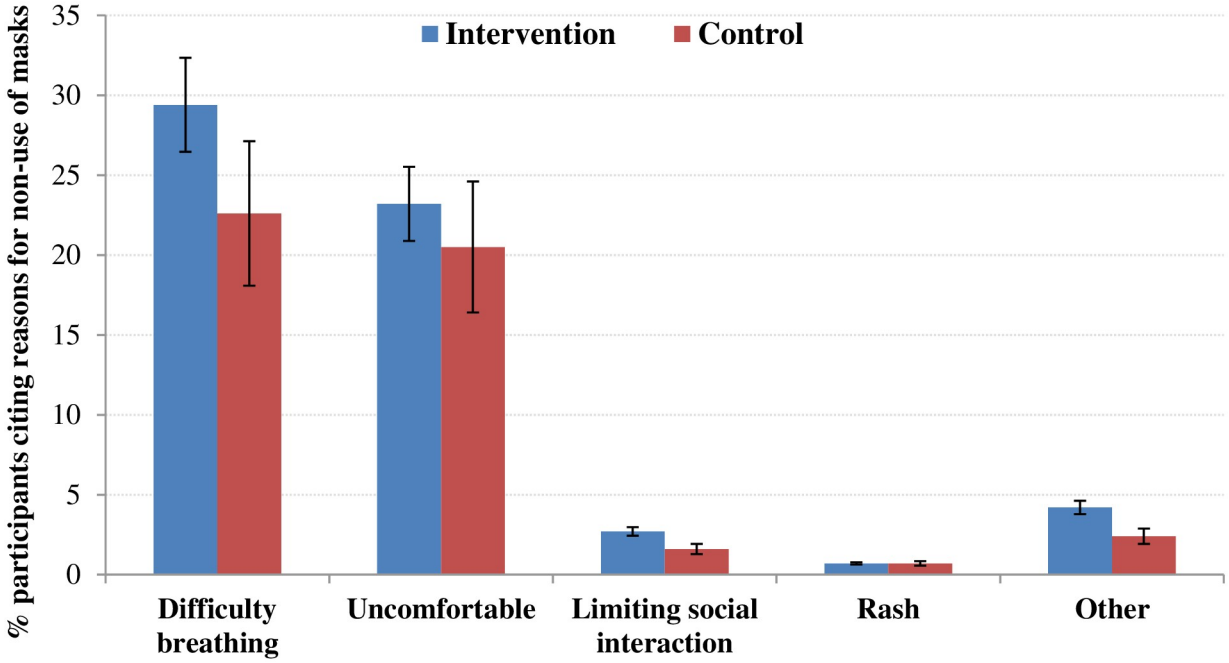


Fig 3. Reasons for not using facemasks across the study arms.

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Table 2. The attack rate of viral respiratory infections during Hajj in both arms.

	Total	Intervention	Control
	N = 650	N = 358	N = 292
	n (%)	n (%)	n (%)
Positive	277 (42.6)	149 (41.6)	128 (43.8)
Rhinoviruses	228 (35.1)	121 (33.8)	107 (36.6)
Influenza A	29 (4.5)	17 (4.7)	12 (4.1)
Influenza A/H1N1	9 (1.4)	5 (1.4)	4 (1.4)
Influenza A/H3N2	14 (2.2)	9 (2.5)	5 (1.7)
Influenza (subtype undetermined)	6 (0.9)	3 (0.8)	3 (1)
Influenza B	1 (0.2)	0 (0)	1 (0.3)
Enteroviruses	10 (1.5)	5 (1.4)	5 (1.7)
Parainfluenza virus 1	5 (0.8)	3 (0.8)	2 (0.7)
Parainfluenza virus 2	1 (0.2)	0 (0)	1 (0.3)
Parainfluenza virus 3	5 (0.8)	3 (0.8)	2 (0.7)
hMPV	2 (0.3)	2 (0.6)	0 (0)
Human coronaviruses	3 (0.5)	2 (0.6)	1 (0.3)
Adenoviruses	3 (0.5)	1 (0.3)	2 (0.7)
RSV	2 (0.3)	2 (0.6)	0 (0)
MERS-CoV	0 (0)	0 (0)	0 (0)
Dual infection	13 (2)	8 (2.2)	5 (1.7)

hMPV: Human metapneumovirus.

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Table 3. Primary and subgroup analyses by intention to treat.

	Intervention n/N (%)	Control n/N (%)	OR (95% CI)	Interaction p value
Clinical respiratory infection	354/3,199 (11.1)	322/3,139 (10.3)	1.1 (0.9–1.4)	
Influenza vaccinated	160/1,677 (9.5)	181/1,631 (11.1)	0.8 (0.7–1.1)	< **0.01**
Not vaccinated or vaccination status reported as unknown	176/1,361 (12.9)	131/1,381 (9.5)	1.4 (1.0–2.0)	
At increased risk	86/621 (13.8)	69/615 (11.2)	1.3 (0.9–1.8)	0.28
Not at increased risk	254/2,439 (10.4)	239/2,399 (10)	1.1 (0.8–1.4)	
Smoking as the single risk factor	40/350 (11.4)	30/311 (9.6)	1.2 (0.7–2)	0.86
Non-smoking	303/2,721 (11.1)	279/2,725 (10.2)	1.1 (0.8–1.4)	
Male	148/1,576 (9.4)	120/1,354 (8.9)	1.1 (0.8–1.5)	0.73
Female	206/1,623 (12.7)	202/1,785 (11.3)	1.2 (0.9–1.6)	
Gulf	332/3,043 (10.9)	287/2,954 (9.7)	1.2 (0.9–1.5)	0.13
Australia	22/156 (14.1)	35/185 (18.9)	0.7 (0.4–1.3)	
Laboratory-confirmed viral respiratory infection	96/218 (44)	60/161 (37.3)	1.4 (0.9–2.1)	-
Influenza vaccinated	44/106 (41.5)	37/102 (36.3)	1.3 (0.7–2.2)	0.85
Not vaccinated or vaccination status reported as unknown	54/95 (56.8)	21/53 (39.6)	1.3 (0.7–2.2)	
At increased risk	20/42 (47.6)	12/31 (38.7)	3 (1.9–4.9)	0.71
Not at increased risk	71/164 (43.3)	45/114 (39.5)	1.2 (0.7–2.1)	
Smokers	11/28 (39.3)	5/9 (55.6)	0.5 (0.1–2.8)	0.33
Not smokers	80/179 (44.7)	53/138 (38.4)	1.3 (0.8–2)	
Male	45/101 (44.6)	28/50 (56)	0.7 (0.3–1.4)	**0.02**
Female	51/117 (43.6)	32/111 (28.8)	1.9 (1.2–3)	
Gulf countries	15/35 (42.9)	17/48 (35.4)	1.4 (0.6–3.4)	0.96
Australia	81/183 (44.3)	43/113/ (38.1)	1.3 (0.8–2.2)	

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Table 4. Per-protocol analysis: Effect of facemasks against clinical and laboratory-confirmed viral respiratory infections.

Respiratory infection		Intervention n (%)	Control n (%)	OR[a] (95% CI; p)
Clinical respiratory infection	*Did not use facemask*			1.3[a] (1.0–1.8; 0.06)
	Symptoms present	55 (8)	141 (9)	
	Symptoms absent	648 (92)	1356 (91)	
	Used facemask			
	Symptoms present	97 (12)	38 (8)	
	Symptoms absent	731 (88)	425 (92)	
Laboratory-confirmed viral respiratory infections based on facemask use	*Did not use facemask*			1.2[b] (0.9–1.7; 0.26)
	Positive	29 (45)	50 (41)	
	Negative	35 (55)	72 (59)	
	Used facemask daily			
	Positive	46 (50)	20 (53)	
	Negative	47 (50)	18 (47)	

[a]Analysis includes only participants from intervention group who used facemasks daily (n = 828) and those from control group who did not use facemasks (n = 1497).

[b]Analysis includes only participants from intervention group who used facemasks daily (n = 93) and those from control group who did not use facemasks (n = 122).

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infection [30]. A meta-analysis of six observational studies has shown influenza vaccine to be significantly protective against laboratory-confirmed influenza (relative risk, 0.56; 95% CI, 0.41 to 0.75) [31].

Females in the intervention group of our cRCT were at higher risk of acquiring laboratory-confirmed viral respiratory infections than in the control group (44% vs. 29%; $p < 0.01$). The reason is unclear, though one possible explanation is Muslim women prefer a loose face cover to a fitted facemask. Over 70% female pilgrims use a face veil during Hajj: one fifth of them use both face veil and mask [32]. Female pilgrims who used a face cover only occasionally (43.2%) tended to have higher rates of clinical respiratory infection compared to those who used it most of the time (36%) [33]. Although we did not assess face cover use by female pilgrims in our study, given that most pilgrims used facemasks only occasionally, the higher rate of viral respiratory infections among women might be due to intermittent use of face cover or even contamination of their masks [9, 33]. When they become wet, facemasks may even increase the transmission of infection, either through becoming more porous or by allowing passage of virus through the mask which is transmitted when the mask is handled [34].

The detection rate of respiratory viruses (43%) in our trial was higher than that reported in other studies (4 to 15%) [35], possibly due to the active case ascertainment strategy employed, including close follow-up of the symptomatic participants. However, the distribution of the viruses was similar to that in other studies: i.e., predominance of rhinovirus, followed by influenza and parainfluenza virus, these three viruses accounting for 97% (269/277) of viruses detected in our study.

No MERS-CoV was detected among the studied participants. Since the emergence of MERS-CoV in Saudi Arabia in 2013, multiple surveillance studies among >10,000 pilgrims from various countries have been undertaken without identifying a Hajj-related case [36, 37]. Now that there is a grave fear of massive acceleration of COVID-19 spread via large population movements [38], other preventive measures including hand and food hygiene, safe drinking water and physical distancing should be encouraged in addition to facemasks [39, 40]. We note that 0.5% of the symptomatic pilgrims tested positive for seasonal coronavirus indicating coronavirus transmission may occur in this setting and that, without the possibility of cross-

protection, it is imperative that the Hajj should be scaled-down until the COVID-19 pandemic ends.

Findings of systematic reviews have been conflicting [17, 18, 39, 41–45], the most recent showing protective effects of masks against respiratory viral infection including pandemic coronaviruses across different populations but with low certainty [39, 41]. An observational study conducted at Hajj over four consecutive years (2014 to 2017) found pilgrims who reported using facemasks had higher likelihood of suffering from influenza-like illness symptoms (adjusted relative risk, 1.42; 95% CI, 1.10 to 1.82) and acquiring rhinovirus infection (adjusted relative risk, 1.30; 95% CI, 1.03 to 1.65) [46]. In an earlier study, 20.7% pilgrims who used a facemask reported fever compared with 15.6% who did not ($p < 0.01$) [47].

The most important limitation of this RCT was that despite much effort to encourage adherence with our protocol, compliance was limited. On the other hand many pilgrims randomized to the control group used facemasks, contrary to the research protocol. The Saudi Arabian Ministry of Health had issued advice to pilgrims to use facemasks while MERS-CoV was circulating in Saudi Arabia during our study period [48], though this was without definitive advice on how to wear masks and the duration of their use. It would have been unethical to counter the Saudi authority's official advice on facemask use. Our trial does indicate, however, that as a public health intervention, facemask use is not practicable. Another important limitation of the study is that nasal swabs were not performed on the first day when subjects were enrolled. We depended on the reporting of clinical symptoms from day one and followed up directly for four days but did not validate the asymptomatic state with virological testing i.e., some asymptomatic pilgrims could have been virus positive. Longer follow-up was attempted through post-Hajj surveillance, but the low compliance precluded any meaningful analysis. Pilgrims moving from place to place to accomplish Hajj rites made it difficult for researchers to follow them as well as planned. While our study protocol required a clinical sample to be collected in participants with clinical respiratory infection, sampling was performed in some who did not meet the clinical respiratory infection definition whilst others were not swabbed when symptomatic. Though a cRCT design, complying as far as possible with CONSORT guidance, not all occupants in the selected tents participated. On average 69% of tent occupants participated in the trial, ranging widely from 10 to 100%, with possible dilution of the effect of facemask use. The trial was conducted over three years, with uneven recruitment over the years, and most participants (58%) recruited in the final year (2015). The rate of clinical respiratory infection over the study years was 15.5% in 2013, 8.3% in 2014, and 10.7% in 2015, reflecting the known seasonal variability of respiratory viruses, which may have affected the outcome of our study. About 9% participants in each study arm failed to return their diaries or returned dairies without recording symptoms, and another 9% in each group were excluded for being symptomatic on day one of our trial.

Another limitation is that participating tents varied between the study arms (intervention: control = 149: 169) because some tents, although designated as separate units, were later found to be parts of a larger tent. This was more common when several small tour groups were managed under a large tour operator and communal activities (e.g., meals, congregational prayers, sermons) were combined in one large tent. It is also possible that some of these tents were allocated to both intervention and control arms and may have further contributed to dilution of the magnitude of the effect or cluster contamination.

The failure of post-Hajj reporting was another limitation of our study. However, the median incubation periods of the three most common viruses (rhino, influenza and parainfluenza) are <3 days [49], indicating that the majority of the detected infections were acquired after enrolment. Though dangerous to presume very little symptomatic disease post-Hajj this is one explanation for non-adherence with post-Hajj follow-up.

Our cRCT, which was a field study in real time, was unable to refute our null hypothesis. Lack of facemask efficacy observed in this trial could be attributed to limited facemask use by participants (only 24.7% used daily and 47.7% used intermittently in the intervention group), the substantial proportion of participants in the control group who used facemasks, the inability to follow participants after Hajj or the likely contamination of masks [9, 26]. Though more in the intervention group consistently wore masks for defined periods daily, facemask use by controls further reduced the ability of the study to detect differences in infection rates between the study arms.

Due to lack of blinding pilgrims in control tents reporting even mild illness may have reported symptoms because they knew that they had not received the intervention. Also research team members may have been biased towards swabbing such participants assuming them to be less protected, which could have led to an overestimate of the effect of intervention.

The high rate of facemask use (almost 80%) observed among French Hajj pilgrims during the 2009 influenza pandemic year [50], compared to about 55% in a non-pandemic year [3], and in pilgrims from Southeast Asia (e.g., 73% among Malaysian pilgrims in 2007) seem to be due to cultural differences and heightened awareness during a pandemic [51]. The lower uptake of facemasks among participants in our cRCT is similar to the uptake among Saudi Arabian (35 to 57%) and Australian pilgrims (53 to 57%) observed in previous surveys [31, 32, 52, 53], while uptake as low as 0.02% was also recorded among some international pilgrims [54]. Although 78% in the intervention group of our cRCT used facemasks, only a quarter used them regularly. The most common reasons for non-compliance, difficulty in breathing and feeling of discomfort, found also in previous surveys among Hajj pilgrims [52], limited the use of facemasks in this cRCT. These might be strong and important limitations to effective facemask use against respiratory infections, since, in a mass gathering, close contact setting, around the clock protection would be necessary.

Given the number of people who attended Hajj and the close proximity within and among the living quarters, contact transmission from direct contact and indirect contact with contaminated surfaces may have been important and perhaps another reason why these results should be considered inconclusive. There is also the possibility of exposure and infection during travel and prior to Hajj itself. This RCT demonstrates the difficulties of participants' adherence to instructions and protocol even with active supervision.

Several previous observational studies at Hajj have failed to show the effectiveness of facemasks in preventing respiratory infections [50–52], possibly due also to poor adherence to instructions, although a recent study showed that changing facemask every four hourly reduced the chance of upper respiratory tract infections among Hajj pilgrims (adjusted OR 0.56; 95% CI 0.34 to 0.92; p = 0.02) [55]. In our cRCT, though pilgrims in both intervention and control groups were close to each other day and night, none wore a mask for 24 hours as advised. This may have been an unrealistic expectation. Mask wearing during the COVID-19 pandemic has highlighted the importance of effective and realistic health messaging.

Additional studies with an even larger sample size and more intense supervision would better test the efficacy of facemasks and the role of other interventions, such as hand hygiene, in a mass gathering setting. These will be especially important to evaluate such interventions during the COVID-19 pandemic.

Conclusion

This trial failed to provide definitive evidence for the effectiveness of facemasks during the Hajj. This was likely due to poor compliance with facemask use. We report difficulties in implementing a large cRCT, evaluating the effectiveness of facemasks against viral respiratory

infections including participants' poor compliance with the protocol, despite active explanation and support.

Supporting information

S1 Checklist. CONSORT, consolidated standards of reporting trials.
(DOC)

S1 Appendix. Members of the Hajj research team and study tools.
(DOCX)

S2 Appendix. Study protocol.
(DOC)

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CORRESPONDENCE



Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden

TO THE EDITOR: In mid-March 2020, many countries decided to close schools in an attempt to limit the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus causing coronavirus disease 2019 (Covid-19).[1,2] Sweden was one of the few countries that decided to keep preschools (generally caring for children 1 to 6 years of age) and schools (with children 7 to 16 years of age) open. Here, we present data from Sweden on Covid-19 among children 1 to 16 years of age and their teachers. In Sweden, Covid-19 was prevalent in the community during the spring of 2020.[3] Social distancing was encouraged in Sweden, but wearing face masks was not.[3]

Data on severe Covid-19, as defined by intensive care unit (ICU) admission, were prospectively recorded in the nationwide Swedish intensive care registry. We followed all children who were admitted to an ICU between March 1 and June 30, 2020 (school ended around June 10) with laboratory-verified or clinically verified Covid-19, including patients who were admitted for multisystem inflammatory syndrome in children (MIS-C, which is likely to be related to Covid-19)[4] according to the Swedish Pediatric Rheumatology Quality Register. (More information on the registry and a link to the World Health Organization scientific brief on MIS-C are provided in the Supplementary Appendix, available with the full text of this letter at NEJM.org.) The Stockholm Ethics Review Board approved the study. Informed consent was waived by the review board.

The number of deaths from any cause among the 1,951,905 children in Sweden (as of December 31, 2019) who were 1 to 16 years of age was 65 during the pre–Covid-19 period of November 2019 through February 2020 and 69 during 4 months of exposure to Covid-19 (March through June 2020) (see the Supplementary Appendix). From March through June 2020, a total of 15 children with Covid-19 (including those with MIS-C) were admitted to an ICU (0.77 per 100,000 children in this age group) (Table 1), 4 of whom were 1 to 6 years of age (0.54 per 100,000) and 11 of whom were 7 to 16 years of age (0.90 per 100,000). Four of the children had an underlying chronic coexisting condition (cancer in 2, chronic kidney disease in 1, and hematologic disease in 1). No child with Covid-19 died.

Data from the Public Health Agency of Sweden (published report[5] and personal communication) showed that fewer than 10 preschool

THIS WEEK'S LETTERS

669 Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden

671 Duration of Culturable SARS-CoV-2 in Hospitalized Patients with Covid-19

673 Five-Year Outcomes for Refractory B-Cell Lymphomas with CAR T-Cell Therapy

675 Osimertinib in *EGFR*-Mutated Lung Cancer

676 Subcutaneous or Transvenous Defibrillator Therapy

679 Women Physicians and Promotion in Academic Medicine

681 The Covid-19 Vaccine-Development Multiverse

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Table 1. Characteristics of the Children with Covid-19, Including Those with MIS-C, Admitted to Swedish ICUs in March–June 2020.*

Age	Sex	SARS-CoV-2 Test Result		Days in ICU†	No. of Admissions	BP and Laboratory Measures at Admission‡	Organ Support	Complications
		PCR	Antibodies					
1 yr§	F	Negative	Positive	5	1	Systolic BP, 70 mm Hg; SaO_2, 99%; BE, +0.6 mmol/liter; lactate, 1.6 mmol/liter	—	MIS-C, septic shock, renal failure
3 yr	F	Positive	ND	38	3	Systolic BP, 75 to 143 mm Hg; SaO_2, 96%; lactate, 1.2 mmol/liter	Invasive mechanical ventilation	*Clostridium difficile* infection
4 yr	F	Positive	Positive	6	1	Systolic BP, 87 mm Hg; SaO_2, 99%	—	MIS-C, renal failure, coagulation disorder
5 yr	F	Positive	Positive	3	1	Systolic BP, 83 mm Hg; SaO_2, 98%; BE, −0.7 mmol/liter	—	MIS-C
7 yr¶	M	Negative	ND	<1	1	Systolic BP, 85 mm Hg; SaO_2, 97%; BE, −0.7 mmol/liter	—	Iron deficiency, coma, fever
7 yr	F	Positive	Positive	35	2	Systolic BP, 115 mm Hg; SaO_2, 90%; lactate, 0.8; BE, +5 mmol/liter	Invasive mechanical ventilation, renal replacement therapy	—
10 yr§	F	Negative	Positive	1	1	Systolic BP, 95 mm Hg; SaO_2, 99%; lactate, 1.1 mmol/liter; BE, −1.5 mmol/liter	—	MIS-C, cardiomyopathy
12 yr	M	Positive	ND	<1	1	Systolic BP, 100 mm Hg; SaO_2, 98%; BE, −6 mmol/liter	—	—
12 yr	M	Positive	ND	2	1	—	—	Viral pneumonia
13 yr	M	Positive	ND	11	2	Systolic BP, 123 to 137 mm Hg; SaO_2, 92%; lactate, 0.9 mmol/liter; BE, +3.2 mmol/liter	—	—
13 yr	F	Positive	Positive	7	2	Systolic BP, 80 mm Hg; SaO_2, 98%; lactate, 3.7 mmol/liter; BE, −9 mmol/liter	Invasive mechanical ventilation	MIS-C, heart failure
14 yr§	M	Negative	Positive	4	1	Systolic BP, 57 mm Hg; SaO_2, 98%; lactate, 3.4 mmol/liter; BE, −1.5 mmol/liter	—	MIS-C, myocarditis, sepsis
14 yr	M	Positive	ND	4	2	Systolic BP, 90 to 100 mm Hg; SaO_2, 83%; lactate, 2.7 mmol/liter; BE, +4 mmol/liter	Invasive mechanical ventilation	—
16 yr	M	Positive	Positive	9	1	—	—	—
16 yr¶	M	Negative	Positive	5	1	—	—	MIS-C, myocarditis with heart failure

* Four children had underlying conditions: 2 had cancer, 1 had chronic kidney disease, and 1 had hematologic disease and had undergone stem-cell transplantation. Two children had additional conditions: 1 had alcohol intoxication, and 1 had sustained a traumatic injury; coronavirus disease 2019 (Covid-19) was diagnosed in these 2 children only when they underwent screening for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the intensive care unit (ICU) (they did not have Covid-19 symptoms). BE denotes base excess, BP blood pressure, MIS-C multisystem inflammatory syndrome in children, ND not done, PCR polymerase chain reaction, and SaO_2 oxygen saturation.

† For patients with multiple admissions, the total duration is reported.

‡ For patients with multiple admissions, the most aberrant value is reported.

§ The patient was identified through the presence of MIS-C according to the Swedish Pediatric Rheumatology Quality Register. Covid-19 was not diagnosed during ICU care, but the results of subsequent antibody testing were positive.

¶ Covid-19 was diagnosed clinically (i.e., SARS-CoV-2 was not detected during the ICU admission).

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teachers and 20 schoolteachers in Sweden received intensive care for Covid-19 up until June 30, 2020 (20 per 103,596 schoolteachers, which is equal to 19 per 100,000). As compared with other occupations (excluding health care workers), this corresponded to sex- and age-adjusted relative risks of 1.10 (95% confidence interval [CI], 0.49 to 2.49) among preschool teachers and 0.43 (95% CI, 0.28 to 0.68) among schoolteachers (see the Supplementary Appendix).

The present study had some limitations. We lacked data on household transmission of Covid-19 from schoolchildren, and the 95% confidence intervals for our results are wide.

Despite Sweden's having kept schools and preschools open, we found a low incidence of severe Covid-19 among schoolchildren and children of preschool age during the SARS-CoV-2 pandemic. Among the 1.95 million children who were 1 to 16 years of age, 15 children had Covid-19, MIS-C, or both conditions and were admitted to an ICU, which is equal to 1 child in 130,000.

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Duration of Culturable SARS-CoV-2 in Hospitalized Patients with Covid-19

TO THE EDITOR: The duration of transmissibility of coronavirus disease 2019 (Covid-19) and the associated level of contagion have been uncertain. We cultured severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in serial respiratory samples obtained from hospitalized patients with Covid-19 to assess the duration of shedding of viable virus.

The data reported here represent all the patients with Covid-19, as confirmed by positive real-time reverse transcriptase–polymerase chain reaction (RT-PCR) testing, who were hospitalized at Chung-Ang University Hospital in Seoul, South Korea, between February and June 2020. The Allplex 2019-nCoV Assay (Seegene) for nasopharyngeal and oropharyngeal samples was used for real-time RT-PCR testing.[1] Patients were isolated until two consecutive negative or inconclusive results on real-time RT-PCR were documented, at least 24 hours apart.[2,3] We endeavored to obtain samples at approximately 2-day intervals, but this was not always possible. Viral RNA was quantitated with the use of the cycle-threshold value for the *N* gene of SARS-CoV-2.[4] Viral cultures were conducted by means of a plaque assay until at least two consecutive cultures showed no growth.

We compared the time from the onset of illness to viral clearance in culture with the time to clearance in real-time RT-PCR tests.[5] Detailed methods and sensitivities of the culture and real-time RT-PCR assay and the definition and estimation of the time to viral clearance are described in the Supplementary Appendix, available with the full text of this letter at NEJM.org.

A total of 21 patients with Covid-19 were enrolled. Their clinical characteristics are shown in Table S1 in the Supplementary Appendix. The

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An Evidence-Based Rebuttal of RIDOH's-Proposed School Masking Regulation *LYSENKOISM*

Andrew Bostom, MD, MS

March 15, 2024

Full slide set available: www.andrewbostom.org



Former RIDOH Interim Director, Dr. James McDonald, 12/2/21, holding his masked Dr. Fauci doll, & a mask

Lysenkoism

Trofim Lysenko believed that acquired traits are inherited, claimed that heredity can be changed by "educating" plants, & denied the existence of genes. Lysenko was supported by Stalin & Communist Party elites

[Borinskaya SA et al. "Lysenkoism Against Genetics: The Meeting of the Lenin All-Union Academy of Agricultural Sciences of August 1948, Its Background, Causes, and Aftermath." *Genetics*. 2019 May;212(1):1-12]

"Professor T.D. Lysenko, vice chairman of The Academy of Sciences of the Soviet Union, and holder of the Order of Lenin, is far ahead of any scientist in the field of genetics. ***He is, in fact, the only scientist who ever grew wax tomatoes from an ordinary vine****...This unusual product was revealed at the Moscow Scientific Congress…One report says that Lysenko's tomatoes were right on the vine. In any case, some scientist managed to stick one in his pocket and give it further examination.* ***The tomato was made of wax****.* ***But Dr. Lysenko is no joke to Soviet scientists****.* ***One leading Russian scientist who happened to dispute his views, Professor Nikolai Vavilov, died in a concentration camp 6-years ago under circumstances that were never explained. Obviously other scientists unwilling to share the fate of Vavilov agree with Lysenko****."*

[Hugh E. Wells. "**How Soviet Shackles Its Scientists**" *The Philadelphia Inquirer* September 26, 1948; p. 152.]

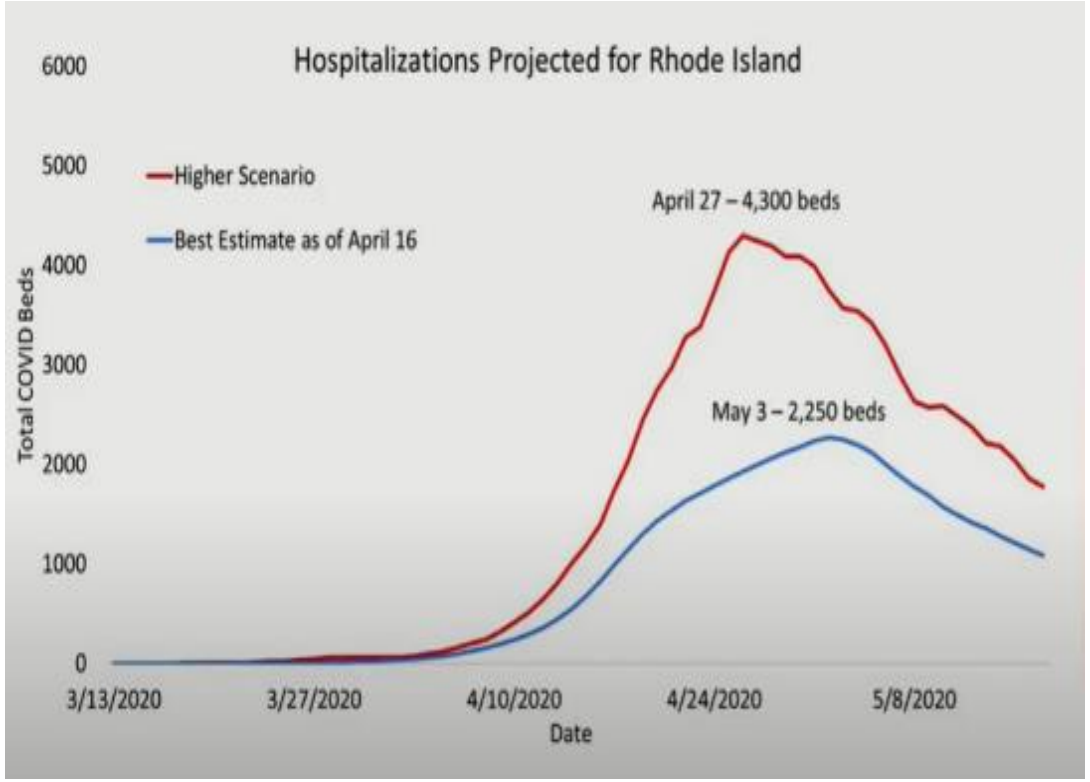
Then Governor Gina Raimondo presser on Rhode Island covid-19 hospitalization "models," 4/16/20, broadcast live on C-SPAN



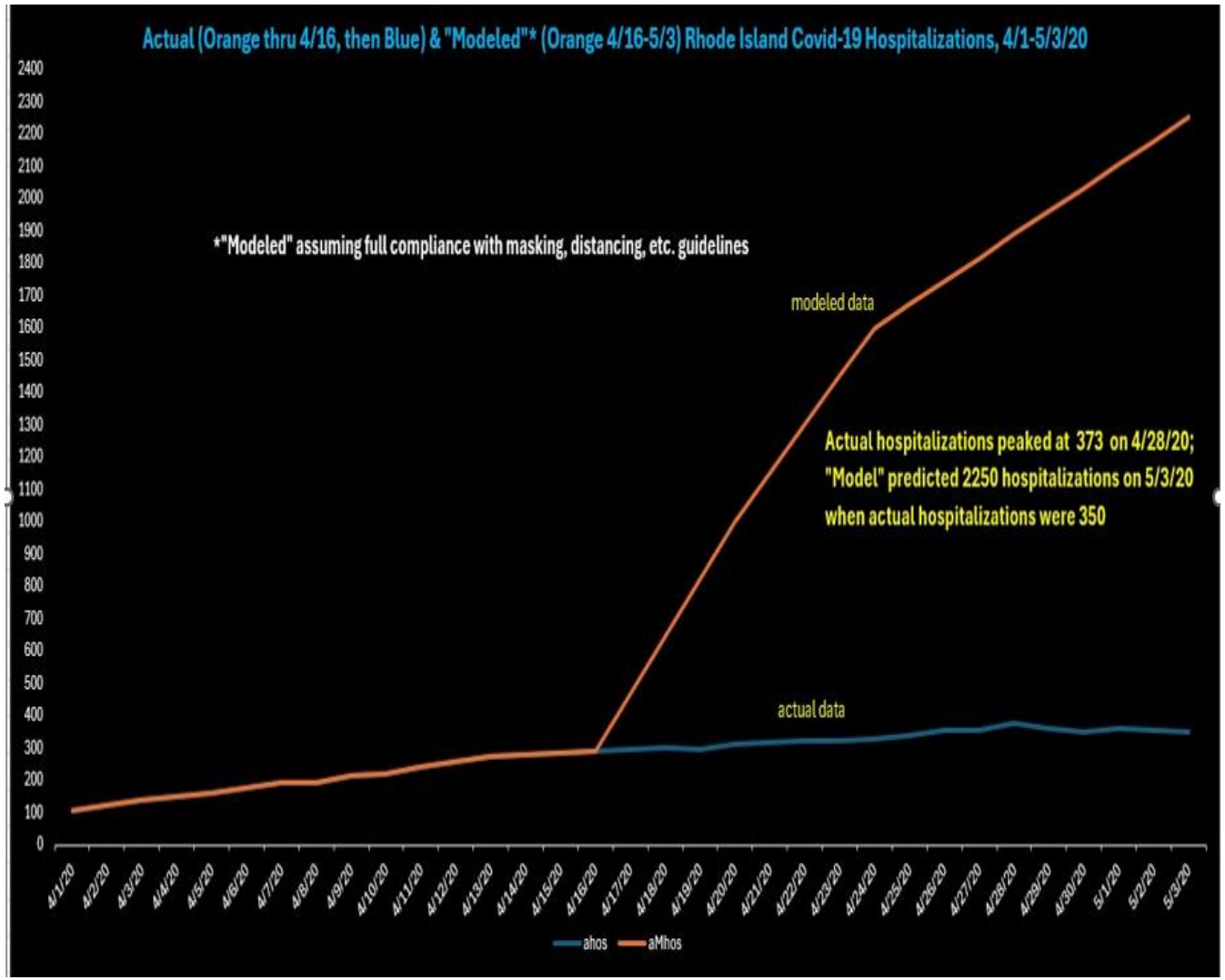
Then Governor Raimondo:
"It's been a collaborative effort with the (Rhode Island) Department of Health [**RIDOH], our own experts, Brown University, and Brown University's Policy Lab**. By the way, **I wanna give a huge shout out of thanks to Brown University**. I called you over a month ago, and **you gave us your very best statisticians and public health experts, and epidemiologists**. Thank you for being a great partner…***The blue line you could think of as our best guess of what we think the next few weeks will look like in Rhode Island. The blue line assumes all of the current restrictions—the stay at home order, the mask wearing, social distancing—are in place, and we are doing a pretty good job of adhering to them***. (Not a perfect job, but a good job of adhering to them.) In that scenario, we thank our peak will be around May 3, 2020, that means last week of April, first week of May, approximately, and at that time, **we will need about 2,250***…(O)n your screen, you should be seeing a red line. That red line represents what we think will happen if we stop taking social distancing seriously. And in that scenario, the peak comes sooner, probably April 27th, and obviously the peak is much higher. In that scenario, the red line that you're seeing, **we'll need closer to 4,300* hospital beds**."

(*Note: Actual absolute peak was n=373, on 4/28/20)

"Modeled" vs. Actual Rhode Island Covid-19 Hospitalizations, 4/27/20 & 5/3/20, were *> 6- to 12-fold higher only ~2-weeks after the predictions were made, on 4/16/20!*



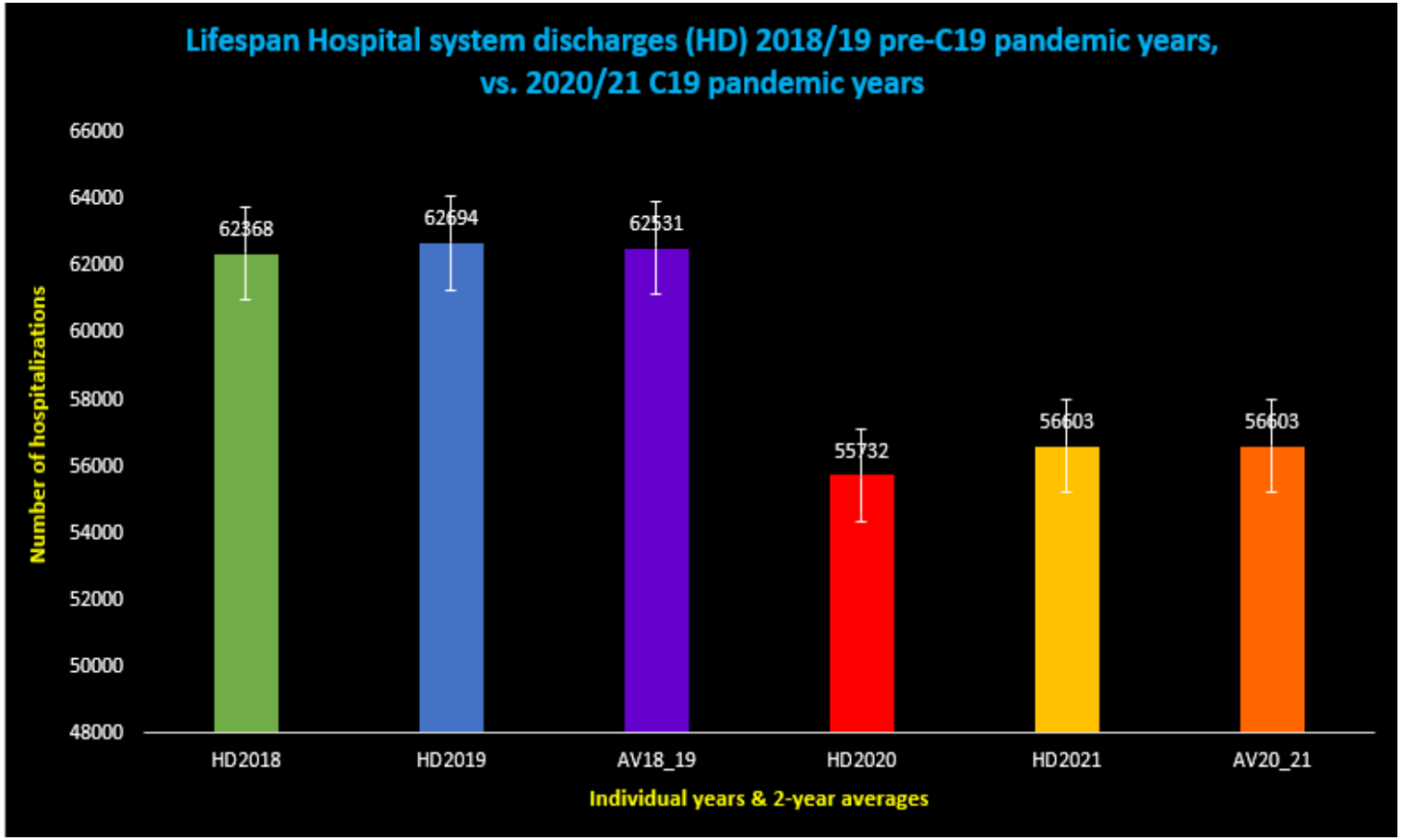
Type of Covid-19 Hospitalizations	Date	Number of Covid-19 Hospitalizations
Poor Social Distancing Model	**4/27/20**	**4,300**
Actual	**4/27/20**	**356**
Good Social Distancing Model	**5/3/20**	**2,250**
Actual	**5/3/20**	**350**



(Again: Actual absolute peak was n=373, on 4/28/20)

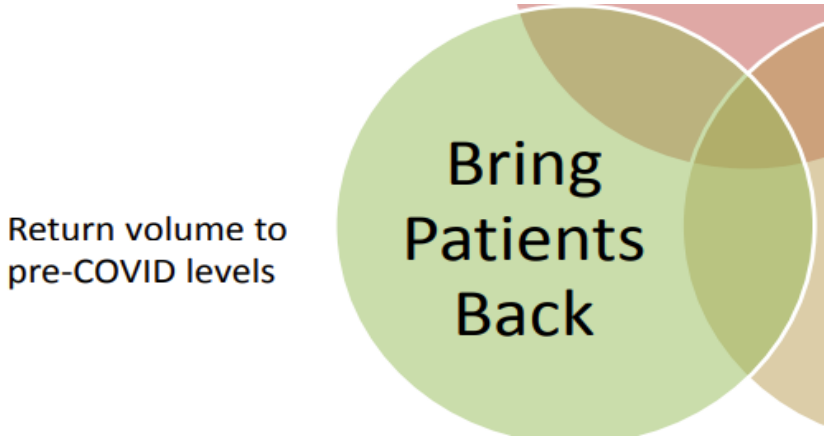
RI Statewide Hospital Discharges, Comparing Pre-Covid-19 Pandemic Years 2018-19, & Covid-19 Pandemic Years 2020-21

- **62,531 avg for 2018-19, Pre-covid-19 pandemic years**
- **56,603 avg for 2020-21 covid-19 pandemic years, i.e., *-9.5% LOWER***



Reference: https://www.lifespan.org/about-lifespan/lifespan-reports

Care New England (CNE) also experienced a decline in hospitalizations, vs. pre-covid levels. Indeed, a public record 8/25/21 CNE conference call featured a campaign of continued encouragement to ***"Bring Patients Back," and "return [hospitalization] volume to pre-covid levels"***



Reference: https://emma.msrb.org/P11522015-P11177370-P11593662.pdf, p. 14

Sweden NEVER "Locked Down," Never Imposed Mask Mandates, etc., & Kept In-Class, Primary School Education Schools Open, Throughout

National Demographer Orjan Hemstrom on Sweden's 2020 Total Mortality:

"We are back to the mortality of 2012…excess mortality is the same as it was a decade ago" 1918 flu pandemic far worse than covid-19



Statistics Sweden Demographer Orjan Hemstrom Reviews Swedish Total Mortality Trends, 1900-2020

From SVT (Swedish National Television), "The price of the Corona battle," Part 8 of 19, Sunday, February 28, 2021
https://www.svtplay.se/video/30291114/vetenskapens-varld/vetenskapens-varld-sasong-34-coronakampens-pris?start=auto&info=visa

SARS-CoV-2/Covid-19 Infection Fatality Rates (IFR)*: Critical Impact of Age

*(*covid-19 deaths/ total infected by SARS-CoV-2 antibody seroprevalence data)*

Age group (years)	IFR
≥70, overall (incl nursing homes)	4.5%
≥70, community dwelling When >85=5% When >85=10% When >85=20%	2.9% 1.2% 1.8% 3.9%
0-69, overall	0.1%
60-69	0.5%
50-59	0.1%
40-49	0.04%
30-39	0.01%
20-29	0.002%
0-19	0.0003%

- **≥ 70, overall, confers 45X the risk of 0-69, overall**
- **≥ 70, overall confers 15,000X the risk of 0-19**
- ***0-19 yos: 1 death per 333,000+ infections; (1 death per million infections since omicron)***

Reminders:

→→ 94% of the world's population is <70

→→ 86% of the world's population is <60

IFR for all ages, combined, ~0.25-0.30%

References:

Axfors C, **Ioannidis JPA**. Infection fatality rate of COVID-19 in community-dwelling elderly populations. Eur J Epidemiol. 2022 Mar;37(3):235-249. doi: 10.1007/s10654-022-00853-w. Epub 2022 Mar 20. PMID: 35306604; PMCID: PMC8934243

Pezzullo AM, Axfors C, Contopoulos-Ioannidis DG, Apostolatos A, **Ioannidis JPA**. Age-stratified infection fatality rate of COVID-19 in the non-elderly population. Environ Res. 2023 Jan 1;216(Pt 3):114655. doi: 10.1016/j.envres.2022.114655. Epub 2022 Oct 28. PMID: 36341800; PMCID: PMC9613797.

Patients with fatal or serious covid-19 disease were disproportionately elderly, & heavily burdened with multiple, chronic comorbidities: Data from ~541K U.S. covid-19 hospitalizations

Table 1. Characteristics of Adults Hospitalized With COVID-19 in Premier Healthcare Database Special COVID-19 Release (PHD-SR), March 2020–March 2021

Characteristic[a]	All Hospitalized Patients in PHD-SR, No. (%)	Hospitalized Patients With COVID-19, No. (%)			
		Full Sample	ICU[b] admission	IMV[b]	Died[b]
Total	4,899,447 (100.0)	540,667 (100.0)	249,522 (100.0)	76,680 (100.0)	80,174 (100.0)
No. of conditions					
≥1[c]	4,438,183 (90.6)	513,292 (94.9)	242,372 (97.1)	75,514 (98.5)	79,434 (99.1)
0	461,264 (9.4)	27,375 (5.1)	7,150 (2.9)	1,166 (1.5)	740 (0.9)
1	402,499 (8.2)	39,776 (7.4)	14,272 (5.7)	2,785 (3.6)	2,087 (2.6)
2–5	1,796,770 (36.7)	212,429 (39.3)	94,405 (37.8)	27,405 (35.7)	25,893 (32.3)
6–10	1,565,845 (32.0)	167,706 (31.0)	84,745 (34.0)	28,774 (37.5)	31,310 (39.1)
>10	673,069 (13.7)	93,381 (17.3)	48,950 (19.6)	16,550 (21.6)	20,144 (25.1)
Sex					
Female	2,860,589 (58.4)	261,078 (48.3)	110,017 (44.1)	30,062 (39.2)	32,939 (41.1)
Male	2,037,012 (41.6)	279,317 (51.7)	139,416 (55.9)	46,587 (60.8)	47,211 (58.9)
Unknown	1,846 (0.0)	272 (0.1)	89 (0.0)	31 (0.0)	24 (0.0)
Age, y					
Median (IQR), y	68 (57–78)	66 (53–77)	67 (55–77)	67 (57–75)	74 (65–83)
18–39	1,304,324 (26.6)	59,697 (11.0)	19,120 (7.7)	4,192 (5.5)	1,299 (1.6)
40–49	428,000 (8.7)	51,591 (9.5)	22,605 (9.1)	5,913 (7.7)	2,710 (3.4)
50–64	1,085,170 (22.1)	144,306 (26.7)	68,791 (27.6)	22,791 (29.7)	14,867 (18.5)
65–74	923,004 (18.8)	121,832 (22.5)	62,056 (24.9)	23,055 (30.1)	21,421 (26.7)
75–84	735,429 (15.0)	103,012 (19.1)	50,891 (20.4)	16,041 (20.9)	23,308 (29.1)
≥85	423,520 (8.6)	60,229 (11.1)	26,059 (10.4)	4,688 (6.1)	16,569 (20.7)

64.2% of those who died, 59.1% requiring mechanical ventilation, & 53.6 requiring ICU admission had ≥ 6 chronic comorbidities

76.5% of those who died, 57.1% requiring mechanical ventilation, & 55.7 requiring ICU admission were ≥ 65 years old

Reference:
Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, Chevinsky JR, Schieber LZ, Summers AD, Lavery AM, Preston LE, Danielson ML, Cui Z, Namulanda G, Yusuf H, Mac Kenzie WR, Wong KK, Baggs J, Boehmer TK, Gundlapalli AV. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020-March 2021. Prev Chronic Dis. 2021 Jul 1;18:E66. doi: 10.5888/pcd18.210123. PMID: 34197283; PMCID: PMC8269743

Rhode Island Covid-19 Mortality: Critical Impact of Age

- **78% of deaths occurred among those ≥ 70**
- **55% of deaths occurred among those ≥ 80 (which is above the state's avg. life expectancy at birth of 79.8)**
- **53% of deaths occurred in nursing home or elder-assisted living facility residents (which further emphasizes the impact of comorbidity)**
- **NO DEATHS occurred in those ≤ 18 during > 3-years (*;**,***), while there were *269 non-covid-19 pediatric deaths* in Rhode Island from 1/1/2020-4/22/23**
- **(Sweden also had ZERO covid-19 pediatric deaths during the 1st [& most virulent] spring 2020 wave, despite ~2 million children attending school in person, without masks)**

*** Then RIDOH official Dr. James McDonald initially perjured himself on the issue of pediatric covid-19 deaths during Southwell v. McKee**

**** Compare this to 3 pediatric deaths in a single 2009-2010 H1N1 swine flu pandemic year in RI**

***** CDC SARS-CoV-2 antibody (nc) seroprevalence data indicates 96-100% of RI children have been infected!**

References:

RIDOH Covid-19 Data Hub: https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=1592746937

RI avg life expectancy: https://247wallst.com/state/heres-how-life-expectancy-in-rhode-island-compares-to-the-nation/

CDC all-cause RI pediatric mortality: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

Ludvigsson JF et al. "Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden" N Engl J Med. 2021 Feb 18;384(7):669-671. https://shorturl.at/adGQ6

For Dr. McDonald's initial perjury see: https://www.andrewbostom.org/wp-content/uploads/2021/10/brief-in-support-of-motion-for-preliminary-injunction_10_25-21.pdf

On 3 RI pediatric deaths from H1N1, 2009-10: (p.15) https://health.ri.gov/publications/surveillance/2011/Influenza.pdf

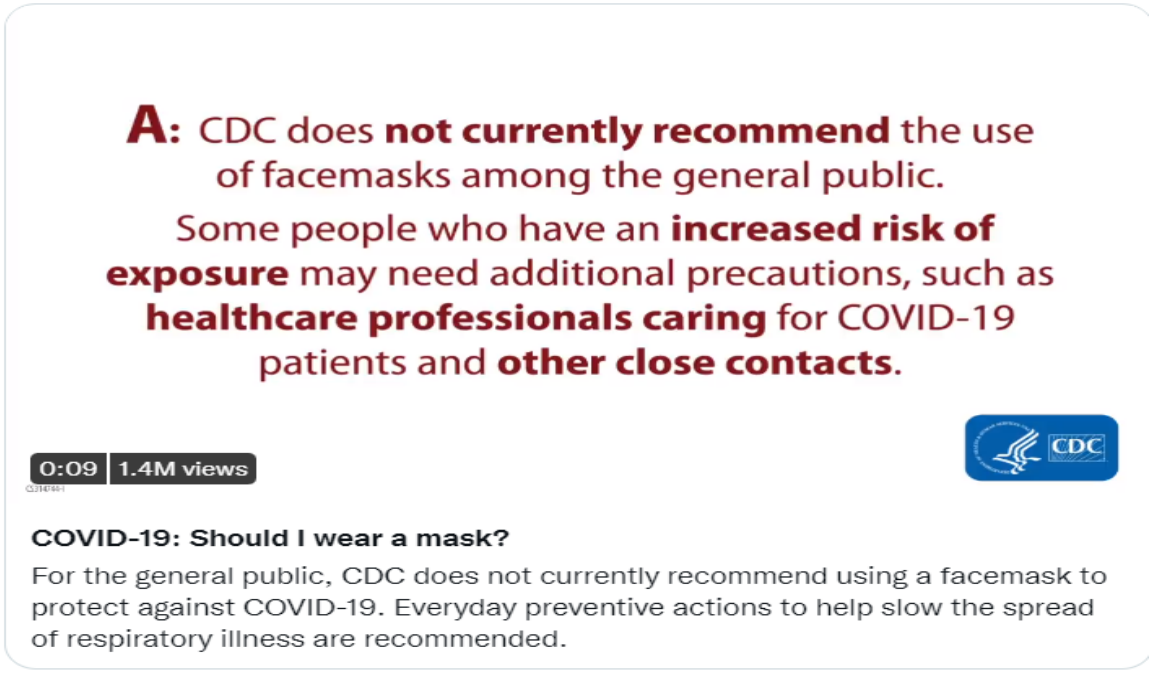
CDC SARS-CoV-2 antibody seroprevalence data for RI children as of 12/22: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence

Original Rational, Evidence-Based Centers For Disease Control & Prevention (CDC) Advice on Masking to Prevent Covid-19, February 27, 2020

← Tweet

CDC
@CDCgov

CDC does not currently recommend the use of facemasks to help prevent novel #coronavirus. Take everyday preventive actions, like staying home when you are sick and washing hands with soap and water, to help slow the spread of respiratory illness. #COVID19 bit.ly/37Ay6Cm



4:00 PM · Feb 27, 2020 · Twitter Media Studio

Masking During the 1918 Influenza Pandemic:
Plus ça change, plus c'est la même chose?

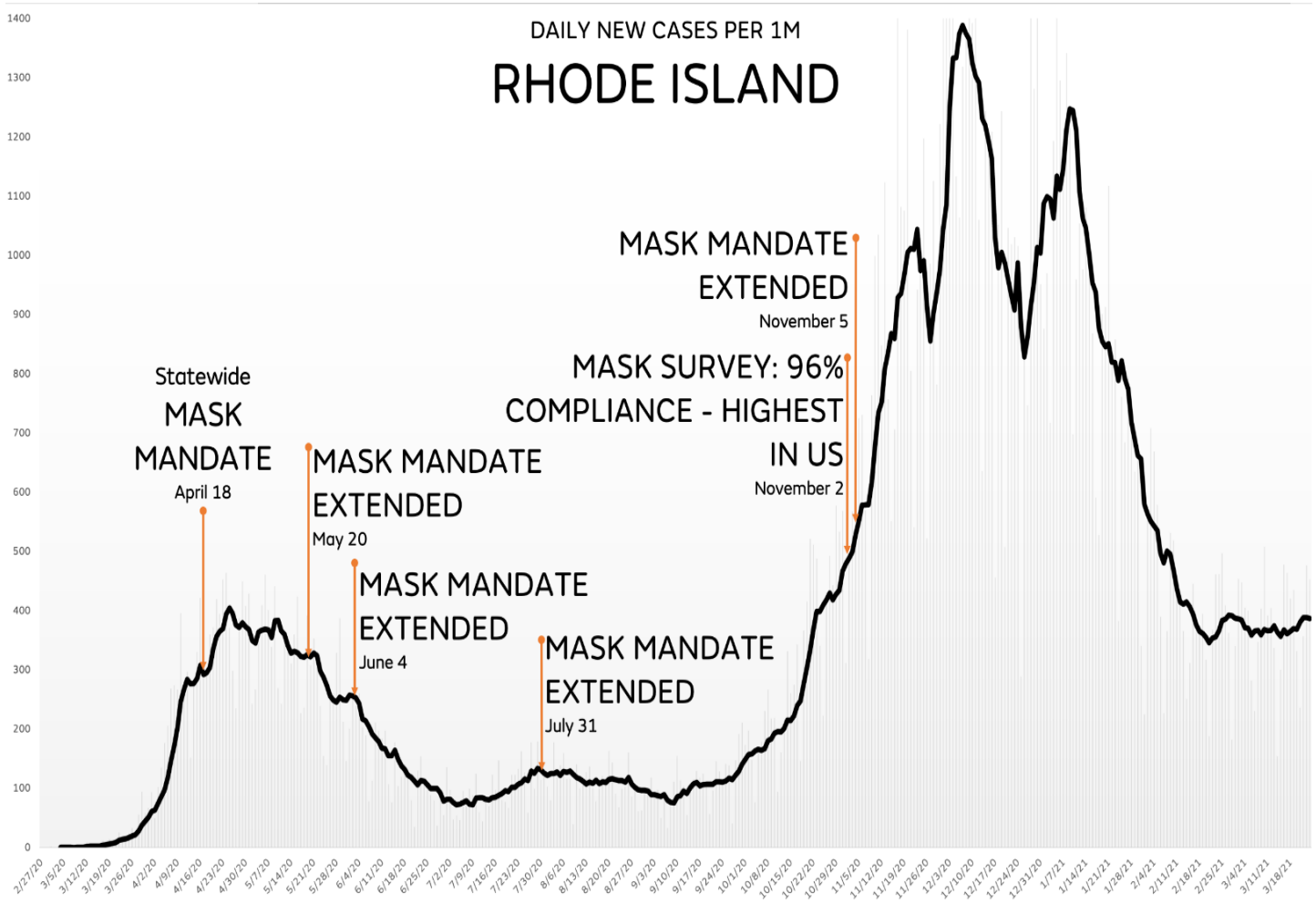
W.H. Kellogg, MD, infectious diseases expert, and then executive officer of the California State Board of Health, made this remorseful, brutally honest 1920 observation on the failure of masking to contain rampant influenza spread during the devastating 1918 pandemic (***Am J Public Health*** *[N Y]*. 1920;10(1):34-42. p. 35):

"The failure of the mask was a source of disappointment, for the first experiment in San Francisco was watched with interest with the expectation that if it proved feasible to enforce the regulation the desired result would be achieved. The reverse proved true. ***The masks, contrary to expectation, were worn cheerfully and universally, and also, contrary to expectation of what should follow under such circumstances, no effect on the epidemic curve was to be seen. Something was plainly wrong with our hypotheses*****."**

Masking in Rhode Island During the Initial Two Waves of the 2020-21 Covid-19 Pandemic: *Plus ça change, plus c'est la même chose*?

- Per a marketing survey of 5,000 Americans, reported 11/2/20, Rhode Island had the highest percentage—96%– of those who wear a mask "every time they go out" https://slickdeals.net/article/news/united-states-face-mask-wearing-habits-survey/

- Yet we still had an enormous late fall, early winter spike in covid-19 positive "cases" despite this 96% mask compliance, and the mandate extension, 11/5/20.



[Raw data for plot from RIDOH google doc]: https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=264100583

Randomized, Controlled Trials as the Requisite Gold-Standard Evidence for *Recommendations* (*Let Alone "Mandates"*)

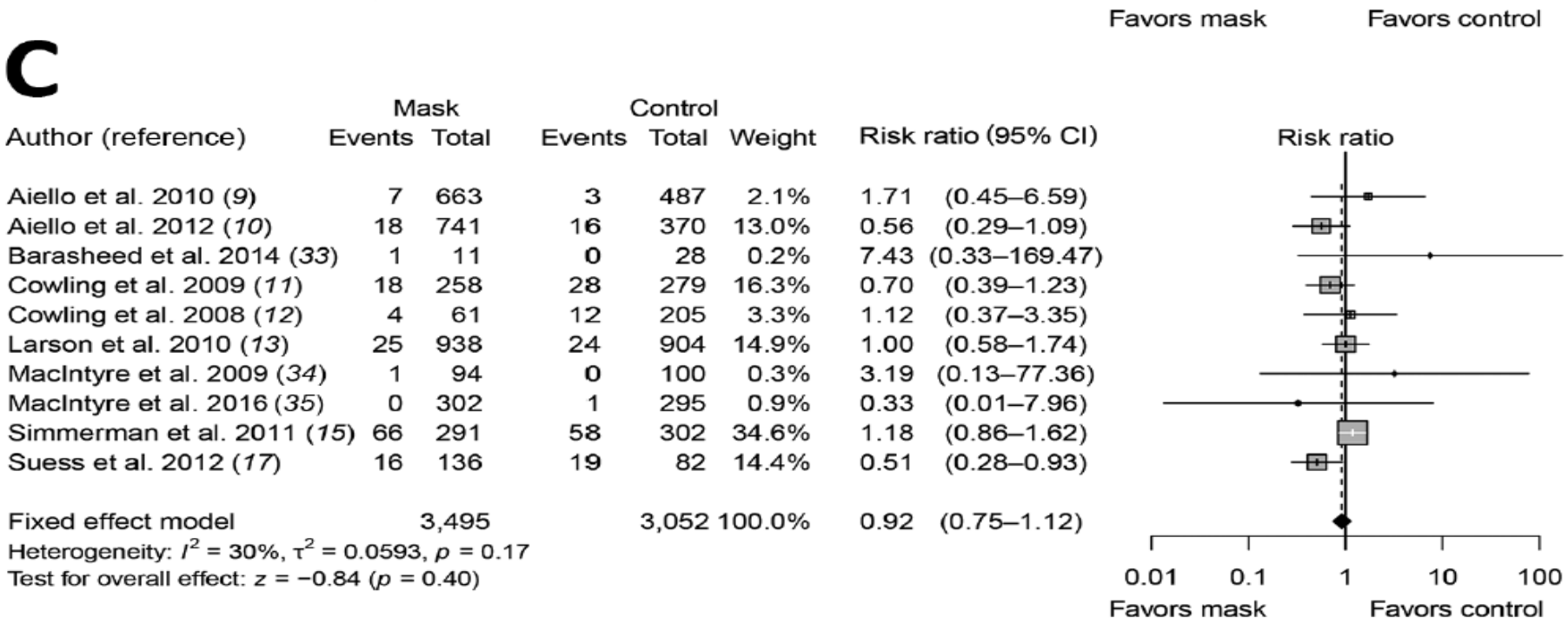
- In 1963 Campbell and Stanley published their seminal monograph on research methodology entitled "Experimental and Quasi-Experimental Designs for Research."
  - This work, which shaped research designs ever since highlighted the major threats to validity that ***are avoided, uniquely, by the randomized controlled trial***—a true experimental design—**but NOT by purely observational studies and all other non-randomized designs lacking parallel control groups**, **which they referred to "*quasi-experimental*", and fraught with intractable biases we attempt to control for, with limited success, after the fact**.
- Guyatt et al in their 2008 BMJ paper "GRADE: an emerging consensus on rating quality of evidence and strength of recommendations" https://www.bmj.com/content/336/7650/924.long, updated and reinforced these ideas, appropriately assigning highest priority to randomized, controlled trial evidence ***FOR MAKING RECOMMENDATIONS, NOT MANDATES!***

Factors that affect the strength of a recommendation

Factor	Examples of strong recommendations
Quality of evidence	Many high quality randomised trials

Uniformly NEGATIVE Randomized, Controlled Trials of Community Masking for the Prevention of Respiratory Viral Infections, Primarily Influenza, Published 2008, to 2020 (I)

- Between 2008-2020, at least 11 negative randomized controlled trials on masking were published. These studies conducted among ~12,000 persons, worldwide, all indicated that masking does not reduce community respiratory virus, especially influenza, infection rates. (1,2)
- Ten negative studies, focusing primarily on influenza, 2008 to 2016, were “meta-analyzed” [their data “pooled”], confirming the individual negative results (1)



Uniformly NEGATIVE Randomized, Controlled Trials of Community Masking for the Prevention of Respiratory Viral Infections, Primarily Influenza, Published 2008, to 2020 (II)

- Independently validating these pooled findings are the results from a single large randomized controlled trial of masking among another cohort of Hajj pilgrims whose enrollment [n=6338] (2) equaled the sum enrollment of all the 10 studies in the May, 2020 “meta-analysis.” Published online in mid-October, 2020, this “cluster randomized” (i.e., by tent) controlled trial confirmed mask usage did ***not*** reduce the incidence of clinically defined, or laboratory-confirmed respiratory viral infections, primarily influenza and/or rhinovirus. Indeed, there was a suggestion masking increased laboratory-confirmed infections by 40%, although this trend was not “statistically significant.” (2).

References

1) “Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures” https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article
2) “Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster randomized trial” https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7553311/pdf/pone.0240287.pdf

Those Pooled NEGATIVE RCTs Likely* Formed the Basis Centers For CDC'S Original Rational, Evidence-Based Advice AGAINST Masking to Prevent Covid-19, February 27, 2020 !

*FOIA request of Dr. Fauci's emails revealed he was shown in Feb 2020, the accepted, pre-publication galleys of the NEGATIVE pooled analysis of masking RCTs, "Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures" https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article



Cochrane Meta-analysis (+2): Randomized, Controlled Trials of Masking (Med-surgical Masks & N95 Masks) Confirm NO BENEFIT for the Prevention of Influenza, or Covid-19

Cochrane—Medical/surgical masks compared to no masks

"***Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks*** (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; **9 trials, 276,917 participants**; moderate-certainty evidence. ***Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks*** (RR 1.01, 95% CI 0.72 to 1.42; **6 trials, 13,919 participants**; moderate-certainty evidence). **Harms were rarely measured and poorly reported (very low-certainty evidence)**."

Cochrane—N95=P2 respirators compared to medical-surgical masks

"***The use of a N95/P2 respirators compared to medical/surgical masks probably makes little or no difference for the objective and more precise outcome of laboratory-confirmed influenza infection*** (RR 1.10, 95% CI 0.90 to 1.34; **5 trials**, 8407 participants; moderate-certainty evidence). **Restricting pooling to healthcare workers made no difference to the overall findings. Harms were poorly measured and reported, but discomfort wearing medical/surgical masks or N95/P2 respirators was mentioned in several studies (very low-certainty evidence)**."

Reference

Jefferson et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database of Systematic Reviews 2023, Issue 1. Art. No.: CD006207. DOI: 10.1002/14651858.CD006207.pub6

TWO ADDITIONAL STUDIES PUBLISHED AFTER COCHRANE META-ANALYSIS

Fit tested N95s vs. medical masks in ~1000 HCWs for SARS-CoV-2 Prevention:

RCT among health care workers comparing fit-tested N95 masks (**n=507**), to medical masks (**n=497**) published 11/29/22 in the pre-eminent internal medicine journal *Annals of Internal Medicine*, found **SARS-CoV-2 infection rates did not differ between the groups**. Confirmed (by RT-PCR) SARS-CoV-2 infections occurred in 52/497 (10.46%) of those assigned to medical masks, vs. 47/507 (9.27%) assigned to fit-tested N95 masks (hazard ratio 1.14 [95% CI, 0.77-1.69).

Enormous (~40K) community RCT of cloth masks in Guinea-Bissau, published in high impact journal *PLOS* :

No benefit in entirety which incl subgroup of 10-18 yo children (~10K)*; suggestion of both slightly increased all-cause deaths (52 vs. 37) & hospitalizations (8 vs. 3) in the mask intervention grp

*(*During Southwell v. McKee, Dr. McDonald claimed it would be "unethical" to conduct an RCT of masking in children...[but ethical to just mask them, in the absence of supportive data from an RCT!])*

References

Loeb M et al. Medical Masks Versus N95 Respirators for Preventing COVID-19 Among Health Care Workers : A Randomized Trial. Ann Intern Med. 2022 Dec;175(12):1629-1638. doi: 10.7326/M22-1966. Epub 2022 Nov 29;

Nanque LM, et al. Effect of distributing locally produced cloth facemasks on COVID-19-like illness and all-cause mortality-a cluster-randomised controlled trial in urban Guinea-Bissau. PLOS Glob Public Health. 2024 Feb 13;4(2):e0002901. doi: 10.1371/journal.pgph.0002901.

October 2019, Brown University & RIDOH Investigators Published a Peer Reviewed Study in the Journal "*Medical Care*," Using, & Praising, The Cochrane Reviews as a Tool for Teaching "Expert Guidance" to "Community Partners in Evidence Synthesis"!

"Good decision-making by policy makers, insurers, health systems administrators and funding agencies requires access to evidence that is applicable to their local context and responds to the needs of their constituencies.[1]" What was ref 1? Armstrong R, et al. "**Tracking and understanding the utility of Cochrane reviews for public health decision-making**." J Public Health. 2012;34:309–313.

"*The training program adapted expert guidance from the Institute of Medicine, Agency for Healthcare and Research Quality Effective Health Care Program, and* ***the Cochrane Handbook for Systematic Reviews of Interventions*** *for the community audience."*



Community-engaged Evidence Synthesis to Inform Public Health Policy and Clinical Practice

A Case Study

Stacey Springs, PhD,*† Valerie Rofeberg, ScM,* Sherilyn Brown, MA,‡ Steven Boudreau,§ Spencer Phillips Hey, PhD,‖¶ and Jay Baruch, MD#

Springs S, Rofeberg V, Brown S, Boudreau S, Hey SP, Baruch J. Community-engaged Evidence Synthesis to Inform Public Health Policy and Clinical Practice: A Case Study. Med Care. 2019 Oct;57 Suppl 10 Suppl 3(10 Suppl 3):S253-S258. doi: 10.1097/MLR.0000000000001180

This *Tripe* is What RIDOH, via CDC, Relied Upon, in Lieu of Valid RCTs: Evaluation of 77 masking "studies" published in CDC's non-peer reviewed, house organ, "Morbidity & Mortality Weekly Reports (*MMWR*)," 2019-2023

"We found that, while <20% of MMWR studies pertaining to masks generated ***any*** **statistical evidence of mask effectiveness *and no randomized [controlled trial (RCTs)] investigations were published***, more than 75% of the publications arrived at a favorable conclusion about using masks, and 70% of studies testing masks used causal language. Similarly, language about the studies' implications, including the importance of masking, was used in multiple publications despite lack of supporting evidence."

Høeg TB, Haslam A, Prasad V. An Analysis of Studies Pertaining to Masks in Morbidity and Mortality Weekly Report: Characteristics and Quality of Studies through 2023. ***Am J Med***. 2024 Feb;137(2):154-162.e1. doi: 10.1016/j.amjmed.2023.08.026. https://www.amjmed.com/article/S0002-9343(23)00580-6/fulltext

"*A number of studies that were particularly influential in shaping policy recommendations around masking in the public and schools were not even among the studies that attempted to properly evaluate masks, as they had no control group or comparative time period*. These studies included the investigation of Missouri hairdressers, the Georgia overnight camp outbreak investigation, and the Marin County, California school outbreak investigation."

Table 2 Select Conclusion Statements Indicating a Causal Relationship Between Mask Wearing and Decreased Case Rates/Transmission from MMWR Mask Studies that Failed to Find Evidence of Mask Effectiveness

Study and Date	Conclusion Statement	Control Group/Time Period	Provided Evidence of Mask Effectiveness
Outbreak investigation of 2 Missouri hairdressers 7/14/2020[7]	"Consistent and correct use of face coverings, when appropriate, is an important tool for minimizing spread of SARS-CoV-2."	No	No
Georgia camp outbreak investigation 8/7/2020[16]	"Consistent and correct use of cloth masks should be emphasized as important strategies for mitigating transmission."	No	No
Marin County Elementary School outbreak 9/3/2021[17]	"Strict adherence to multiple nonpharmaceutical prevention strategies, including masking, are important to ensure safe school instruction."	No	No

Negative effects of masking in children

REMINDER: Judge Lanphear in Southwell v. McKee, ruled masking caused, "(some) irreparable harm"

–The discomfort of a mask distracts some children from learning, & can cause social isolation as described during the 2003 SARS-CoV-1 epidemic in a Hong Kong study of preschool children.

–A 2019 controlled randomized, crossover study of N95 masking in children reported that within 5-minutes, masking significantly raised blood CO2 concentrations vs. a controlled 5-minute period when unmasked

–A 2022 controlled study of 72 children, aged 6–14 years old using the Cambridge Face Memory Test, a validated measure of face perception performance, revealed *"substantial quantitative and qualitative alterations in the processing of masked faces in school-age children,"* which *"could have significant effects on children's social interactions with their peers and their ability to form relationships with educators."*

Rao N. "Sars, preschool routines and children's behaviour: Observations from preschools in Hong Kong" *Int J Early Child*. 2006;38(2):11-22.

Goh DYT et al. "A randomised clinical trial to evaluate the safety, fit, comfort of a novel N95 mask in children" *Sci Rep.* 2019 Dec 12;9(1):18952.

Stajduhar A et al. Face masks disrupt holistic processing and face perception in school-age children. *Cogn Res Princ Implic*. 2022 Feb 7;7(1):9.

Covid-19 Policy Negative Educational Outcomes in US/ RI Schoolchildren

REMINDER: Judge Lanphear in Southwell v. McKee, ruled masking caused, "(some) irreparable harm"

2022

Test Scores Show Historic COVID Setbacks for Kids Across US

New national test results show that the pandemic spared no part of the country as it caused historic learning setbacks for America's children.

By Associated Press | Oct. 24, 2022, at 5:37 p.m.

"Across the country, math scores saw their largest decreases ever. Reading scores dropped to 1992 levels. Nearly four in 10 eighth graders failed to grasp basic math concepts. Not a single state saw a notable improvement in their average test scores, with some simply treading water at best. Those are the findings from the National Assessment of Educational Progress — known as the 'nation's report card' — which tested hundreds of thousands of fourth and eighth graders across the country this year. It was the first time the test had been given since 2019, and it's seen as the first nationally representative study of the pandemic's impact on learning."

2023

Study: R.I. students suffered significant learning loss during pandemic

By **James Bessette** - 05/11/2023

Providence Business News

Harvard & Stanford University, "Education Recovery Scorecard" Study:

"According to the researchers' findings – based on a points system to determine the results – **Rhode Island students statewide lost more than four months of learning math during the pandemic and more than two months of learning reading**. Some districts, though, have suffered greater losses. **In South Kingstown, students there have lost close to nine months of learning in math and more than five months of learning reading**. Students in **Newport, per the research, have experienced almost eight months of learning loss in math and more than six months of learning loss in reading. The Providence Public School District, currently under R.I. Department of Education control, has seen its students lose close to six months of math learning loss and almost four months of lost learning in reading**. Students in Woonsocket, Westerly, North Providence, Cranston, West Warwick, Pawtucket, East Providence and Chariho have also lost about six months of learning math due to the pandemic, according to the research. Students in those same districts have experienced approximately three months of learning loss in reading. Meanwhile, **only Narragansett students have not experienced learning loss in both math and reading during the pandemic, per the research**."

Covid-19 Policies WITHOUT NEGATIVE Educational Outcomes in Swedish Schoolchildren

ELSEVIER

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No learning loss in Sweden during the pandemic: Evidence from primary school reading assessments

Anna Eva Hallin [a], Henrik Danielsson [b], Thomas Nordström [c], Linda Fälth [d]

Highlights

- No COVID-19 related learning loss in reading in Swedish primary school students.
- The proportion of students with weak reading skills did not increase during the pandemic.
- Students from disadvantaged socio-economic backgrounds were not especially affected.

No More Lysenkoism & a Return to Experiential, Evidence-Based Medicine (I)

D. A Henderson (d. 2016), MD, MPH, who was Dean of the Johns Hopkins University School of Public Health, and a leading figure in the WHO's successful smallpox eradication program, was the senior author on a paper about respiratory virus, esp. influenza, pandemic planning, circa 2006

Perhaps Henderson's very calm, sober perspective was shaped by dealing with a much more catastrophic illness—smallpox—which had a 20–60% fatality rate (persisting at 15-30% in its last endemic century), whose survivors were often maimed by the disease. This scourge, and the havoc it wrought, destroyed entire civilizations, and killed some 300 million in the 20th century, alone.

> "There are **no historical observations or scientific studies that support the confinement by quarantine of groups** of possibly infected people for extended periods in order to slow the spread of influenza... **The negative consequences of large-scale quarantine are so extreme (forced confinement of sick people with the well; restriction of movement of large populations)... that this mitigation measure should be eliminated from serious consideration...** During seasonal influenza epidemics, public events with an expected large attendance have sometimes been cancelled or postponed, the rationale being to decrease the number of contacts with those who might be contagious. **There are, however, no certain indications that these actions have had any definitive effect on the severity or duration of an epidemic**... Schools are often closed for 1–2 weeks early in the development of seasonal community outbreaks of influenza primarily because of high absentee rates, especially in elementary schools, and because of illness among teachers. This would seem reasonable on practical grounds. **However, to close schools for longer periods is not only impracticable but carries the possibility of a serious adverse outcome...**

No More Lysenkoism & a Return to Experiential, Evidence-Based Medicine (II)

...In Asia during the SARS period, many people in the affected communities wore surgical masks when in public. **But studies have shown that the ordinary surgical mask does little to prevent inhalation of small droplets bearing influenza virus. The pores in the mask become blocked by moisture from breathing, and the air stream simply diverts around the mask.** ***There are few data available to support the efficacy of N95 or surgical masks outside a healthcare setting. N95 masks need to be fit-tested to be efficacious and are uncomfortable to wear for more than an hour or two***... **The problems in implementing such measures are formidable, and secondary effects of absenteeism and community disruption as well as possible adverse consequences, such as loss of public trust in government and stigmatization of quarantined people and groups, are likely to be considerable…*Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted***. Strong political and public health leadership to provide reassurance and to ensure that needed medical care services are provided are critical elements. If either is seen to be less than optimal, **a manageable epidemic could move toward catastrophe**."

From Henderson's senior author paper: "Disease mitigation measures in the control of pandemic influenza." Biosecur Bioterror. 2006;4(4):366-75. doi: 10.1089/bsp.2006.4.366. PMID: 17238820.

RCT evidence-based ultimatum to RIDOH, from parents, & their advocates :

"There will be no regulation requiring masking in schools for the alleged prevention of respiratory viral infections until evidence of BOTH their effectiveness, & lack of harm, has been demonstrated convincingly by multiple, rigorous, randomized controlled trials (RCTs) in school age children, published in peer reviewed journals."

SARS, PRESCHOOL ROUTINES AND CHILDREN'S BEHAVIOUR:
OBSERVATIONS FROM PRESCHOOLS IN HONG KONG

Nirmala Rao

SUMMARY

All schools in Hong Kong were closed in April 2003 to prevent the spread of SARS. This paper considers the influence of the SARS epidemic on children's routines and behaviour when preschools re-opened, after a six-week closure. Observations were made in 20 kindergartens and principals of another 10 kindergartens completed questionnaires. The influence of SARS was evident in all preschools, be it through teachers and students wearing masks, notices on hand washing or the provision of alcohol dispensers for hand disinfection. The outbreak impacted noticeably upon children's routines and social exchanges. In all schools, physical contact among children and sharing of food were not allowed. Children were also prohibited from talking to their peers when they had removed their masks. The SARS outbreak provided us a "natural experiment" to consider the influence of epidemics on preschools.

RÉSUMÉ

En avril 2003, toutes les écoles de Hong Kong ont été fermés pour empêcher la propagation du SRAS. Cet article considère l'influence de l'épidémie de SRAS sur les routines et le comportement des enfants une fois que les établissements préscolaires ont été réouverts, après une fermeture de six semaines. On a fait des observations dans 20 jardins d'enfants et les directeurs d'autres 10 jardins d'enfants ont rempli des questionnaires. L'influence du SRAS était évidente dans tous les établissements où les éducateurs et les élèves portaient des masques, il y avait des indications sur le lavage des mains ou bien on a placé des dispenseurs d'alcool pour la désinfection des mains. L´éruption a affecté de manière perceptible les routines et les échanges sociaux des enfants. Dans toutes les écoles, on n'a pas permis le contact physique parmi des petits même que le partage de la nourriture. Des enfants ont été également interdits de parler à leurs pairs quand ils avaient enlevé leurs masques. L´éruption du SRAS nous a fourni "une expérience naturelle" pour considérer l'influence des épidémies chez les établissements préscolaires.

RESUMEN

El SARS - rutinas y comportamiento de los niños pequeños: El estudio da cuenta de observaciones realizadas en establecimientos preescolares en Hong-Kong. Todo ello nace ya que en abril de 2003, todas las escuelas de Hong-Kong cerraron para evitar la propagación del SARS. Este artículo analiza la influencia de esta alerta de epidemia, en la rutina y el comportamiento de los niños / as. Cuando se reabrieron los establecimientos preescolares, que debieron permanecer cerrados durante 6 semanas, se realizaron observaciones en 20 jardines infantiles y los directores de otros 10 jardines respondieron cuestionarios. El SARS y las medidas que se tomaban para evitar posibles contagios, influyeron en forma evidente en todos los establecimientos preescolares, ya que educadores y estudiantes usaban máscaras, se colocaron avisos que advertían la importancia de lavarse

las manos o se instaló una gran cantidad de dispensadores con alcohol para desinfectarse las manos. El brote y las medidas de prevención, afectaron en forma perceptible la rutina y el intercambio social de los niños. En todas las escuelas, se prohibió el contacto físico entre los pequeños, los que tampoco podían compartir alimentos. Además, a los niños no les estaba permitido hablar con sus pares si se habían quitado la máscara. El brote de SARS nos proporcionó un "experimento natural" para analizar la influencia de las epidemias en los establecimientos preescolares.

KEYWORDS: SARS, Preschools, Early childhood education

During the past 100 years, there have been five killer viruses, including the Spanish flu (1918), the Asian Flu (1957), the Hong Kong flu (1968), Severe Acute Respiratory Syndrome (SARS) (2003) and the Avian Flu (2004) (Dunne, 2005). Flu pandemics have led to the closure of schools as it is assumed that infectious diseases can be rapidly transmitted in school premises. Previous research indicates that school closure reduces the incidence of viral respiratory diseases among children during an influenza outbreak (Heymann, Chodick, Reichman, Kokia & Laufer, 2004). It has been suggested that one of the reasons that Hong Kong flu (1968) was less deadly than the Spanish and Asian influenzas is that it peaked during the school holidays and children did not spread the virus in school. Research also indicates that Upper Respiratory Infections (URIs) are much more common in preschool children in centre-based care than those who are looked after at home (NICHD ECCRN, 2005). Hence, medical research indicates that preschool closure prevents the spread of viral respiratory diseases and that children in centre-based care are more susceptible to URIs. On the other hand, because of the nature of transmission mechanisms, there is an extremely small likelihood that viruses like HIV/AIDS will be spread in preschools.

Schools were closed in Britain and the United States during the Spanish flu (Billings, 1997). More recently, in 2003, schools were closed in Canada, Mainland China, Singapore and Hong Kong to prevent the spread of SARS. Five schools were closed in Ontario, Canada (Health Canada, 2003). On the other hand, there were mass school closures in Asia. In Singapore, all schools were closed on March 27 and re-opened in phases after April 14 (Singapore Government, 2003), and in Hong Kong, schools were closed for at least 6 weeks and also re-opened in phases with secondary schools re-opening before primary schools. Preschools in Hong Kong were officially closed between March 29 and May 18, 2003.

Appendix 1 provides the WHO report on the course of the SARS outbreak in Hong Kong. There were a total of 1,755 SARS cases in Hong Kong and 399 deaths occurred because of SARS (Government of Hong Kong, 2003). It should be noted that there were many unknowns about the transmission of SARS at the height of the outbreak. The high population density of Hong Kong puts her at risk for the rapid spread of infectious diseases. Further, since Hong Kong is used

as a gateway between Mainland China and the rest of the world, control of the epidemic was a top priority for the Hong Kong government.

In Hong Kong, preschool institutions are in the private sector. They include child-care centres which serve children from 6 weeks to 6 years and kindergartens which enrol children ranging in age from 2 years 8 months to 6 years. Most kindergartens offer bi-sessional classes of around three hours each, while most child care centres offer whole-day programs. About 95% of children over 3 years of age in Hong Kong attend preschool programmes. The extent of coverage reflects both government policy and the value that Chinese parents traditionally attach to early childhood education.

The government determines, monitors, and enforces standards for preschools. Adult-child ratios are currently about 1:10 in kindergartens and curriculum guidelines are issued by the government. The 1996 Guide to Pre-primary Curriculum advocates a child-centred approach and stresses all-round development (Government of Hong Kong, 1996). It espouses contemporary views on effective early teaching and learning, and provides suggestions for facilitating intellectual, communicative, personal, physical and aesthetic development.

The Hong Kong government was concerned that some kindergartens went too far in presenting formal academic curricula, using inappropriate teaching methods for children below the age of six. Hence, in 1999, a list of 'Dos and Don'ts' for kindergartens was published (Government of Hong Kong, 1999). The list of 'Dos' includes having a curriculum that covers moral, cognitive, physical, social, and aesthetic aspects of development by organizing activities that promote all-round development; organizing various child-centred learning activities; using the mother tongue as the language of instruction, and respecting individual differences. Good programs in any country achieve all these goals, but some are especially pertinent to Hong Kong idiosyncrasies. For example, Chinese culture emphasizes moral development, and it is recommended that the curriculum attends to this perspective.

As in other societies, pedagogical practices in Hong Kong preschools are influenced by cultural beliefs about early learning. In the past, the Chinese teacher was characterised as a fountain of knowledge who force-fed Peking ducks. However, children spend more time in play-based learning now than in the past and there has been a corresponding decrease in expository teaching. It appears that traditional Chinese cultural beliefs about early learning have taken a back seat to what is considered as good educational practice. Cultural beliefs about childhood and education also influence pedagogy. For example, kindergartens tend to have highly structured days. This is partly due to children's age, but also a reflection of Chinese cultural beliefs about the early years being a time for training young children to be disciplined and behave properly (Rao, McHale & Pearson, 2003).

During visits to preschools when they re-opened after the mandatory closure, the author was struck by the marked changes in preschool routines.

Hence this study was undertaken to provide an objective documentation of these changes.

The main objectives of the study were to (i) consider the influence of the SARS epidemic on children's routines and behaviour when preschools re-opened after a six-week closure; and (ii) consider principals' perspectives on the lessons that had been learned about promoting children's learning and managing preschools during an epidemic.

METHOD

SAMPLE

A retrospective study was conducted. The sample, although not randomly selected, was representative of Hong Kong preschools in terms of location, sponsor, status, size, and tuition fees. Surveys were completed by observers in 20 preschools (18 kindergartens and 2 child care centres), and principals in another 10 preschools completed questionnaires.

Survey completed by observers. Items on the survey fell into 6 categories including: Information about the preschool and children (21 questions); Routines before the SARS outbreak (4 questions); Learning during School Closure (2 questions); Preparing the kindergarten for re-opening (2 questions); Students return to kindergartens (18 questions); Lessons from SARS (4 questions); and Demographic information about the observers. The 18 items on Students' return to kindergartens included questions on Daily routines (3 questions); Health issues (2 questions); Social Interaction among children (6 questions); Preschool Management (3 questions); and School Holidays (4 questions). The majority of questions required responses in a fixed choice format. Examples of items are presented in the Appendix.

Questionnaires completed by principals

Questionnaires were completed by principals of 10 kindergartens. These addressed similar categories as those in the survey given to the observers but reflected their different perspectives and access to information. The questions to principals included ones on: Learning during school closure (18 questions); Preparing the kindergarten for re-opening (5 questions); Students return to kindergartens (25 questions); and Lessons from SARS (5 questions). We were particularly interested in gathering information from principals about learning during preschool closure. This is because schools in Hong Kong and Mainland China took particular advantage of the information and communication technology available to ensure that learning could take place even though schools were closed. The questions on "Learning during school closure" included those related to: Decisions about when to close and re-open the school (4 questions); Teaching and Learning (5 questions); Contacting students (2 questions); Homework (3 questions); and Computer-supported Learning (4 questions).

Documentary analyses
Government guidelines and regulations for preschools issued between March and May 2003 were perused.

PROCEDURE

The survey for observers and the questionnaire for principals were developed in English and the observers, all of whom were completely bi-lingual (English-Chinese), completed the English version of the survey. The questionnaire for principals was translated into Chinese and a back-translation procedure was used to ensure accuracy of the translation. Principals completed Chinese versions of the questionnaire.

Surveys of 20 preschools (18 kindergartens and 2 child-care centres) were conducted by 3 experienced lecturers, who were responsible for the practicum supervision of students in early childhood teacher education programmes. They were given training in the use of the survey, in which to record their observations and they consulted with the student-teacher they were supervising in completing the survey. Surveys were conducted within a month of preschools' re-opening. Questionnaires were distributed to principals in July and returned by late August.

RESULTS

The aim of this study was to document the influence of the SARS epidemic on children's routines and behaviour, and consider principals' perspectives on promoting children's learning and managing preschools during an epidemic. In the following section, information garnered from the survey is presented under the following headings: School closure; Learning during school closure; School re-opening; Changes in routines; Change in curriculum/pedagogy; and Changes in social interactions. Principals' perspectives are presented in the last section.

SCHOOL CLOSURE

As noted earlier, preschools were officially closed between March 29 and May 18, 2003. However, 15 % of the preschools closed before that date. The majority of preschools re-opened on May 19, 2003. Teachers in all schools contacted students at least once per week during school closure and 15% of teachers contacted children twice a week or more often. The mode of contact varied from telephone calls (4 preschools), circulars (4 preschools) and e-mail (3 preschools).

LEARNING DURING SCHOOL CLOSURE

In the preschools which were observed, a variety of assignments were distributed for home-based learning. These included worksheets (18 preschools); Exercise books (12 schools); Reading assignments (8 schools); suggested

parent-child activities (5 schools); CD ROMs for demonstrated teaching (3 preschools); and suggested websites for home learning (8 preschools).

SCHOOL RE-OPENING

According to the observers, many changes were apparent in the school environment when children returned to preschool. All schools had visual displays about hygiene and the preschool environment was much cleaner. Disinfection kits were located in most rooms. Further, in many schools, teachers wore aprons to hold alcohol spray and extra masks.

CHANGES IN ROUTINES

Observers reported that 85% of the preschools instituted a moderate change in routine. In keeping with government guidelines, children's temperature was measured when they came to preschools and they washed their hands several times a day. In 15% of the preschools, there was a drastic change in routines, including a shortening of the length of school day. Free play was curtailed and snack time was cancelled in some schools. In schools where it was continued, children had to face the wall while eating their snack. Physical Education (P.E.) and music lessons were cancelled and group size decreased in all schools.

A specific example of a change in routine comes from the requirements for children when they entered preschool. In several preschools, children stepped on the disinfection mat outside the main door of the preschool and had their temperature and hands checked. They then had to remove their shoes and wash their hands. In fact, in some schools children had to wash hands up to 5 times within a 3-hour period.

CHANGE IN CURRICULUM/ PEDAGOGY

During the SARS outbreak, the Education and Manpower Bureau of the Hong Kong Government issued a curriculum for children ranging in age from 3-6 years. This included the following 7 independent lessons: Learning about SARS; Personal hygiene (1); Personal hygiene (2); Concern and respect for a SARS patient; SARS symptoms, wearing masks and washing hands; Learning to prevent SARS. In all preschools, the curriculum was modified to include SARS education. All preschools talked about protection from SARS, proper washing of hands, not touching face, and not sharing food.

There was a decrease in instructional time in all preschools. Some preschools introduced new themes and did not address previously planned themes. Activities and games to raise awareness about the prevention of SARS and the importance of personal hygiene were included in some schools. Observations indicated that some schools accelerated teaching in order to "finish" all themes. Teachers typically did not initiate activities such as circle-time or story-telling with the whole class. Instead more activities were conducted with small groups of children and there was more small group

teaching. The latter is considered more developmentally and pedagogically appropriate in the early years (Bredekamp & Copple, 1997).

Changes in social interaction

The SARS outbreak influenced interactions between the teacher and children and those among children. Children and teachers could not see each others' facial expressions because of masks and both children and teachers experienced discomfort when talking while wearing masks.

There was also a reduction in social interaction among peers. Sharing of toys was prohibited. Children were given individual toy packs in some schools and toys/equipment were sterilized every time they were used. It should be noted that physical contact among children was prohibited. This was a function of the government guidelines which specified that physical contact among children should be discouraged. Observations revealed that in 30% of the preschools, desks were moved into rows and children had to face the wall during snack time.

There were fewer opportunities to interact in large groups as group sizes were reduced. For example, there was less interactive teaching and opportunities for learning in groups. School activities were affected by SARS. Field trips were cancelled and outdoor play was suspended or restricted to small groups.

Observers brought back photographs from the preschools which they visited. All children were wearing masks, and children had individual "stationery" and "toy" kits as sharing was prohibited. In some preschools, teachers wore aprons with pockets which contained alcohol spray, tissues and gloves.

Documentary analysis

As mentioned earlier the Education and Manpower Bureau of the Hong Kong Government developed a programme for preschool children on SARS. This was disseminated to all preschools. Reports indicate that about 20 per cent of parents refused to pay preschool fees during the school closure. This, coupled with the decrease in demand for preschool education in Hong Kong because of the falling birth rate, caused financial hardship to many kindergartens. The Permanent Secretary of Education and Manpower urged property owners to reduce rents for kindergartens and child care centres, and in an open letter to parents of preschool children, pleaded with them to pay the school fees. The letters to parents were sent out on April 30 and May 7, 2004.

Principals' views

Some principals felt that that the government's response to the SARS outbreak was too slow. They believed that the decision about mandatory school closure came too late and some preschools had closed before that date. Interactions among adults were affected and this possibly indirectly affected children. Principals reported that there was more staff teambuilding and better

communication between the school and parents. One principal reported that since many social activities were cancelled, preschool children had the opportunity to spend more time at home with their families. They also felt that children developed an awareness of news and community events.

By September 2003, preschools appeared to revert to their previous routines. However, the government continued to issue circulars on preventing the resurgence of SARS.

DISCUSSION

The aim of this study was to objectively document changes in preschool routines as a result of the SARS outbreak in Hong Kong. Some of the changes are similar to those made in Singapore when it was confronted with a potential epidemic. For example, the Singapore Government (2003) issued the following guidelines to keep kindergartens SARS free: Clean and disinfect kindergarten premises; Educate children, teachers and parents on precautionary measures against SARS; Daily temperature screening procedures for all children; and Children who had travelled to SARS-infected areas had to stay away from kindergartens for 10 days after their return to Singapore. Others changes in routines in Hong Kong preschools are a reflection of their specific circumstances and broader Chinese beliefs of learning.

All schools were closed during the mandatory period while some closed even before this. The latter reflects the autonomy given to preschools. Preschool education in Hong Kong is not part of the main compulsory education system although over 90 per cent of children ranging in age from 3 to 5 years are enrolled in some form of preschool education (Wong & Rao, 2004). The government does, however, ensure and monitor standards of service and through a fee remission scheme, the government seeks to ensure that no child is deprived of early childhood education because of its financial reasons (Rao, Koong, Kwong & Wong, 2003).

Preschools prepared a variety of assignments for children during school closure. Eighteen out of 20 preschools which were observed distributed worksheets while others sent exercises and reading assignments home. Some preschools burnt CDs so children could watch their teacher's instruction. Summer holidays were also curtailed so children could "make-up" for missed classes. The provision of assignments and the longer school year reflect the relatively high academic focus prevalent in kindergartens in Hong Kong and the emphasis placed on completing the syllabus prescribed by the preschool.

There were fairly marked changes in children's routines. While all would agree that children's temperature should have been taken before they came to school and they should wash their hands soon after they get there, the drastic changes in some of the routines may be considered excessive. Was it necessary for children to wash hands 5 times within 3 hours? Did preschool teachers really need to wear aprons with carry alcohol spray, tissues and gloves? Did children

really need to face the wall while eating their snack? However, these behaviours must be considered in the light of the general context. At the time of the SARS outbreak, there were many unknowns about the transmission of SARS, and there was panic in the general population. Hong Kong's typically crowded streets were less so, and about 30% of the population was wearing surgical masks. A 14-year-old boy played a prank on the internet and indicated that the territory was going to be quarantined. This led to panic buying and supermarkets ran out of basic supplies. It is also important to re-iterate that Hong Kong is a very densely populated city and this can lead to fairly rapid transmission of viruses.

All preschools modified their curriculum to include education about SARS and the government should be credited for the speed at which it prepared curriculum guides and materials for preschools. However, the emphasis on early pre-academic skills evident in some preschools in Hong Kong is reflected in the fact that some preschools accelerated their teaching in order to finish their syllabus/themes. Further all local schools delayed the summer holidays by at least two weeks to make up for the school closure. On the other hand, nearly all international schools in Hong Kong closed on schedule for the summer holidays.

One of the most dramatic changes noticeable was the decrease in social interaction among children. Children experienced discomfort when talking while wearing a mask and teachers and students could not read each others' facial expressions because of the masks. Children's desks were moved into rows and they were not allowed to change seats during the day. Group size was decreased and there was less interactive teaching. There was an increase in solitary play and children were not allowed to share toys and physical contact among children was prohibited. All the changes in social interaction reflected government guidelines.

In conclusion, the Hong Kong government acted efficiently and effectively during the period of school closure. Guidelines on the preschool environment were issued, and curriculum materials relevant to SARS were available to schools before they re-opened. However, some principals felt that the decision to close schools was made too late. There were moderate to drastic changes in children's routines when preschools re-opened after the closure. SARS led to modifications in school activities, and all extra-curricular activities such as school trips were cancelled. There was, not surprisingly, an increased awareness about SARS and how to prevent it as a result of visual displays and curriculum changes. There was more small-group teaching and less social interaction among children. In hindsight, we can consider whether some of the changes which resulted in decreased social interaction among children were really necessary. However, it is clear that preschool educators were very resourceful and tried to ensure that the suspension of school did not mean the suspension of learning.

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Appendix 1

COURSE OF THE SARS OUTBREAK IN HONG KONG

….“SARS was first carried out of southern China into Hong Kong, and then on to Hanoi, Toronto, and Singapore in late February. Some 16 visitors and guests to the ninth floor of a Hong Kong hotel became infected through contact, in ways that remain mysterious, with a symptomatic medical doctor from Guangdong Province, who stayed in the hotel’s room 911. The index case for Hong Kong’s first outbreak, in the Prince of Wales Hospital, visited an acquaintance staying on the same floor during the critical days in February. Additional clusters were also subsequently linked to the hotel.

SARS had not yet been identified as a dangerous new disease when the outbreak hit Hong Kong’s hospitals. Doctors and nurses, unaware of the need to isolate patients and protect themselves, became the first victims as they struggled to save lives. In a particularly unfortunate incident, the index patient at Prince of Wales, admitted on 4 March, was treated four times daily with a jet nebulizer, which probably aerosolized the virus and greatly increased opportunities for spread.

In late March, Hong Kong suffered a major setback when a large cluster, eventually numbering more than 300, of almost simultaneous new cases was traced to a single building in the Amoy Gardens housing state. That event, which raised the possibility of an environmental source of infection or even airborne spread of the virus, was investigated by teams of local specialists. The outbreak was attributed to an “unlucky” convergence of environmental conditions that allowed the contamination of vertically-linked apartments. This conclusion, subsequently confirmed by additional studies, calmed fears that the SARS virus might be airborne.

From the day when the first cluster of cases was recognized, Hong Kong officials have provided open, honest, and abundant information about SARS to both the public and the media. Hong Kong also benefited from the contribution of its outstanding scientists, epidemiologists, and clinicians, who were at the forefront of efforts to track down source cases in the various clusters, identify the causative agent, develop diagnostic tests, and work out treatment protocols.

Faced with the largest outbreak outside mainland China, Hong Kong also pioneered many of the control measures used to successfully contain smaller outbreaks elsewhere. It is gratifying that these measures have now brought Hong Kong to the point of victory over the virus, although continued vigilance remains vital.

On 2 April, WHO advised the public to consider postponing all but essential travel to Hong Kong. That recommendation was removed more than 7 weeks later, on 23 May”.

Source: World Health Organization (June 23, 2003)
Update 86 - Hong Kong removed from list of areas with local transmission
http://www.who.int/csr/don/2003_06_23/en/

Appendix 2

EXAMPLES OF ITEMS FROM THE QUESTIONNAIRES

Section A: Background Information

10. Were there any SARS cases in the preschool district? If so, about how many?

Section B: Before the SARS Outbreak

2. Were all toys disinfected at least once a week?

Section C: School Closure

Kindergartens were officially closed between March 29, and May 18,2003

1. When did the kindergarten actually close?

Section D: Preparing the Kindergarten for Re-Opening

1. When you went to the school, what changes had the kindergarten made to prepare for the children's return to school? (Please tick)

- o Thoroughly cleaned and disinfected preschools
- o Disinfected all toys
- o Installed alcohol spray dispensers How many?_____
- o Placed disinfectant mats
- o Provided liquid soap in all bathrooms
- o Provided paper towels in bathrooms
- o Installed extra taps for washing hands How many?_____
- o Provided aprons with pockets for teachers

If yes what did teachers have in the pockets e.g., disinfectant, gloves, tissues, alcohol spray?_____

Section E: Students Return to Kindergartens

Heath issues

4. In the few days after children returned, were there sessions to teach children about (please select):

- o the SARS virus; Protecting themselves
- o Proper washing of hands
- o Avoiding touching their faces, noses and eyes
- o Avoiding playing with friends
- o Not sharing food and drink with friends
- o Proper wearing of masks

5. Comment on the children's use of face masks

Social Interaction among children

3. What rules were developed to curtail physical interaction among children?
7. Was there a snack time when the kindergarten reopened after SARS?

Preschool Management

5. About how many children in the preschool did not return to school by June 23, 2003?
8. When was the kindergarten scheduled to re-open for the summer holidays?
9. When will it re-open now?

Section F: Lessons from SARS

2. What were the main changes in preschool routines because of SARS?
3. Were there any benefits for preschool education from the SARS outbreak?

Proposed Mask Ruling

Lee Ann M. <leeannmm85@yahoo.com>
Thu 3/14/2024 5:06 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
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Report Suspicious

Dear Mr. Garceau,

I am writing to you on behalf of my children. One who is in the second grade right now and one who will start kindergarten in 2025. My eldest child had started kindergarten in 2021. He had to wear a mask his first day of school.

MY LITTLE 5 YEAR OLD CHILD AT THE TIME HAD TO WEAR A MASK TO SCHOOL ON HIS VERY FIRST DAY! He did not get to see smiles from his teacher or any of his new classmates.

On that first day of school in 2021, as a parent, I was already a wreck sending my first born off and having him MANDATED to wear a mask absolutely put me over the edge. Not only was he nervous and scared on his first day, but he really didn't want to wear the mask to begin with because it was very uncomfortable for him and he said HE COULD BEARLY BREATHE! He also would tell me after school it was very heard to hear his teacher and peers talk due to the mask. I did not have the privilege at the time to homeschool my child, otherwise, I would have signed him out of the public school system long before having to send my child to school in a mask.

Throughout the 2021 and part of 2022 school year, my son STILL GOT SICK EVERY MONTH even though he was MANDATED TO WEAR A MASK EVERY DAY at school. MASKS ARE ESSENTIALLY INEFFECTIVE at preventing illness as my son was sick every month while wearing said mask, and not to mention his mask would come home full of nasal secretions and spit that he had to breathe in all day at school.

MY HEART HURT TO SEE MY SON SO UNCOMFORTALBE AND COMPLAIN HE COULD BARELY BREATHE FOR ALMOST 7 HOURS PER DAY AT SCHOOL WHILE FORCED TO WEAR A MASK!

So finally, on the glorious day of March 7, 2022, my son was able to go to school without a mask! HE WAS ECSTATIC! I was so happy to see him happy! As I walked my son to school that day, my heart sang as I saw all the smiling kids giggling and goofing like normal kids all WITHOUT MASKS!

I'm writing this email both very angry and sad. Angry because even though the Department of Health just settled a lawsuit against them this past January 2024, they are NOW ARE TRYING TO GAIN AUTHORITY AGAIN TO MASK OUR CHILDREN AND IT IS ABURD! I will quote from a news article from WPRI with regards to the lawsuit (link will be at the bottom of this email) "R.I. Department of Health spokesperson Joseph Wendelken said there are “no plans to reimplement any masking requirement in Rhode Island schools” at this time." I am sad but more angry because the Department of Health wants authority to MASK OUR CHILDREN AGAIN for whatever reason they choose even though they settled the lawsuit just a few months ago! There are no mask mandates anywhere in the state or country. Masks are NOT readily available anymore and especially not in children's sizes because NO ONE IN THE COUNTRY IS MASKING CHILDREN ANYMORE! WHY ARE ONLY RHODE ISLAND SCHOOL CHILDREN BEING TARGETED? WHY NOW after two years of the mask mandate

being lifted, life being "normal" for these school kids, and everyone being fine living life, why now? I'd appreciate more information on this matter.

In closing, I implore to the person(s) who will be reviewing this proposal to REJECT IT and not allow authority for RI Department of Health to issue mandates for school children! People are still going to get sick from the many viruses out there no matter what protocols are in place. It is also important for our immune system to be exposed to these pathogens to create some immunity to them! MASKS WILL NOT PREVENT ILLNESS, ESPECIALLY OUR CHILDREN! Please let our children be children, learn, thrive, and be comfortable at school as they used to be before the mask mandates.

Thank you for taking the time to read my email.

Sincerely,

LeeAnn McMahon

Reference to the quote above:
https://www.wpri.com/health/ri-department-of-health-settles-lawsuit-over-masking-in-schools/ [wpri.com]

OPPOSE 216-RICR-30-05-4

Kathryn Laplante <kate@baxterbehavioralhealth.com>

Thu 3/14/2024 6:26 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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I strongly oppose this proposed “Masking in School” regulation as well as any regulation that would allow the implementation of mask requirements/mandates in the future, especially when it concerns children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data. Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority!

--
Kathryn LaPlante, MSN, PMHNP-BC
Baxter Behavioral Health
1130 Ten Rod Road D101
North Kingstown, RI 02852
(o) 401-267-4485
(f) 401-267-4534

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OPPOSE 216-RICR-30-05-4

Kate Papa <11katepapa@gmail.com>

Thu 3/14/2024 6:28 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

My husband and I strongly oppose this proposed “Masking in School” regulation as well as any regulation that would allow the implementation of mask requirements/mandates in the future, especially concerning children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data. Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority.

Thank you,
Kathryn and Andrew LaPlante
107 Oak Tree Ave, Warwick, RI 02886

RIDOH proposed Mask Mandate

Kristen Moniz <kmoniz81@gmail.com>

Thu 3/14/2024 8:16 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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To Whom it May Concern,

My family and I are 100% against any form of mask mandate in RI schools and if you try to enforce another mask mandate we most certainly will be removing our children from the RI public school system! We would much rather homeschool, or do online school then be forced to EVER wear masks again. Masks in schools have caused irreparable harm to our youth and should never be used again.

Our two children were negatively impacted by having to wear a mask! They wore masks for in person learning, at Wilbur & McMahon School, for an entire year and then had to wear a mask for another half of a year before the state lifted the mandatory mask mandate. Their school was in person for the entire length of time, and wearing a mask had to be one of the most awful experiences of their life. Having to wear a mask made my children anxious, depressed, withdrawn from social activities, and all around hating having to go school. Any excuse to take their masks off, they did, and half the time my children and their classmates were not even wearing them correctly which is a joke because this would negate wearing them at all.

My children complained of headaches and dizziness after wearing a mask too long and they even missed out on after school activities because they refused to wear a mask after wearing one for 6+ hours school. Did you know that students were forced to wear masks outside during recess, while playing sports, or while they were doing music (both chorus and band) and theater? This is absolutely ridiculous and should have never been allowed!

Covid-19 is not going away, we need to stop living in fear and figure out a way to live through this. If you move forward with this legislation that would mean we would probably have our children wearing masks indefinitely.

There is no immediate threat to students in grades K-12, so our precious children should no longer be forced to wear a mask for 6+ hours a day, unable to breathe and unable to see their teachers and their classmates.

As a RI public educator I have experienced teaching while wearing a mask for over one and a half years and it was the absolute worst experience of my life. I would rather quit teaching and find a new career than be forced to have to work under those conditions again. I myself had trouble breathing, felt nauseous, irritable and anxious pretty much every day I had to wear a mask. As a reading specialist and elementary classroom teacher I have witnessed first-hand the

negative impacts masks have had on my students, both socially, emotionally and academically, and I sincerely hope that the State of RI NEVER imposes a mask mandate again!!!

-Kristen L. Moniz
Little Compton, RI

Support masking

Renu E <renuenglehart@gmail.com>

Thu 3/14/2024 8:18 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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To Whom It May Concern:

Please support Masking in School (216-RICR-30-05-4), in the event of a further public health emergency. I am the mother of a now adult son who had severe asthma as a child. While masking may be a nuisance, in regards to safeguarding those who may be compromised or live with someone who is compromised, masking requirements benefit all of us and help prevent the spread of further disease.

Thank you
Renu Englehart
East Greenwich RI

https://foundation.womenandinfants.org/capital-campaign [foundation.womenandinfants.org]

Mask Mandates

crystlewelch <crystlewelch@protonmail.com>

Thu 3/14/2024 8:45 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Good evening,

I am writing on behalf of my children and the impact of the State of Rhode Island's over reaching mask mandates. I wrote a long letter but deleted it simply because the science and data are not on your side. Masks do not work and these mandates have caused irreparable damage to our children. When these mandates were in place child suicide rates increased along with depression and anxiety. Our children are so far behind in school because they missed out on so much between lockdowns, quarentines, and masks. They're also socially and emotionally delayed. We have plenty of evidence to reference and it's clear that masks do not work and harm are children. There is no reason for the State of RI to reserve the right to force mask our children without any scientific evidence. We the parents to not consent. These are our children and we know what is best for them.

Thank you,
Crystle Welch

Sent with Proton Mail [proton.me] secure email.

Oppose mandate

Candace Magnett <candacerfarrell@gmail.com>

Thu 3/14/2024 9:37 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello,

I am writing to you as a mom of three school age children. My older two were greatly affected by having to wear a mask in school. I could go on and on as I have done in the past at local school meetings and previous state hearings but I'll leave this short and simply state I oppose this mandate and I hope you do as well. Our children have suffered enough.

Thank you
Candace Magnett

OPPOSE Mask Mandate Regulation

Kerri Croft <kerric626@gmail.com>

Fri 3/15/2024 12:40 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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To Whom It May Concern,

I am writing to express my strong opposition to the proposed mask mandate regulation currently under consideration for future infectious diseases. As a lifelong RI resident and concerned citizen, I believe that such mandates infringe upon our personal liberties and fail to address the complexity of public health policy as it relates to individual freedoms.

While I understand the importance of public health measures to mitigate the spread of a virus, putting a mandate in place without scientific backing is negligent and irresponsible, at the very least.

I strongly request that you oppose the mask mandate regulation and prioritize policies that promote voluntary measures and respect individual rights. Our collective response to an infectious disease should be rooted in evidence-based solutions and respect for personal freedom.

Thank you for considering my perspective on this important issue.

Sincerely,

Kerri Crescenzo-Croft

Cranston

Testimony Opposing RIDOH's Proposed School Masking Regulations 216-RICR-30-05-4

Rhonda Martin <rmartin_417@hotmail.com>

Fri 3/15/2024 5:18 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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To Whom It May Concern,

I am writing to vehemently oppose this proposed rule for the following reasons (these are not in any particular order):

1. A filthy, bacteria and virus laden, spit and snot covered piece of paper or cloth over a child's face for 6+ hours a day will NEVER be better for them than breathing in fresh air.

2. Before Covid, if my child had said to her teacher, “My Mom straps a piece of fabric or paper over my mouth and nose for 7 hours a day and makes me sit there and be quiet, it’s hard to breathe, I get hot, and I get headaches,” her teacher would have certainly reported me. Yet, during Covid for 2 years, RIDOH forced schools to do something similar, in an effort to “protect” our kids from a virus that, even with the Delta and Omicron variants, has proven to be a small risk of serious outcomes in those under 18.

3. Ethically, the onus is on RIDOH to show that the benefits of masking kids outweigh the costs through empirical evidence gathered from numerous quality, random controlled studies (not weak observational and/or modeling studies). RIDOH has seemed to be focused on what they tout are the "benefits" of school masking, with the only focus being the potential outcomes on the virus and never mentioning the overwhelming number of risks. Masking children is associated with: ***increases [healthpolicy.usc.edu]*** in anxiety and depression; ***decreases [healthpolicy.usc.edu]*** in communication and socialization skill development; ***increases [ncbi.nlm.nih.gov]*** in headaches, face rashes and redness, and impaired facial recognition; and ***increases [abc13.com]*** in tooth decay.

4. Parents have the authority to make medical decisions for their children, not bureaucrats. If we were shown solid evidence that masks would protect our kids with minimal risk, then we would be the first to have them wear them, but

that is simply not the case. It's insulting and unacceptable that RIDOH took parents out of the decision-making process from the very beginning.

5. Not having exemptions for neuro-divergent and disabled children was and is criminal. I heard horror stories from parents in several school districts that adults were literally shoving masks on the faces of special needs kindergartners and first graders or punishing them with time outs to get them to comply with the mandate. RIDOH never spoke out against anything like that. The kids who needed the most compassion to get through this were denied comfort by the adults who were supposed to be their voice.

6. At the time, my daughter was a middle school student with high-functioning Autism, severe ADHD and sensory processing issues. She was devastated when the school mask mandate was announced. She went from a kid who would have lived at school 24/7 if you let her because she LOVED school, to a kid who cried when she thought of going to school. I was prepared to homeschool her to protect her from masking, but she loved school so much that she begged me to let her go. Every day, she said stuff like, “I wish we didn’t have to wear masks at school. I tried hard in 6th grade but I couldn’t hear my teachers. I can’t focus at all. I don’t want headaches anymore. I feel hot and dizzy in Gym.” She was more tired and irritable. Our visits to the pediatrician increased due to rashes on her nose and ears, and infections on her fingers from picking her nails due to anxiety from not seeing the teachers’ faces and not being able to hear them clearly. She visited the school nurse regularly complaining of having a hard time breathing and for most of the issues I just mentioned. Calls from the school to pick her up increased because she was complaining of headaches, stomach aches, and being unable to reset after emotional outbursts from the anxiety of having a bad interaction with a teacher or other student because she couldn't read social cues since she couldn’t see anyone’s faces. Once at home without a mask, she immediately felt better. Many mornings, she had panic attacks before she had to put her mask on while in the car line. She even fell twice because her glasses fogged up and the mask moved while she was walking, blocking her view. Even now, she lives in constant fear that the mask mandate will return. When Lifespan brought back their inane, ineffective mask mandate this winter for doctors' offices, she immediately had a panic attack in the waiting room. The nurse who took her vitals said her heart was racing and she was hyperventilating. So much for "Do no harm." Luckily, her doctor allowed her to remove her mask. I told her doctor that I was never doing that to her again and that we would find a doctor who is not at LIfespan.

7. Masking and lack of social interaction led to a big increase in suicide attempts, depression and anxiety among minors. We spent 2 long nights in the Hasbro ER because my daughter was having intrusive thoughts and

suicidal ideations when she started 8th grade. The pediatric psych waiting room was packed. She had never had any signs of these extreme feelings before and when the hospital clinicians drilled down, it was determined that she was suffering from severe anxiety from thoughts of a mask mandate returning because she kept reading news articles stating that Covid numbers were on the rise and that maybe mask orders should return. She felt ashamed that she was worried about something "so little" (that's what she was told by a teacher at school - that it was "just a little thing").

8. Proponents of forced school masking claim that kids are “fine” with it and are “resilient” and use these excuses to keep them masked. If that were true, then why did schools have punitive policies to enforce masking when kids did not wear their masks or did not wear them correctly? The fact that kids were getting detention for this shows that kids were not OK with it. Also, I’ve seen and heard from so many parents that as soon as their kids got vaccinated, their children immediately asked if they could stop wearing masks, much to the parent’s surprise because they never complained about wearing one. If kids were resilient, then we wouldn’t have multiple generations of adults walking around with unhealed childhood trauma. Kids are resilient when they fall off a bike – not when you mask them up, isolate them, tell them they are killing people by breathing free air, view them as disease vectors, and mess with their psyches for almost 4 years. I can assure you as a Girl Scout Troop Leader and a Sunday school volunteer teacher that they were NOT OK with it but tried hard to follow rules,

9. Whether a cloth mask (which was the predominant mask in school settings and declared by the CDC to be far less effective than other masks) or a disposable mask is used – we have no idea what the long-term effects of exposing developing brains to the chemicals used to launder cloth masks or manufacture paper masks will be. Will there be an uptick in cancers from breathing it in all day? Laundry products seem like harmless, everyday substances but they were never meant to be breathed in for 6-8 hours a day by people whose brains are still maturing. The disregard for and willingness to sacrifice the youth for scared adults is one of the great tragedies of Covid.

10. I now work in an elementary school as a Teaching Assistant and I see the effects of the school mask mandate. When my daughter left the school 4 ½ years ago, we had 1 speech language pathologist and 1 occupational therapist. We now have 2 of each and they still don't have enough availability to work with all the students who need their services. The kids don't know how to interact socially - they need more adult assistance for conflict resolution, and initiating play and taking turns.

For all of the above reasons and more, RIDOH should NOT implement another school mask mandate based on capricious beliefs, especially for illnesses for which children were never masked before - we've lived with many of these viruses for several millennia without masks. The decision to mask in school should be based on parental choice. RIDOH should be presenting quality scientific evidence (no less than several random controlled trials with conclusive substantial evidence that mask efficacy outweighs all of the bad outcomes) in order to justify their belief that masks are needed, but in the end, it should be parental choice. This is how it should have always been.

This is the generation who will be caring for all of us in the next 10-20 years. If we can't show them the compassion and understanding they so desperately need, we will pay a steep price as a society in so many ways. Thank you for your time.

Sincerely,
Rhonda T. Martin
26 Sweet Briar Lane
West Warwick, RI 02893
401/864-7369

RIDIH Mask-Wearing Hearing

Nycny@hotmail.com <nycny@hotmail.com>

Fri 3/15/2024 6:54 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Good Morning,
I am writing because I am unable to attend your RIDOH Mask Regulation Hearing in person.
2020 was a scary year because so much was unknown. Mask-wearing was enacted. 6-feet social distancing was enforced. School buildings were closed. Businesses shut down. We've learned a lot since then. Recently, Dr. Fauci admitted that 6-feet social distancing "just sort of appeared" lacking scientific basis. Dr. Fauci also has admitted to the lack of efficacy of mask wearing. We've learned that mask wearing more harm than good. Speech delays in children have increased drastically. The number of children who suffer from mental-health challenges is staggering. There's no question that being able to see someone's face and mouth is vital in learning in learning to speak and reading social cues. Children need to see smiles. Children need to see faces. Everyone needs to see faces and hear voices clearly for human connection. I implore you, please do not entertain enforcing this social experiment. It's not 2020. We know better now.
Thank you,
Monique Bouvier

Do not mask children

Christopher Barker <chrisbarker4ri@gmail.com>

Thu 3/14/2024 8:27 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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I am writing today to voice my strong opposition to the proposed masking requirement below

216-RICR-30-05-4TITLE 216 – DEPARTMENT OF HEALTH
CHAPTER 30 – INFECTIOUS DISEASES SUB-CHAPTER 05 – INFECTIOUS DISEASES PART 4 – MASKING IN SCHOOL
4.1 Authority and Purpose
A. These Regulations are promulgated pursuant to the authority conferred under ride. Gen. Laws §§ 23-1-17 and 23-1-18, for the purpose of publicly setting forth the rationale for a masking requirement in the event a future masking requirement is promulgated by the Rhode Island Department of Health for students in grades Kindergarten through twelve in Rhode Island.

My reasoning for this is the fact that without the strictest controls and highest quality of masks the resulting protection from infection is minimal at best. I also feel that trading for near a barely minimum of protection in exchange for the potential developmental and learning difficulties imposed on students will further burden already under-performing Rhode Island schools. The social learning and mental well-being of students far outweighs a benefit that experts have defined as negligible. This would also be an over-reach of multiple governmental offices.

Sincerely,

Christopher Barker

Warwick RI 02888

Do Not Mask Children

Sharon Clark <sharonwtg1@gmail.com>

Thu 3/14/2024 8:35 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;Leclair, Cheryl (RIDOH) <Cheryl.Leclair@health.ri.gov>

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I am writing today to voice my strong opposition to the proposed masking requirement below
216-RICR-30-05-4TITLE 216 – DEPARTMENT OF HEALTH
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Sincerely,

Sharon Clark

Warwick RI 02888

Mask Mandate Opposition

Stephanie Hines <stef.glaser@gmail.com>

Thu 3/14/2024 10:53 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good evening,

I am writing to formally submit my opinion against the mandatory masking of school children regulation. As a parent of three, I experienced first hand what the masks did to my oldest son during the 2021-2022 school year. We kept him home for kindergarten due to the COVID policies in place. At the start of his first grade year, we were told there were no true mandates in place for private schools. That quickly shifted in September. My son immediately fell back into a reserved manner. He was unable to assert himself in class and establish friendships and look at his classmates' faces. In addition, he would come home with soiled masks most of the time. I will include some pictures of this. I would see mucus and food remnants from his silent, distanced lunch. When the mandate was removed that school year, he began to cry when I told him. As a mom, it broke my heart because while I knew that this was the wrong decision for my son, I didn't know that he personally understood all of the impacts. For the record, he was later diagnosed on the Autism Spectrum and Social Anxiety Disorder. Mandatory masking did nothing for my son's development and growth. He was diagnosed with COVID two months after the mandate in his school, he was minimally impacted. He experienced zero long term effects from COVID, yet I cannot say the same thing for mask wearing.

My second son was diagnosed with a speech development delay in articulation. Strangers and family alike had a difficult time understanding him. Had he been elementary school aged (he was in pre school at the time), the mandatory masking would have dramatically inhibited his ability to communicate effectively. He would NOT have been granted as medical exemption from this. How do I know this? Because I was a teacher and I saw students with severe and profound needs with their faces covered, while their masks were soiled and wet from saliva that they could not control. How would the school grant my son with articulation problems an exemption if they didn't for others?

Next, I have my third child. I will forever be grateful that she was merely a baby in March of 2020. She never had to wear a mask. Even the doctors and nurses at Hasbro knew it was inappropriate to ask her to put it on in January 2023 when she had surgery.

At this point, with multiple means of scientific evidence, I strongly urge you to listen to the testimonies and emails you receive regarding this potential mandate. There is a reason why this forum is being held on March 15, 2024. The RIDOH and its leaders have already stated many facts, under oath, that prove that mask wearing cannot be proven to help stop the spread of infectious diseases. I'm begging you, do not allow this to happen to our children again.

I wish I could be there to support this in person. I pray you listen to the testimonies of the individuals who attend the forum with an open heart. I'm sure many people at RIDOH entered the medical field to make a difference for the better, this is one of those opportunities to do just that.

Thank you,
Stephanie Hines





Sent from my iPhone

Oppose 216-RICR-30-05-4

Christine E. Dowding <c.dowding718@gmail.com>

Fri 3/15/2024 7:56 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I strongly oppose this proposed "Masking in School" regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially for children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data. Masking in public and private places should never be a 'requirement', whether imposed by RIDOH or by any other authority. If someone wishes to wear a mask, for personal health reasons, then so be it.

Christine Dowding
118 Howie Ave.
Warwick, RI 02888

Subject: OPPOSE 216-RICR-30-05-4

Betty Wilson <betty.a.wilson@gmail.com>

Fri 3/15/2024 7:59 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

I strongly oppose this proposed “Masking in School” regulation as well as any regulation that would allow implementation of mask requirements/mandates in the future, especially in relation to children. There is no doubt that masking is harmful to the mental and physical health of children, and masking is unsupported by scientific data. Masking in public and private places (including but not limited to schools) should never be a 'requirement', whether imposed by RIDOH or by any other authority it should be at the discretion of the child’s parent / guardian.

Betty Anne Wilson MS MT(ASCP)
22 Bay St, Charlestown, RI 02813

Mask Mandates

Allie Austin <avadnais1@gmail.com>
Fri 3/15/2024 8:00 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good Morning Mr. Garceau,

I am writing in response to the court hearing that is occurring today for mask mandates in schools. Children learn through body language and mimicking. Under no circumstance should it be deemed necessary to mask children in their learning environment (or ever). If a health situation should occur that is of greater concern, I would ask that the health department consider different solutions other than masking our children. Literacy rates are down because of masking and distance learning. We need to stop looking at options that didn't work and consider new options instead.

Thank you for your time,
Alexandra Austin
Coventry, RI

Against Mask Mandates

LisaMarie Leavitt <lisamarie@creativeambianceevents.com>

Fri 3/15/2024 12:28 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Good morning mask forcers of Rhode Island. I write today as you, the people that did this to our children -with these mask mandates have hurt untold numbers at all ages willfully. You have to be intelligent enough with all of your degrees and certifications that you were totally starving their brains of healthy levels of life giving Oxygen and made them suffer the inhalation of toxic fumes from their own exhaust.

There are children that could not understand others verbally or simple lip reading communication. Some are deaf and some are just learning to speak. Many have lost their development of social skills and it has duly effected those that were already handicapped in an extreme way. It has caused anxiety, and interfered with key developmental skills and landmarks. Some became terribly sad and withdrawn, and some killed themselves because they simply never saw a smile.

They couldn't understand their teachers and they couldn't understand their friends. They were bullied by adults they were supposed to trust when they merely tried to take a break and breathe.
So many gave up on learning, and some caved to phobias with breakdowns, and just plain hated school and refused t attend. Attendance of these generations may never recover. They couldn't make friends because they couldn't even see their friends smile and laugh. You forced them to cover their faces in shame. My youngest, in particular, was forced to exercise in a mask. It hurt his body -he was already inflicted by severe asthma attacks- it made it hard to breathe, like he was being slowly smothered to death. He missed out on football in high school where masks were ridiculously required under a hot helmet and the coach punished him for not being physically able to perform with masks - he instituted more warm ups for him. Yeah that sounds like a smart thing to do. I wonder if that coach wanted to kill my son. He was terrorized and so were we. Several times he was taken to the ER because of this cruelty. I do not ever want us to have to wear a mask again. I am just a mom, and I always try my best to know about everything that my kids need- and I wholeheartedly know that you hurt our children.

Studies in infectious disease proclaim loud and clear that these do nothing. Military protocol states these paper masks do not protect against such a disease or virus. You must wear a gas mask with a charcoal filter. You knew this and yet you still pushed it on us-on innocent little children and ruined the lives of teens!

I oppose your horrible, sick, malicious mask mandates. And I should think that all should oppose your complete and utter violation of our 1st Amendment rights, our rights to take care of ourselves, and our rights under the American Disabilities act. You have violated us all. I could not be more opposed to anything. Thank you for hearing my words and stepping forward to hopefully bury this as a mistake and as an apology to everyone.

Ps: WE WILL NOT EVER FORGET.

LisaMarie Leavitt, Mother of 7
401-413-4042

Re: Against Mask Mandates

MICHAEL IACOBBO <miacobbo@cox.net>

Fri 3/15/2024 8:04 AM

To:LisaMarie Leavitt <lisamarie@creativeambianceevents.com>;Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

Bravo!! This is a hall of fame letter. We need more of this, not limp lasagna noodle prose.
Godspeed,
Michael

On 03/15/2024 12:27 AM EDT LisaMarie Leavitt <lisamarie@creativeambianceevents.com> wrote:

Good morning mask forcers of Rhode Island. I write today as you, the people that did this to our children -with these mask mandates have hurt untold numbers at all ages willfully. You have to be intelligent enough with all of your degrees and certifications that you were totally starving their brains of healthy levels of life giving Oxygen and made them suffer the inhalation of toxic fumes from their own exhaust.

There are children that could not understand others verbally or simple lip reading communication. Some are deaf and some are just learning to speak. Many have lost their development of social skills and it has duly effected those that were already handicapped in an extreme way. It has caused anxiety, and interfered with key developmental skills and landmarks. Some became terribly sad and withdrawn, and some killed themselves because they simply never saw a smile.

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Studies in infectious disease proclaim loud and clear that these do nothing. Military protocol states these paper masks do not protect against such a disease or virus. You must wear a gas mask with a charcoal filter. You knew this and yet you still pushed it on us-on innocent little children and ruined the lives of teens!

I oppose your horrible, sick, malicious mask mandates. And I should think that all should oppose your complete and utter violation of our 1st Amendment rights, our rights to take care of ourselves, and our rights under the American Disabilities act. You have violated us all. I could not be more opposed to anything. Thank you for hearing my words and stepping forward to hopefully bury this as a mistake and as an apology to everyone.

Ps: WE WILL NOT EVER FORGET.

LisaMarie Leavitt, Mother of 7
401-413-4042

Opposition: DOH Masking In Schools

Niyoka Powell <npowellsdi@gmail.com>

Fri 3/15/2024 8:05 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

1 attachments (56 KB)

Niyoka Powell, Opposition to DOH Mask Mandate Powes in Schools (2).pdf;

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I've attached my opposition to the proposed Mandating powers of the Rhode Island Department of Health's ability to Mandate Masking in School.

Niyoka Powell
15 Huxley Ave #3
Providence, RI 02908
860.460.2335

Senate District 1 Providence, Resident
Second Vice Chair, RI GOP State Central Committee
State of Rhode Island MLK State Holiday Commission
Providence City Director, Blexit RI

Niyoka Powell
Providence
Testimony 3/15/23 @ 0900 RI DOH

Good morning, Thank you to the Department of Health for hosting this public hearing in accordance with R.I. Gen. Laws § 42-35-2.5, to consider the proposed adoption of mandating rights to mask our children. Unfortunately this meeting was not held at a time or place all persons interested therein will be heard subject to R.I. Gen. Laws Chapter 42-46, Open Meetings. It's March 15, 2024. A Friday morning, a time when most parents have either just dropped their kids off at school across the state, or have been at work already for a few hours. I had to take the day off for this meeting.

My name is Niyoka Powell and I strongly oppose the adoption of Masking in School (216-RICR-30-05-4) for the purpose of publicly setting forth the rationale for a masking requirement in the event a future masking requirement is promulgated by the Rhode Island Department of Health for students in grades Kindergarten through twelve in Rhode Island.

I was born in Jamaica and immigrated to the United States at a young age. I am a 19 year resident of the City of Providence. I am a nurse and mother to a lively little girl. I have volunteered my time to community service in a vast array of situations - was certified in disaster response, assisted with energy conservations, community outreach, and most recently, working with the Rhode Island Disaster Medical Team during covid, covering Block Island for the summer of 2020, of which I am still a member.

I am a former detox nurse at Butler Hospital, until October 2021. I currently work in occupational health in manufacturing in the State of Massachusetts. The decision to leave Rhode Island for work came when I had to decide between my own experiences with the Department of Health's hasty decisions and lack of investigation, our child's well-being, and corporate implications on our health.

In 2006, at the age of 19, I was exposed to a patient with Tuberculosis, while working at a Chartercare Hospital in the City of Providence as a nurse's aid. I remember the patient well. I encouraged doctors to take precaution and told them the patient had all the signs of TB. The culture was ordered and the results came back positive. The patient was moved to a negative pressure room. Months later, I received a call from the Infection Control Nurse who said "I was exposed and needed to be tested for TB." I was to get a PPD done. I told the nurse I received the BCG vaccine as a child in Jamaica (a contra indication). I was still given the PPD anyway.

Surprise, surprise, the PPD came back positive according to the infection control nurse. Next, I received a letter from the Department of Health threatening failure to treat would result in criminal actions against me. I had to take INH for 9 MONTHS and I would be

Niyoka Powell
Providence
Testimony 3/15/23 @ 0900 RI DOH

followed by the RISE Clinic on 3rd Street in Providence. I was 19 at the time. It was my first year away from home.

Fast forward to Covid. The State of Rhode Island was making blind decisions that were detrimental to the wellbeing of our families and contributed to disastrous consequences of blatant discrimination against a diverse group of individuals with direct contact in the field without repercussion nor accountability, just that we had to comply. Where's the equity, where's the 'my body my choice' sentiment? Those rules don't apply here.

In November 2020, our vibrant and energetic 3 year old daughter went limp in my arms. She ended up in the ICU at Hasbro and my family descended on the city from Connecticut, Massachusetts, and New York, but were all not allowed in the hospital due to covid regulations.

Over the next 4 years, our daughter would have an enormous amount of hospital stays, testing, and medication changes to finally determine her diagnosis of Refractory Epilepsy with the help of Hasbro Children's Hospital, her primary neurologist, and Boston Children's Hospital. Her triggers included but were not limited to a slew of natural allergens, lights, face coverings, temperature, the common cold, and strong odors.

At Boston Children's Hospital in April 2023 it was noted that she presented with over 160 micro seizures a day. In the four years our 3 year old has been prescribed and still utilizes several antiepileptic medications. She's endured Lamictal, Keppra, Depakote, Vimpat, Fycompa, Diastat, cetirizine, and for emergency episodes Valtoco nasal spray. We've met with genetics and switched to a Ketogenic diet.

At one point there were discussions about brain surgery. She and I have the same blood type. There was no research to prove transfusion readiness. Initially, the Red Cross refused covid vaccinated blood (the website was then changed to say you **may or may not** be allowed to donate after citizens expressed concern and their supplies dropped). When it came to schooling, we found schools that did not require masking of the children, which has cost us financially in an already inflated economy.

I will not bore you with the data this Department of Health has conveniently pushed to the side, others here have and will dive into it on the ineffectiveness of masking our children. Since October 2021, many of us realize, decisions are made at the top, not with the boots on the ground, and that's dangerous.

Niyoka Powell
Providence
Testimony 3/15/23 @ 0900 RI DOH

As parents, our rights are being stripped by the departments in the State of Rhode Island. It's legal to abort, but not to decide on what's right for the health of our own children. This is a disadvantage to all children when the state openly allows illegal immigrants with what I know as poor vaccine schedules to enter the schools where our children go, and require our children to deal with the department's lack of proper procedures to deal with infection control methods because of feelings. Stop punishing the kids for your lack of responsibility and accountability on providing effective infection control methods that don't infringe on the lives of our children.

Currently our little one has learning concerns and speech concerns that have been amplified by previous masking policies and her diagnosis. In the push for 21 Century learning, give parents more choices, not restrictions. That's how you solve this issue.

Thank you.

Please do NOT regulate mask mandates!

Lidia Carroll <lidia.carroll@hotmail.com>

Fri 3/15/2024 8:06 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4ri@hotmail.com <consent4ri@hotmail.com>

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I am a RI resident and I oppose RIDOH's proposed permanent regulation for future mask mandates. Please do not approve this mandate.
Thanks.
Lidia Carroll

RIDOH Rule Hearing

Devi Jennings <devijennings@yahoo.com>
Fri 3/15/2024 8:28 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Concerned Citizens of Rhode Island,

We as a community, local, state and global, are now moving into the fifth year of a life changing globally orchestrated event. It has been called the "Great Reset" by the UN/WHO or WEF; many of the People are calling it the "Great Awakening." It has been a painful process.

The response from most within our state governance in addressing Covid-19 has been an abysmal failure especially in regard to honoring our God given and Constitutional Rights. Our legislative branch did little to protect our rights and the state executive branch empowered themselves under the state emergency powers act Executive Order 20-02. That order states that the WHO had designated the novel Corona virus outbreak on January 30, 2020 as a Public Health Emergency of International Concern. The RIDOH established an "Incident Command System Response" to Covid-19 the following day.
The US HHS under Secretary Alex Azar II declared a National public health emergency also on January 31st. It appeared all the western countries of the world and many of the other countries were in lock step and were embracing the moniker of "Build Back Better."

The People started to gather and push back against this top down governance. It was/is antithetical to our very individual sovereignty and to the American spirit. There were efforts to appeal to our state representatives and the AG and through the courts to get this whole top down orchestration of this event back into the hands of the people. The success of the Barrington Parents United group with counsel Greg Piccirilli, Esq in the RI courts, in regard to the masking of our children, was a crowning achievement! It was a two year effort for the plantiffs and counsel. There was an understanding that masking is of little benefit for spread of respiratory viral infection that was backed by scientific study. Now the RIDOH appears to want to disregard this "win" and decide it can enact mask mandates on a whim even in the absence of scientific evidence that masks are effective. RIDOH is trying to put in place a permanent regulation for mask mandates, which includes children, for whatever the RIDOH might deem an infectious disease. That is Proposal 216-RICR-30-05-4. This cannot be allowed to happen.

I am a retired RN and know that medical/surgical masks and the N95/P2 masks have little effect in protecting one from the spread of flu-like or respiratory illness. The Cochrane organization has conducted research and published those same assertions.

In June/early July of 2020 I assembled a body of evidence with a dozen or more references and put it in an article format where I addressed many aspects of the state responses to the SARS-CoV-2 so called pandemic, including the ineffectiveness of masks. I was asking questions and imploring folks to

look at the evidence, the science. I sent it to every RI state rep and senator and a number of people. I only got a response from two within the General Assembly.

The damage that was inflicted on the children, physiological, emotional and psychological through mask wearing was abusive and disease spreading, in itself. We are supposed to be breathing in oxygen and breathing out carbon dioxide; the lungs are an organ that naturally eliminate harmful and toxic substances. We don't want to be breathing in our own waste. Why would that function be thwarted, especially in young bodies?

In conclusion, I looked at this publication entitled "Community-engaged Evidence Synthesis to Inform Public Health Policy and Clinical Practice" that came about in 2016. It appears to be a consortium of organizations in RI that have partnered with academicians and the RIDOH. It was set up to "facilitate analysis on arts-based interventions in healthcare." I sure didn't see any implementation of that organization's objectives in our community during these years. I do know we have to bring back the healing arts and human compassion and move away from the health care industry that is our system of medicine here since the late 1800s. It has now become the Pharma Industrial War Machine. This is a Brave New World and we must act together to restore transparency, heart, empathy, vitality, and the tried-and-true practice of health and healing. It is upon all of us.

Sincerely,

Deborah H Jennings, RN

Sent from Yahoo Mail for iPhone [mail.onelink.me]

Check out this article: Requiring Kids to Wear Masks Does More Harm than Good

kara evans <bristolcountyfd@gmail.com>

Fri 3/15/2024 8:58 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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https://www.deseret.com/opinion/2021/8/13/22623659/requiring-kids-to-wear-masks-all-day-at-school-does-more-harm-than-good-utah/ [deseret.com]

https://www.aier.org/article/the-cdcs-mask-mandate-study-debunked/ [aier.org]

Hello,

My name is Kara Evans. I can see first hand the damage that was done to children through force masking. My own daughter was kicked out of school for refusing to wear a mask, even with a medical reason not to. Because she wears glasses, wearing a mask made it difficult for her to see, as well as breath. Getting enough oxygen during the day is paramount to learning and growing- things we should be concerned about as parents and teachers. It is also proven that when children wear masks, they touch their faces more often, leading to even more illness and days absent. There is no world where I would ever put a mask on my children ever again and make them breath in their own CO2 - and if you actually cared about children, you wouldn't either.

--

Kara Evans
Bristol County Fifes & Drums [bristolcountyfifesanddrums.org]
Facebook [facebook.com]
Facebook Fans [facebook.com]
Instagram [instagram.com]

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AIER (https://www.aier.o

The CDC's Mask Mandate Study: Debunked



Paul E. Alexander (https://www.aier.org/people/paul-e-alexander/) – March 4, 2021 (/custom-search-results/?post_date=03042021) Reading Time: 9 minutes



The US Centers for Disease Control and Prevention (CDC) recently published a February 2021 MMWR report (https://www.cdc.gov/mmwr/volumes/70/wr/mm7006e2.htm) entitled "Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates — 10 States, March–October 2020." This report focused on 10 sites that had been included in the Covid-19 Associated Hospitalization Surveillance Network.

This CDC report described a decrease in hospitalization rates of growth of up to 5.6% in adults (18-65 years old) and attributed this to the use of masking and/or the introduction of mask mandates in the various sites. These rates were compared to those

obtained from a 4-week period of time prior to the introduction of mask mandates. In so doing, and by way of regression analysis, the reduced rates of hospitalization were attributed to the introduction of statewide mask mandates.

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Firstly, the initial publication by the CDC (February 5/February 12th, 2021) was plagued with important inaccuracies that were then fortunately addressed in an updated *erratum* (https://www.cdc.gov/mmwr/volumes/70/wr/mm7008a4.htm?s_cid=mm7008a4_w) (February 26th 2021). We applaud the CDC for taking the steps required to correct these errors. Reporting done by the CDC, which is generally considered as the premier public health agency in the US, must be of the highest quality, particularly since advice rendered by the CDC is also relied upon worldwide.

En face, CDC's conclusion on mandates might appear to make sense unless one is familiar with the scientific data pertaining to the ineffectiveness of masking for prevention of the spread of Covid-19 (e.g. references 1 (https://www.aier.org/article/masking-a-careful-review-of-the-evidence/), 2 (https://www.acpjournals.org/doi/10.7326/M20-6817), 3 (https://www.nejm.org/doi/full/10.1056/NEJMoa2029717), 4 (https://www.aier.org/article/the-year-of-disguises/), 5 (https://www.aier.org/article/the-year-of-disguises/), 6 (https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article), 7 (https://www.cidrap.umn.edu/news-perspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data), 8 (https://www.nejm.org/doi/full/10.1056/NEJMp2006372), 9 (https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a5-H.pdf), 10 (https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1),

11 (https://www.aier.org/article/the-strangely-unscientific-masking-of-america/), 12 (https://www.medrxiv.org/content/10.1101/2020.05.01.20088260v1.full.pdf), 13 (https://www.cebm.net/covid-19/masking-lack-of-evidence-with-politics/), 14 (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30985-3/fulltext), 15 (https://www.fhi.no/globalassets/dokumenterfiler/rapporter/2020/should-individuals-in-the-community-without-respiratory-symptoms-wear-facemasks-to-reduce-the-spread-of-covid-19-report-2020.pdf)) in which case the findings in fact contradict most of what is now known. The CDC's conclusion might have made more sense if the real-world evidence we have about mandates did not actually exist (e.g. references 1 (https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/), 2 (https://www.theepochtimes.com/face-mask-mandates-seem-to-make-ccp-virus-infection-rates-climb-says-study_3629627.html?utm_source=morningbrief&utm_medium=email&utm_campaign=mb-2020-12-23&fbclid=IwAR1OlncsLOdYRg-vt2afCphIGj3z6Curfcp3G-U9_EEjQi-MXId5IzwZRBw), 3 (https://www.conservativereview.com/horowitz-comprehensive-analysis-of-50-states-shows-greater-spread-with-mask-mandates-2649589520.html), 4 (https://twitter.com/justin_hart/status/1340725095573024768)).

Does the CDC really think that masks prevent the wearer from getting Covid, or from spreading it to others? The CDC admits that the scientific evidence is mixed, as their most recent report glosses over many unanswered scientific questions. But even if it were clear – or clear enough – as a scientific matter that masks properly used could reduce transmission, it is a leap to conclude that a governmental mandate to wear masks will do more good

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than harm, even as a strictly biological or epidemiological matter. Mask mandates may not be followed; masks worn as a result of a mandate may not be used properly; some mask practices like double masking can do harm, particularly to children; and even if a mask mandate results in some increased number of masks being worn and worn properly, the mandate and the associated publicity may reduce the public's attention to other more effective safeguards, such as meticulous hygiene practices.

Thus, it is not surprising that the CDC's own recent conclusion on the use of nonpharmaceutical measures such as face masks in pandemic influenza (https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article), warned that scientific "evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission…" Moreover, in the WHO's 2019 guidance document (https://apps.who.int/iris/bitstream/handle/10665/329438/9789241516839-eng.pdf?ua=1) on nonpharmaceutical public health measures in a pandemic, they reported as to face masks that "there is no evidence that this is effective in reducing transmission…" Similarly, in the fine print to a recent double-blind, double-masking simulation the CDC stated (https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm?s_cid=mm7007e1_w) that "The findings of these simulations [supporting mask usage] should neither be generalized to the effectiveness …nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings."

Just look at the data from Jonas F. Ludvigsson that is emerging from Sweden (https://www.nejm.org/doi/full/10.1056/NEJMc2026670) in children 16 years old and under when preschools and schools were kept open and there were no face masks though social

distancing was fostered. The result was zero (0) deaths from COVID-19 in 1.95 million Swedish children across the study period. The number of infections was exceedingly low, the number of hospitalizations was exceedingly low, and there were no deaths in children with COVID-19, all this despite not wearing masks due to no schoolwide mask mandate. Is this merely a perfunctory and legally prudent warning by the CDC that "your mileage may vary?" Or is it more like a hot mutual fund telling you that "past performance is no guarantee of future results." What is the CDC really trying to say about face masks and why so much confusion?

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We have reservations about the methodology employed and conclusions drawn in the CDC double mask study (https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm?s_cid=mm7007e1_w) which we will address in a separate discussion but again their disclaimer as noted above: "The findings of these simulations should neither be generalized to the effectiveness …nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings" seeds thoughts of doubt in relation to the value of this report. Why then, would the CDC even bother to publicize these findings? What is the public health impact? What is the benefit?

Moreover, the CDC even indicated in the double mask study (https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm?s_cid=mm7007e1_w) that there are harms e.g. impediments to breathing, due to double masking. Indeed, the harms (e.g. reference 1 (https://science.orf.at/stories/3201213/), 2 (https://corona-transition.org/maskentragen-noch-ungesunder-als-gedacht), 3 (https://corona-transition.org/13-jahrige-maskentragerin-stirbt), 4 (https://www.thatsmags.com/china/post/31100/student-deaths-lead-schools-to-adjust-rules-on-masks-while-exercising), 5

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(https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/), 6 (https://corona-transition.org/der-maskenzwang-ist-verantwortlich-fur-schwere-psychische-schaden-und-die), 7 (https://engineering.stanford.edu/magazine/article/covid-19-prompts-team-engineers-rethink-humble-face-mask), 8 (https://twitter.com/MMaccruiskeen/status/1307266527662669825?s=20), 9 (https://pubmed.ncbi.nlm.nih.gov/18500410/), 10 (https://www.aier.org/article/the-year-of-disguises/)) are very real when face masks are used yet are often dismissed and not even discussed by the media medical establishment or government bureaucrats.

In relation to this, Dr. Anthony Fauci of the NIAID created appreciable confusion by initially suggesting (https://www.cnbc.com/2021/01/25/dr-fauci-double-mask-during-covid-makes-common-sense-more-effective.html) and encouraging the use of double masks instead of one. Dr. Fauci then reversed his statements (https://www.washingtonexaminer.com/news/anthony-fauci-masks-double) on the use of double masks. Dr. Fauci's advisories took on a form of double speak which has an appearance of randomness or worse, capriciousness. This can only distort the desperately needed advice by the public at large; unsound advice can be very damaging on several levels. This random form of advice-giving was not reflective of a single event. For example, while touting vaccines as the only way for society to emerge back to normal from the pandemic, Dr. Fauci is now advising that in fact, even with vaccinations, people should still not attend public gatherings and restaurants (https://www.businessinsider.com/fauci-vaccinated-people-should-not-indoor-dine-go-to-theaters-2021-2), and that such restrictions could be in place until end of 2021

(https://www.aier.org/article/vaccine-central-planning-fails-too/). While changes in advice are required when new data emerge, we hold that this was definitely not the case with respect to masking (or vaccination for that matter).

Below are the main scientific shortcomings or analytical ambiguities in the CDC's most recent MMWR report on mask mandates (https://www.cdc.gov/mmwr/volumes/70/wr/mm7006e2.htm):

1. The CDC's main evidence, a regression study based on selected sites in ten states with masking mandates from March through October 2020, did not include the four-month period from November through February 2021 (which might have controlled for other possibly contributing factors such as sunlight and vitamin D) and did not appear to take into account the possible effects of such factors as school closures or changes in social distancing practices. We point out that during the period of March 22, 2020 to October 12, 2020 this is actually representative of the spring, summer and early fall seasons when outdoor activity increases. Of course, this leads to more exposure to sunlight with the attendant generation of active vitamin D metabolites, while at the same time there are marked reductions in confinement within enclosed spaces which would necessarily reduce the opportunities for transmission of disease. A more stringent approach to the analyses, including the use of *all* available data (i.e. not excluding a full 4-month period of time), might have led conceivably to a conclusion that there was in fact no significant effect of mask mandates on disease or case

rates. And in concert with the CDC's disclaimers noted above, the CDC indicated in their own report that the conclusions described in the study in favour of masking were, at best, only moderately reliable.

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2. **The CDC analyzed changes in hospitalizations, but did not compare** infection, disease, or death rates between states with and without masking mandates. Available evidence of that nature suggests that the course of the pandemic was not affected by state masking mandates.

3. The CDC used a least squares fit regression analysis (OLS) (using "x" as mask wearing and the dependent/outcome to the "y" variable which is the number of Covid cases) despite the fact that simple regression is not the optimal approach and, we believe, should be replaced with Orthogonal Distance Regression (ODR) which would yield more reliable findings.

4. Based on the reporting, it appears that the CDC's regression analysis was based on data from limited sites within a state, and not the entire state.

5. The CDC report failed to address/discuss recent potent research data based on high-quality case-controlled analyses, as well as a high-quality Danish randomized controlled trial study (https://www.acpjournals.org/doi/10.7326/M20-6817)published in the *Annals of Internal Medicine* which found no statistically or clinically significant impact of

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mask-use in regard to the rate of infection with SARS CoV-2, or a recent *NEJM* publication (https://www.nejm.org/doi/full/10.1056/NEJMoa2029717) (prospective cohort CHARM study) where researchers studied SARS-CoV-2 transmission among Marine recruits at Parris Island (n=1,848) who volunteered, underwent a 2-week quarantine at home that was followed by a second 2-week quarantine in a closed college campus setting. The predominant finding was that despite the very strict and enforced quarantine, including 2 full weeks of supervised confinement and then enforced social distancing and masking protocols, the rate of transmission was *not* reduced and in fact seemed to be higher than expected, despite the strong experimental design and the rigor associated with carrying out the study.

6. The CDC report does not address and contextualize substantial "real world" experience showing that adding mandates where there is already substantial mask wearing has little effect, and that mask mandates that were followed can be correlated with increased case counts (e.g. references 1 (https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/), 2 (https://twitter.com/justin_hart/status/1340725095573024768), 3 (https://www.theepochtimes.com/face-mask-mandates-seem-to-make-ccp-virus-infection-rates-climb-says-study_3629627.html?

utm_source=morningbrief&utm_medium=email&utm_campaign=mb2020-12-23&fbclid=IwAR1OlncsLOdYRg-vt2afCphIGj3z6Curfcp3G-U9_EEjQi-MXId5IzwZRBw), 4 (https://www.conservativereview.com/horowitz-comprehensive-analysis-of-50-states-shows-greater-spread-with-mask-mandates-2649589520.html)). This obviously may not be cause and effect, but the same criticism can be levied against correlations or regressions going in the opposite direction.

Based on our assessment of this CDC mask mandate report, we find ourselves troubled by the study methods themselves and by extension, the conclusions drawn. The real-world evidence exists and indicates that in various countries and US states, when mask mandates (https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/) were followed consistently, there was an inexorable increase in case counts. We have seen that in states and countries that already have a high frequency of mask wearing that adding mandates had little effect. There was no (zero) benefit of adding a mask mandate in Austria, Germany, France, Spain, UK, Belgium, Ireland, Portugal, and Italy, and states like California, Hawaii, and Texas (https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/). Importantly, we do not ascribe a cause-effect relationship between the implementation of mask mandates and the rise in case rates, but we also demand the same approach when it comes to claiming some sort of causal relationship between the introduction of mask mandates and likely claims by the CDC that their findings could support their implementation countrywide.

We think that inclusion of such (https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/) evidence on the

failures of masks mandates globally and states within the US would have made for more balanced, comprehensive, and fully-informed reporting. Specifically (https://www.theepochtimes.com/face-mask-mandates-seem-to-make-ccp-virus-infection-rates-climb-says-study_3629627.html?utm_source=morningbrief&utm_medium=email&utm_campaign=mb-2020-12-23&fbclid=IwAR1OlncsLOdYRg-vt2afCphIGj3z6Curfcp3G-U9_EEjQi-MXId5IzwZRBw), when we consider the evidence on mask mandates, "in states with a mandate in effect, there were 9,605,256 confirmed Covid-19 cases, which works out to an average of 27 cases per 100,000 people per day. When states didn't have a statewide order—including states that never even had mandates, coupled with the period of time states with mandates still didn't have a mandate in place—there were 5,781,716 cases, averaging 17 cases per 100,000 people per day. In other words, protective-mask mandates have a poor track record insofar as fighting this pandemic (https://www.theepochtimes.com/face-mask-mandates-seem-to-make-ccp-virus-infection-rates-climb-says-study_3629627.html?utm_source=morningbrief&utm_medium=email&utm_campaign=mb-2020-12-23&fbclid=IwAR1OlncsLOdYRg-vt2afCphIGj3z6Curfcp3G-U9_EEjQi-MXId5IzwZRBw). States with mandates in place produced an average of 10 more reported infections per 100,000 people per day than states without mandates." The blind acceptance of the current unsupported dogma has become so entrenched that if cases do go up, the experts wedded to the universal use of masks then claim that this is good news and infer that the masking mandate *prevented even more cases* from occurring. This is a fine example of tautology and defies reason. We are very troubled by this type of scientific reporting and inference, for it is based on assumptions, supposition, and speculation.

Masks for the general population as they are currently used (surgical masks and the cloth masks), are ineffective (particularly when used without other mitigation) and the body of evidence (https://www.aier.org/article/masking-a-careful-review-of-the-evidence/) (see AIER) is clear. A recent op-ed in the *Washington Post* (https://www.washingtonpost.com/history/2020/04/02/everyone-wore-masks-during-1918-flu-pandemic-they-were-useless/) spoke to mask wearing by everyone during the 1918 flu pandemic, with the conclusion that masks were useless. We embrace fully the contention by Klompas in the *NEJM* (https://www.nejm.org/doi/full/10.1056/NEJMp2006372?query=TOC) that "what is clear, however, is that universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. **Focusing on universal masking alone could, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."** We are particularly alarmed by the harms of masking and the failure by top US agencies and leadership (as well as the media and 'media' medical experts) to discuss or highlight harms in any discourse on masking.

We end by imploring the CDC to take our critique in the spirit in which it was generated. We welcome continued, rigorous scientific examination of these important societal lockdowns, school closures, and masking and broader mask mandate issues by CDC and others. We are entirely willing to consider any evidence that contradicts what we have seen which suggests that societal lockdowns and school closures are not effective, and as

presented here, suggests that mask mandates are ineffective. Most importantly, to maintain the validity of scientific research as a tool, and the public's confidence in such research, reports of the results of such research should more comprehensively address the weakness or ambiguities that exist, as well as the conclusions the reporting agency supports.

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Trusting the science means relying on the scientific process and method and not merely 'following the leader.' It is not the same as trusting, without verification, the conclusory statements of human beings simply because they have scientific training or credentials. This is especially so if their views and inquiry have become politicized. Dr. Martin Kulldorff of Harvard's Medical School has recently commented on the present Covid-19 scientific and research environment by stating, "After 300 years, the Age of Enlightenment has ended (https://mobile.twitter.com/MartinKulldorff/status/1317768803862839301)."

Sadly, we must agree, that it's not just that the age of enlightenment has come to an end, but indeed, that the science itself has been politicized and severely corrupted.

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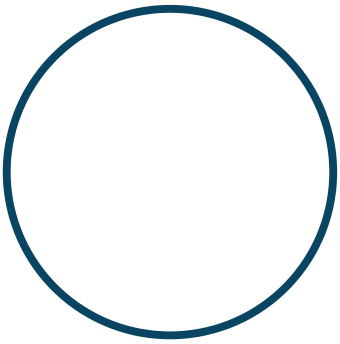
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OPINION

Opinion: Requiring kids to wear masks all day at school does more harm than good

While we all want to 'do something' to reduce suffering, we ought to act prudently and guard against unintended consequences

Published: Aug 13, 2021, 10:00 p.m. MDT

VIEW COMMENTS SHARE



Do masks provide a genuine benefit to school children without causing harm? | Kelly Sikkema, Unsplash

By Autumn Foster Cook

With the significant mental health implications of masking children, and the tenuous case for masks providing a significant benefit, requiring children to wear masks all day in

school does more harm than good.

When COVID-19 came on the scene, we naturally followed the human tendency to want to "do something." For a county or school district hoping to create the best scenario for students and faculty, advocating for wearing face masks is an understandable way to try to "do something." But do masks provide a genuine benefit to school children without causing harm?

As we head back into the school year, debate is heating up over this question, with parents, teachers and administrators debating whether to require masks in school in an effort to prevent the spread of COVID-19. In Utah, most school districts have announced their intent to hold school as normal.

Some parents and teachers are relieved, and some are upset.

Everyone wants to prevent unnecessary suffering, but when a communicable disease is in the picture, there's a lot of room for disagreement about what prevention should look like.

We know that smart hygiene practices — washing hands, covering coughs and sneezes, keeping children home when they're ill — provide measurable benefits in reducing the spread of disease. But the research on using face masks is much less conclusive, even for their use in surgical settings.

For many parents and teachers who dealt with the physical, psychological and emotional effects of mask mandates last year, that's not enough evidence to subject children to masks again.

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Perspective: I tried to show the struggle of kids in masks. The internet shamed me as a mom, instead

Since advocates and opponents of mask mandates for children can both point to research in support of their positions, let's take a look at data on actual outcomes. A report updated and released weekly by the American Pediatric Academy and the Children's Hospital Association tracks COVID-19 statistics in children. It shows cumulative cases per 100,000 children state by state (over the past 18 months). Utah sits right in the middle at about 6,200 cases.

What's significant is that the distribution of higher and lower rates of cases doesn't correlate with state mandates. States that held school mostly online last year, states that had in-person school with mask mandates and states that had school without mandates are scattered fairly evenly across the list.

A number of factors could be at play here, but first impressions suggest that masking doesn't appear to have affected children's health outcomes. If it did, we would expect states with strict mandates and delayed in-person school to have fewer cumulative cases as a rule.

Data collected by the COVID-19 School Response Dashboard, run by education groups including the School Superintendents Association, found that schools and school districts without mask mandates had lower case rates than schools with mandates.

Face masks were designed to be worn in hospitals to prevent saliva droplets from landing on patients and fellow staff. But for students, wearing a face mask for up to seven hours per day — 10 for students in extracurriculars — along with social distancing in school and constant reminders of danger presents some hygiene health risks — and significant mental health risks.

RELATED

The political battle over the pandemic has come to the classroom

One second grade teacher in Utah County said she saw children playing with masks and touching their faces more frequently. "It was often the children who wore masks faithfully who experienced more sick days."

This isn't surprising, considering that the human body is designed to expel wastes through exhaling. Holding those wastes against the face creates a whole new set of problems as children inhale the bacteria and viruses their body is trying to get rid of, and those wastes sit in a moist environment on the skin.

The same teacher said she saw emotional strain under last year's mandates. "Children rely on facial expressions to interpret what they hear. They respond to facial cues to interact and respond appropriately to teachers and peers." The harm done when that key part of human interaction is eliminated should not be underestimated.

Many families also dealt with "maskne" — mask acne — this year. This is no small matter when the maskne is a staph infection that is hard to get rid of and may develop into a long-term problem.

A Utah County kindergarten teacher with 15 years of experience said she is concerned about the long-term mental health effects on her students. She said many teachers dealt with significant behavior issues last year. She is seeing children who have developed an unhealthy worry that they will make everyone around them sick.

Teachers and parents of children all the way through high school have described the same paralyzing fear in children. In some cases, it has

caused anxiety levels leading to withdrawal from social interactions.

View Comments

While we all want to "do something" to reduce suffering, we ought to act prudently and guard against unintended consequences. Masks for children appear to do more harm to their development than provide effective safeguards against spreading disease. Without more solid evidence that points to masks providing a measurable protection against respiratory illness among school-age children, requiring kids to wear masks risks teaching them to be afraid of their bodies and afraid of their peers.

There's strong support among parents and teachers in Utah to go back to school without masks. For the sake of children's immediate and long-term mental health, it's time to do just that.

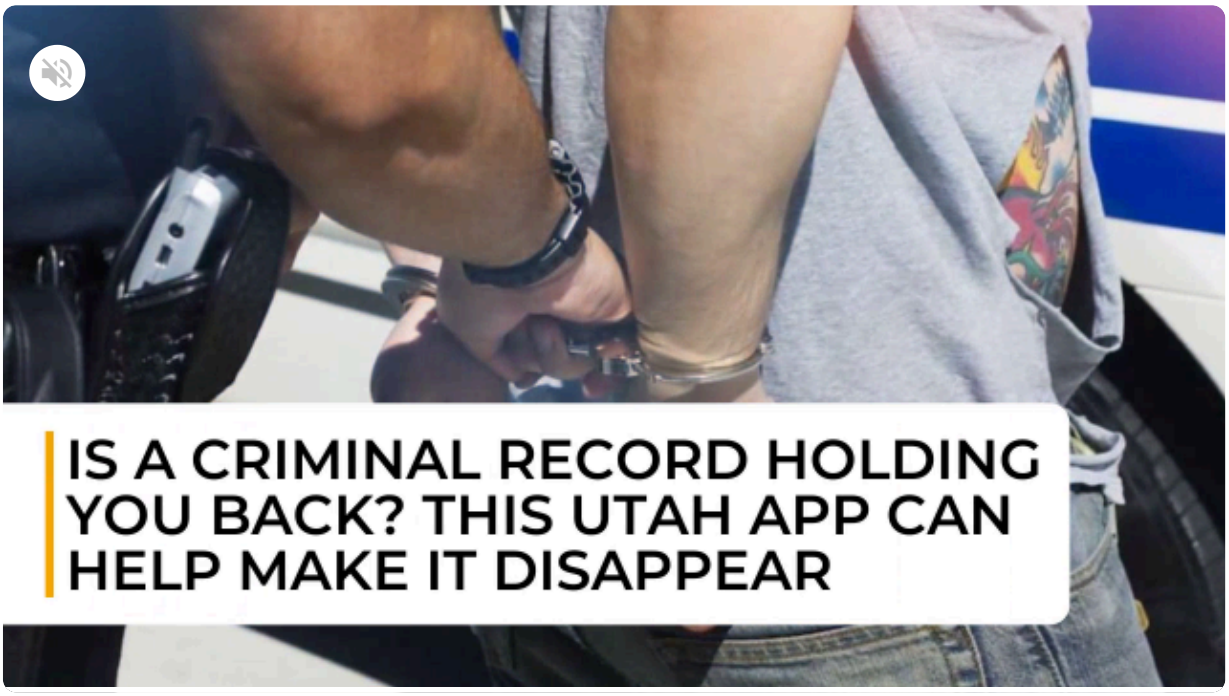
Autumn Foster Cook is a freelance writer from Utah.

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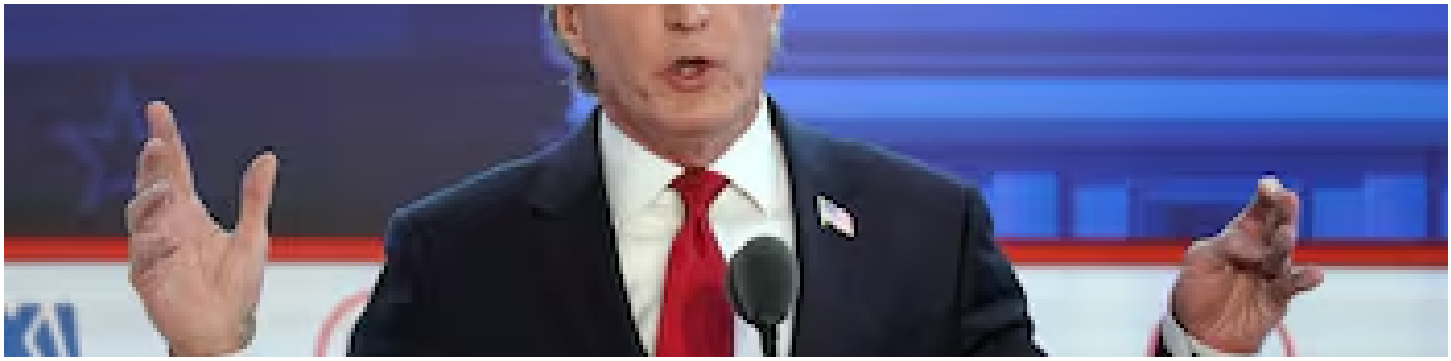
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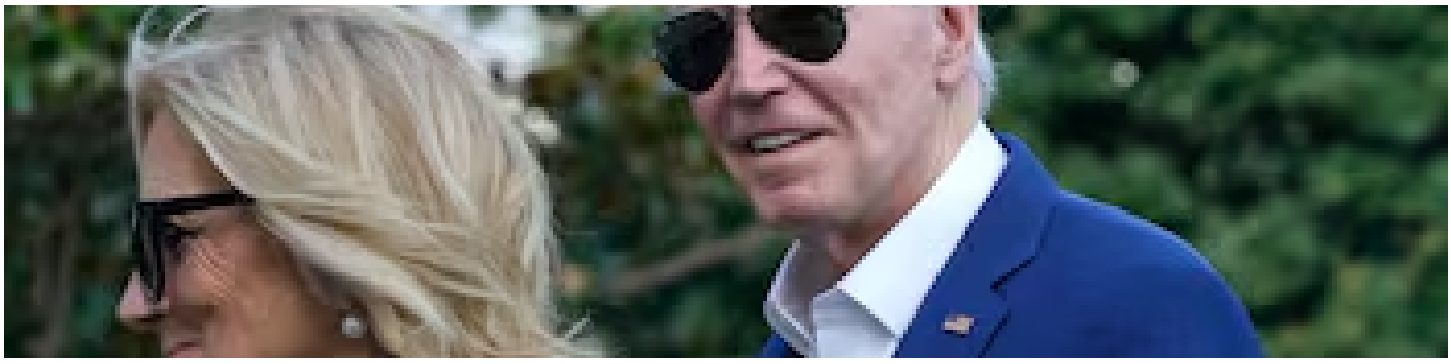
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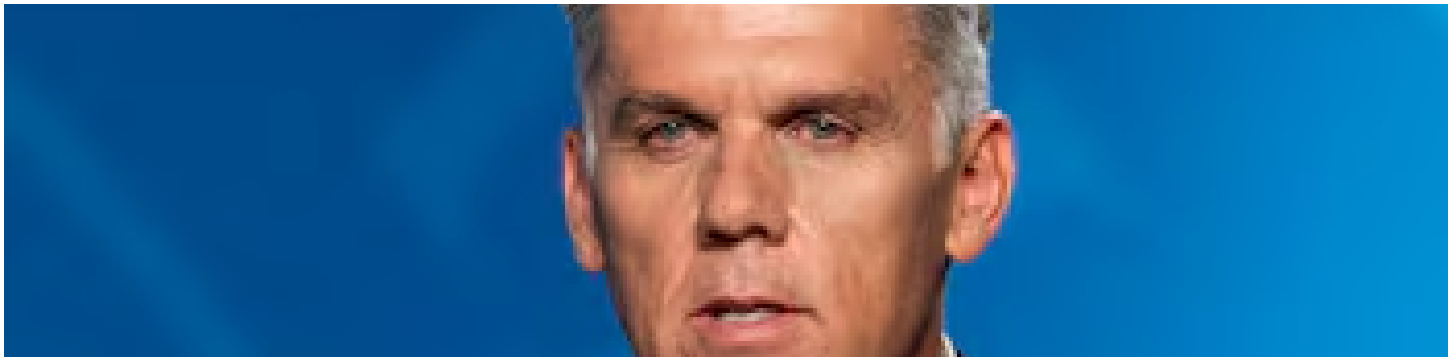
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322 At Las Vegas event, Kamala Harris supporters ask: Why not her?

212 Perspective: Republicans must have the courage to speak moral truth

135 House passes bill requiring proof of citizenship to vote. What's next?

122 BYU football: Cougars express a quiet confidence at Big 12 football media days that their fortunes in 2024 will be better than their first year in the league

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Mask regulation testimony 3/15

Lisa Pomeroy <lisapomeroy@mindspring.com>

Fri 3/15/2024 9:00 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;consent4RI@hotmail.com <consent4RI@hotmail.com>

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Report Suspicious

I am appalled that you would even consider approving a regulation giving RIDOH authorization to once again impose mask mandates on our children. You know as well as I do that masking our school children did nothing to prevent the spread of covid nor did it prevent the spread of any other viral upper respiratory infections. You so much as admit that in your first proposed regulation where you state:

"An absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the Department from considering a face mask requirement."

Enough with this charade of claiming to want to "protect" our children. The masks in school did nothing of the sort. All they did was force our children to rebreathe stale air and expose them to harmful fungi, bacteria, and chemical substances present in the masks. They caused rashes and illnesses, headaches, difficulty breathing, learning loss, stunting of our children's emotional development and exacerbated the already growing mental health crisis in our kids. To once again consider forcing our kids to mask at your whim is a complete abrogation of your responsibility towards the health of the citizens of Rhode Island, particularly our children. You should be ashamed of yourselves. Do not project your fears onto our children!

Lisa Pomeroy, MD
401-480-2280

Sent from my iPhone

RIDOH MASK REGULATION HEARING

Sharon Santos <sharonsantos83@gmail.com>
Fri 3/15/2024 9:01 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Since beginning this journey of having school aged children and seeing how invasive many of RIDOH policies are, and then going through this pandemic I really must say that I can understand those that can afford to homeschool making that choice.

It seems like since the pandemic we have been speeding towards policies that do not stand firm on "medical science". This pandemic and masking was started with a lie and so it is extremely difficult to "trust the science" that is offered. When you look into and ask questions, you are made to seem your education is inadequate, however most of the people making these decisions are in fact able to read the opposition to their opinion in a variety of medical papers, but seem to generally not want to be bothered.

I have a special needs daughter that even though I sent her to school with a face shield and asked not to have a mask put on her due to her inability to control her saliva and subsequent difficulty with lung function as a result of having a wet napkin left on her face. I would have loved to just keep her home, but do not financially have the ability to do that. So compelling those in a position like mine to vaccinate or mask or stay "home" is not really an option.

Whatever mask that is worn is really to assist in your own personal comfort level.
https://nypost.com/2023/02/14/face-masks-made-little-to-no-difference-in-preventing-covid-study/ [nypost.com]

As seen in the below article from NIH, during the pandemic when we were told/sold a variety of masks touted as "safe and effective" there are clear issues with the reality.

Metal leaching from antimicrobial cloth face masks intended to slow the spread of COVID-19

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8479130/ [ncbi.nlm.nih.gov]

Please consider that before you vote on this rule to hand over more authority to RIDOH and "the director" , what is accurate. Please stop trying to chip away at parental rights as we also want our children to be safe.
Thanks,
Sharon

US NEWS

Face masks made ‘little to no difference’ in preventing spread of COVID: study

By Melissa Rudy, Fox News

Published Feb. 14, 2023
Updated Feb. 14, 2023, 2:06 p.m. ET

184

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COVID-19's lasting impact: 'Less attractive' people wear masks

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Women more likely to suffer from ‘long COVID’

After initially claiming face coverings weren’t necessary, the CDC changed course in April 2020, calling on all Americans — even children as young as 2 — to mask up.

That September, then-CDC Director Dr. Robert Redfield said during a Senate hearing that “face masks are the most important powerful health tool we have,” even suggesting that they might offer more protection than vaccines.

Those recommendations likely played a large part in 39 US states eventually enacting mask mandates.

Now, a new scientific review — led by 12 researchers from esteemed universities around the world — suggests that widespread masking may have done little to nothing to curb the transmission of COVID-19.

Published by Cochrane Library, the review dug into the findings of 78 randomized controlled trials to determine whether “physical interventions” — including face masks and hand-washing — lessened the spread of respiratory viruses.

When comparing the use of medical/surgical masks to wearing no masks, the review found that “wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (nine studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (six studies; 13,919 people).”

Next, the review compared medical/surgical masks to N95 respirators (or P2 respirators, which are used in Europe).

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Metal leaching from antimicrobial cloth face masks intended to slow the spread of COVID-19

Zoe A. Pollard, Madeline Karod, and Jillian L. Goldfarb

Abstract

Global health organizations recommend the use of cloth face coverings to slow the spread of COVID-19. Seemingly overnight, companies whose primary business is in no way related to health-care or personal protective equipment—from mattresses manufacturers to big box stores—transitioned into the "mask business." Many companies advertise antimicrobial masks containing silver, copper, or other antimicrobials. Often, the techniques used to load such antimicrobials onto mask fibers are undisclosed, and the potential for metal leaching from these masks is yet unknown. We exposed nine so-called "antimicrobial" face masks (and one 100% cotton control mask) to deionized water, laundry detergent, and artificial saliva to quantify the leachable silver and copper that may occur during mask washing and wearing. Leaching varied widely across manufacturer, metal, and leaching solution, but in some cases was as high as 100% of the metals contained in the as-received mask after 1 h of exposure.

Subject terms: Environmental chemistry, Chemical engineering, Materials chemistry

Introduction

One of the most politicized and now commercialized aspect of the COVID-19 pandemic is the use of cloth face coverings among the general public to mitigate the spread of SARS-CoV-2[1]. Decades of research demonstrate the effectiveness of medical-grade surgical and N-95 masks against aerosolized disease transmission[2–4]. A new corpus overwhelming agrees that even cloth face masks provide some protection against infection of the wearer and effectively reduce community spread of SARS-CoV-2[5–7]. As the US death toll from COVID-19 mounts, with cases surging above

Feedback

36.5 million (as of 12 August 2021), mask-wearing was recently called one's "civic duty, a small sacrifice reliant on a highly effective low-tech solution that can help turn the tide favorably in national and global efforts against COVID-19[8]." While the precise level of effectiveness of cloth face masks varies by fabric, number of layers, and fit, fabric masks may filter out greater than 95% of the virus present in aerosols > 5 μm[9], with tight-weave fabric blends capable of removing up to 80% of particles smaller than 300 nm in size[10].

Global health guidelines to wear a cloth face covering were (initially) motivated by limiting community spread[11], especially by asymptomatic infected persons[12]. However the increased use of cloth face masks by the US population (from roughly 62% of people in April to 76% in May, 2020) is strongly attributed to the belief that mask-wearing reduces one's own risk of infection[13]. On 27 July 2021, the US Centers for Disease Control and Prevention (CDC) reversed its recommendations, which previously (with guidance issued on 18 May 2021) exempted vaccinated individuals from mask-wearing in public, in light of the highly contagious Delta variant. At publication, the current CDC recommendation is that even vaccinated individuals should wear masks indoors when the risk of transmission is high or substantial, including in schools[14]. This has perhaps fueled the commercialization of masks with "enhanced" features, such as antimicrobial properties. There are now hundreds of retailers selling antimicrobial cloth face masks across the internet from biomedical fiber companies to clothing retailers to mattress makers. Some companies, such as Sonovia Ltd., claim to have scientific testing that proves their mask—impregnated with zinc oxide nanoparticles—is over 90% effective at killing SARS-CoV-2, even after 100 washings[15]. The majority of companies selling so-called antimicrobial masks add disclaimers to their products, such as "This product makes no claims that it will cure or prevent Corona Virus, Influenza, or Covid-19[16]." In a recent NBC news story, Jeffrey Keane, CEO of Noble Biomaterials, claimed that antimicrobial masks help reduce the risk of virus transmission by eliminating cross contamination from fabric to skin[17]. This optimism is tempered by comments from medical experts suggesting such claims are over-inflated and may imbibe the wearer with a false sense of protection[17]. Regardless of the effectiveness of antimicrobial masks against SARS-CoV-2, metal-infused face masks may pose a potential risk to wearers in the form of metal leaching.

Many antimicrobial textiles are metal impregnated, often with copper or silver engineered nanoparticles (ENPs)[18–25]. These ENPs provide antimicrobial benefits by releasing metallic ions (Ag^+ or Cu^{2+}) or reactive oxygen species which can damage the bacterial wall in an aqueous environment[26]. However, once loosened from the fabrics, these metal species could leach into graywater (via washing) or onto the consumer's skin during wearing. In one of the first studies to demonstrate the potential leaching behavior of commercially available ENP-impregnated textiles, Benn and Westerhoff observed up to 650 μg of silver leached into 500 mL of distilled water from a single commercial sock[27]. Washing and rinsing of silver-impregnated textiles can release everything from coarse particulate matter (45 μm and larger), to nanosilver, to dissolved silver[28]. Detergents, basic in nature (pH > 10) with a variety of complexing agents and ions, can interact with silver present, leading to AgCl and Ag_2S formation[28,29]. Bleaching agents can oxidize nano-Ag and lead to dissolution[30] and AgCl formation[31]. Similar results are noted for leaching of copper from Cu-ENP-impregnated textiles[32]. Overall, the release and transformation of ENPs from antimi-

crobial textiles is mediated by (1) initial metal incorporation into the fibers[32] (location, adhesion method, textile composition, ENP/metal salt form); (2) textile application (body temperature, sweat level, abrasion/activity); (3) washing/cleaning (modality and chemicals); (4) disposal[33].

To our knowledge, there are no studies (to date) that assess the potential for saliva to promote metal leaching from textiles, likely owing to the previously limited use of face coverings pre-COVID-19. Oral ingestion, inhalation, and dermal adsorption of leached metals from wearing a copper- or silver-infused face mask are potential metal exposure pathways. Studies from the dental literature show the potential for decomposition of, and metal leaching from, metal alloys used in dental implants due to the antioxidant properties of saliva[34]. This led us to hypothesize that saliva could promote the leaching of silver and/or copper from a fiber matrix. While silver exhibits relatively low toxicity as compared to other metals, ingestion and dermal adsorption can result in argyria and argyrosis (irreversible skin and eye pigmentation)[35] at low concentrations. Generalized argyria can result from inhalation and application of silver to mucosal membranes, which has led to seizures and organ damage[36]. At higher concentrations, soluble silver inhalation can cause respiratory irritation and reductions in glutathione, critical for red blood cell functions[37]. Copper, while being an essential micronutrient, can cause gastrointestinal issues with chronic adult exposure at doses above 5.3 mg[38]. Exposure to copper dust can cause respiratory irritation, headache, vertigo, and hepatomegaly[39]. As such, the present study examines the potential for leaching of silver and copper from anti-microbial face masks due to exposure to saliva and during simulated wash/rinse cycles to shed light on both human and environmental health implications. For this study, 9 masks with advertised antimicrobial benefits (and one without any advertised antimicrobial properties as a control) were selected from varying manufacturers and the potential for metal leaching from each mask was investigated. Mask descriptions are provided in Table 1.

Table 1

Commercially available “antimicrobial” masks analyzed (for fiber composition, “inner” refers to fabric touching the mouth, “outer” to the fabric facing outwards, “fill” to any lining material between the inner and outer fabric).

Mask number	Primary industry of manufacturer	Fiber composition	Product labeling re: antimicrobial properties	Manufacturer’s washing notes	Mass of as-received mask (g) and (size)
1	Mattresses	2-layer cotton with polyester fill	Copper infused threads	Washable	15.81 (large)
2	Sportswear	3-layer cotton	Contains silver and copper	Machine washable up to 15×	14.58 (large)
3	Clothing	2-layer polyester with cotton fill	Anti-microbial fabric; 60% cationic, 40% polyester	Washable	21.37 (M/L)
4	Shoes	Inner: Cu-lined ionized quartz yarn fabric, outer: polyester	Anti-microbial copper	Washable up to 50×	11.96 (large)
5	Medical clothing	Inner: polyester, outer: 84% polyester, 11% rayon, 5% spandex	Treated with Silvadur™	Washable	15.46 (one size)
6	Medical clothing	Inner: cotton, outer: 97% cotton, 3% spandex	Treated with Silvadur™	Washable	12.73 (one size)
7	Clothing	2-layer 65% polyester, 35% rayon with polyester fill	Anti-microbial coating	Washable up to 30×	15.44 (large)
8	Materials consulting	2-layer polyester	Antimicrobial SilverKiss™	Washable	20.02 (L/XL)
9	Athletic accessories	2-layer cotton with 1 layer polypropylene fill and 1 layer polyester fill	Copper infused	Washable	12.80 (one size)
10	General	2-layer cotton	None	Washable	11.78 (L/XL)

Results and discussion

Initial silver and/or copper loading in each as-received mask was measured via Inductively Coupled Plasma - Mass Spectrometry (ICP-MS) (Table 2); at least two masks per manufacturer and one sample per mask were used to ensure a representative sample. Silver is present in Masks 2, 4, 5 (up to 2 mg per mask with masks weighing between 11.96 and 15.46 g), and at considerably higher concentrations in Mask 8 (upwards of 100 mg per mask with a total mask mass of 20.02 g). Copper was detected in Masks 1, 2, 4, 6 and 9 at levels between 2 and 14 mg per mask. We note that while Mask 6 was advertised as being treated with DuPont's Silvadur™, multiple repeated experiments across three separate masks from the same manufacturer detected no silver (yet found significant copper) upon complete digestion of the mask. In addition, Mask 4 was advertised as containing "copper impregnated threads," though silver was also detected. Masks 3 and 7 are advertised as being made from an antimicrobial fabric, but as they contain no (detectable) silver or copper; antimicrobial properties are likely imparted by a quaternary ammonia compound coating. As such, Masks 3 and 7 are excluded from the remaining discussion in terms of potential Ag and Cu leaching. It is important to note that since the nature of the antimicrobial coating is often not advertised (or, as we have found, mis-advertised) there is potential for additional health hazards resulting from the exposure to other chemicals used. Only Cu and Ag leaching are investigated in this work. As expected, Mask 10 (Control) contains no detectable silver or copper, demonstrating the validity of the analysis method with a null finding. The high reproducibility of metal concentrations across at least two samples per mask analyzed at least thrice each (evidenced by the tight 95% confidence intervals around each data point) and our continuous ICP-MS blank and calibration checks (between every 10 samples analyzed) suggest minimal ICP-MS carry-over and no cross-contamination of samples.

Table 2

Total silver and/or copper present in as received masks; n.d. denotes samples where metal was not detected.

Mask	Metal present in mask (mg_{metal}/g_{mask})									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Silver	n.d.	0.02	n.d.	0.16	0.03	n.d.	n.d.	5.27	n.d.	n.d.
Copper	0.80	0.09	n.d.	1.11	n.d	0.11	n.d.	n.d.	0.65	n.d.

Standard deviation for every value is less than 0.01 mg metal/g mask.

Figure 1 presents the leaching of silver (1a) and copper (1b) into treatment solutions and the percentage of silver (1c) and copper (1d) remaining in masks post water rinse, simulated washing, and saliva exposure. Only data for masks initially containing metal (1, 2, 4, 5, 6, 8, 9) are shown here, though all masks were subjected to every test (tabulated values for all experiments available in Supplemental Information Table S1 (silver) and Table S2 (copper), available online). Figure 1a,b show the quantity of silver and/or copper that has the potential to leach from an antimicrobial

mask into a given solution. A high degree of leaching for both metals was observed in a single wash detergent cycle, indicating the potential for graywater contamination because of washing the antimicrobial masks. It is important to note that after 10 detergent cycles the leaching levels in solution (Fig. 1a,b) are considerably lower than after 1 cycle. This is not because the metals were stabilized by the detergent (as after 10 washes there is considerably less metal remaining in the mask), but rather that metals were leached by the detergent in the previous cycles (wash water from wash cycles 2–9 was not analyzed due to experimental constraints). The ratio of the original metal remaining after treatment is shown in Fig. 1c,d and was determined by digesting and analyzing the masks as received and after treatment. A mass balance on each metal was performed by summing the metal present in the soak solution and the residual metal present in the mass, divided by the metal detected in the as received mask. The majority of the samples had mass balance closure within ± 10% of the as received mask data. Given well-documented potential heterogeneities of metal application in the mask fibers themselves[40], this high mass closure validates our experimental methods. We note that the mass closures for the single detergent cycle are highly variable (between 31 and 106%), due likely to both metal distribution heterogeneity *and* the rinse cycles used. While we attempted to analyze the metals present in the water rinse following washing, the metals were below limits of detection due to the rinse volume.

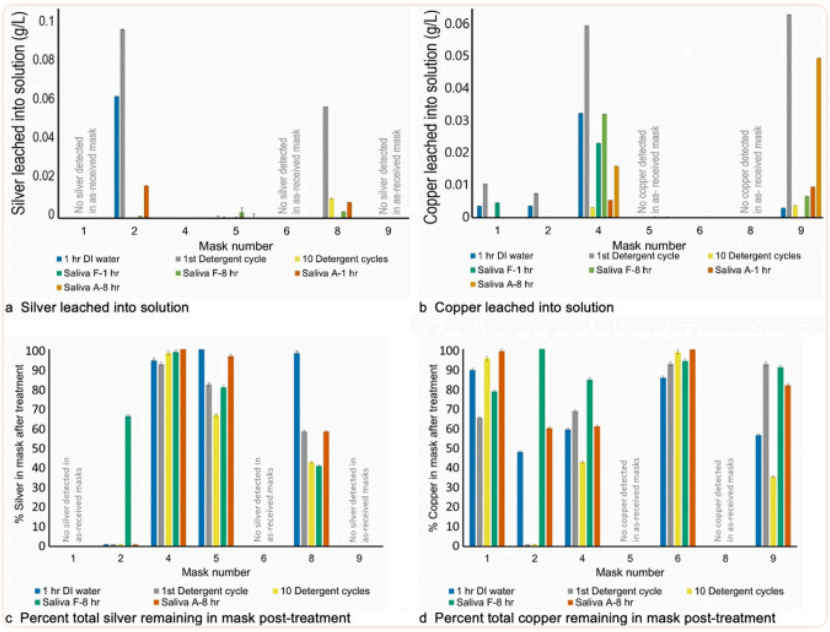


Figure 1

Total silver and/or copper leached into treatment solution (**a**,**b**) and present in masks post-treatment (**c**,**d**); error bars represent ± one standard deviation about the mean.

Overall, we note that the total amount of metals leached does *not* correspond to the amount initially present, suggesting that initial metal concentration is not driving partitioning to the solution phase. For example, Mask 2 has a relatively low metal loading (0.236 ± 0.003 mg_{Ag}/mask + 1.29 ± 0.04 mg_{Cu}/mask), yet the silver appears to leach almost entirely after just one wash/rinse cycle,

and extensively in both water and Saliva A. (No silver was detected in the 10th wash cycle solution as the silver was completely removed by the first wash cycle.) While water alone was sufficient to remove the majority of Ag from this mask, it did not have the same impact on the Cu present. Only 52% of the copper leached from Mask 2 during the 1-h water soak, but 100% was lost after 1 wash cycle. No leaching was detected in the 10th wash cycle for either metal, as all the metals leached from Mask 2 in the first cycle. As detergents are intended to remove foreign matter from fabric, it is not surprising that the detergents washes show, on average, the largest amount of leaching for both metals and across all masks. The complexing agents present in detergents were previously demonstrated to interact with silver metals present in textiles, leading to AgCl formation and dissolution[28,29].

As compared to Mask 2, Mask 8 has a considerably higher silver loading (105.4 ± 0.5 mg_{Ag}/mask), but rather low silver leaching, retaining all its silver following the DI water soak and close to 50% of silver following the other treatments. Mask 6 (also with low loading of 1.44 ± 0.04 mg_{Cu}/mask) has a constant copper concentration across the treatments, suggesting its potential to leach metals either onto the wearer's saliva or during washing is minimal. This suggests that the metals are more tightly bound to the textile of the mask. As such, neither detergents nor the acidic and oxidizing nature of the saliva solution removed them from the fiber matrix.

Given that the differences in the amount of metal leaching during washing cannot be attributed to initial concentration, they may be due to the method of metal loading and the fiber content of the mask. Reed et al. found that textiles coated with elemental silver released less than 2% of loaded silver in both DI water and detergent, whereas tethered-AgNP and electrostatic Ag-NP attachments resulted in more than three quarters of Ag released during DI washing and half during detergent washing. Silver salt-coated textiles were between these, with about 20% silver released during DI water and detergent wash cycles[41]. Pasricha et al. synthesized AgNPs via solution reduction and physically loaded the particles onto three fabrics. The cotton fiber, having a 31% initial loading, leached 12% of the silver after three washes, nylon fibers with 11% initial Ag loading leached 14% of the silver after three washes, whereas wool, with an initial 10% Ag loading, leached over one quarter of the silver[42]. From these and other examples, we know that metal leaching is a function of fiber content, loading method and leaching solution. The masks examined in this study exhibit a wide range of metal leaching behavior. Mask 4 maintains a high percentage (> 90%) of its initial silver across all treatments, however it leaches between 20 and 60% of the copper initially present.

In general, copper appears more susceptible to leaching when at higher concentrations than the silver across treatments. Masks 6 and 9 both contained copper. Mask 6 is predominantly cotton fiber, whereas Mask 9 is a blend of cotton, polypropylene, and polyester. Mask 9 leached significant amounts of copper after 10 washes (approximately 65% of its initial concentration) and into Saliva A (almost 20%) in contrast to Mask 6 which exhibited minimal leaching in any aqueous environment. In addition to the variability in fiber type (both loading metal and fiber content), this leaching behavior could be attributed the incorporation method of the metal. Mask 6 is advertised to be treated with a polymer-based coating, while the fibers of Mask 9 were 'infused' with copper.

Saliva A is reported to be more aggressive in terms of its oxidation properties[43], but its impact here versus Saliva F is mask- and metal-dependent. Saliva A leaches more Ag than Saliva F for Masks 2 and 4 (which contains both Ag and Cu) but leaches less Cu for either mask than Saliva F. Masks 5 and 8 (containing only Ag) and Mask 1 (containing only Cu) exhibit less leaching in Saliva A than in Saliva F. This may be attributed to the lower pH of Saliva F; the acidity of the saliva solutions may stabilize the silver. Mask 9 leaches between 10 and 20% of its copper into artificial saliva A and F, respectively, after 8 h, suggesting that over the course of a workday. The greatest risk from copper leaching appears to be posed by Mask 4 and 9, and from Ag leaching from Mask 8, especially if it is not pre-washed.

The degree of toxicity of silver is dependent on its oxidation state and morphology; silver nanoparticles (AgNPs) are less toxic than silver ions[44]. However, the moist environment of a face mask and the known rapid dissolution of AgNPs to Ag[45] suggests that the total Ag measurement in this study is representative of the most toxic potential silver exposure possible as the metals are in a dissolved form. These conditions are representative of what many essential workers endure, including preparing food in hot kitchen, waiting tables, working construction, and hauling goods, where it is likely for masks to become saturated over the course of a workday[46]. Studies have shown that in humid environments, or when worn for long periods of time, masks quickly become saturated[47] with saliva droplets[48,49] that are expelled during talking, sneezing, or coughing[50]. In the most extreme cases, if we assume an average adult weighs 70 kg, the potential exposure[51] (over an 8 h. workday, simulated saliva) to silver could be as high as 900 µg/kg (Mask 8) and to copper as high as 75 µg/kg (Mask 4). To further explore this, UV–Vis spectrophotometry was used as a screen for metal nanoparticles in the treatment solutions. The lack of any significant UV–Vis absorption bands in the 400–460 nm range, which would indicate surface plasmon resonance of AgNPs, confirm that the Ag is in dissolved form[52] (see Supplementary Figures S1 and S2 online). Spectrophotometry results are less conclusive concerning the form of Cu leached; Cu nanostructures tend to show broad and weak localized surface plasmon resonance responses, though the lack of peaks above 500 nm suggest the copper is more likely in a dissolved form[53]. However, some evidence of red shifts for Masks 1, 2 and 9 for Saliva F and detergent solution-based samples cannot rule out nano-Cu forms completely[54], especially for Mask 2 that shows peaks at 275 and 375 nm for several leaching solutions[55].

Public calls to temper the enthusiasm over antimicrobial masks (and their unlikely ability to protect oneself against COVID-19 infection beyond non-enhanced cloth masks) are supported by the likelihood that wearers are exposed to metals leaching from the mask fibers. For masks produced by a shoe manufacturer (Mask 4) and a materials consulting firm (Mask 8), this leaching is promoted in the present of saliva, providing a direct exposure route for the wearer. A series of 10 masks, 7 of which contained copper and/or silver as antimicrobial agents, were exposed to deionized water, commercial laundry detergent (1 and 10 simulated washing cycles), and two artificial saliva solutions. While some masks showed minimal loss of metals, others, such as one manufactured by a sportswear company (Mask 2), leached 100% of its silver after exposure to deionized water, detergent, and Anfor artificial saliva solution and 35% after exposure to Fusayama artificial saliva solution. This exposure risk could be reduced by first washing the masks, however metal leaching in detergent solutions likely reduces any antimicrobial activity and leads to graywater contamination. Overall, the results of this investigation suggest that metal-impregnated antimicro-

bial masks have the potential to contaminate wastewater streams and increase human exposure to silver and copper, which may pose a health risk at even the low concentrations detected here. While manufacturers rapidly shifted production lines to meet the demand for masks at the onset of the pandemic, the present investigation suggests that not all so-called antimicrobial masks are equal, with some posing a greater threat to humans and the environment than others.

Materials and methods

Masks labeled as "antimicrobial" were purchased from a variety of internet retailers in July 2020 as detailed in Table 1. A set of control "plain" cloth masks with no antimicrobial features was purchased at a local "big box" retail store where over 50% of Americans shop nationwide[56]. Masks were cut with new fabric shears into 2 cm × 2 cm ^{2} through all layers of the masks with straps and seams excluded.

Simulated product lifecycle exposure via washing

The CDC recommends daily laundering of cloth face masks by including the mask with one's "regular laundry" at the "warmest appropriate water setting for the cloth used to make the mask"[57]. Tide Original HE Turbo Clean was chosen as a representative laundry detergent as it is the best-selling laundry detergent in the US for over 70 years[58]. Detergent washing solution was prepared by diluting 20 mL Tide in with 980 mL Milli-Q water. To simulate washing, a 2 cm^2 sample of each mask was soaked in 6 mL of detergent solution at 37 °C while shaking at 100 rpm for 1 h in an Innova 44R Incubator Shaker (Eppendorf New Brunswick). Samples were rinsed in 10 mL of Milli-Q water, at 37 °C with shaking at 100 rpm for 1 h. For repeated washing cycles the wash and rinse were repeated ten times with the rinse and soak solutions analyzed for the first wash and the tenth wash.

Simulated product lifecycle exposure via wearing

Prior studies on metal leaching from textiles consider an article of clothing worn on the body, where sweat and abrasion would be the most common causes for metal release. In the case of a face mask covering the mouth, the environment is warm air/CO_2, humidified by saliva, a fluid with known antioxidant properties. Fusayama artificial saliva solution (denoted saliva F; pH = 5)[59] and Anfor saliva solution (denoted saliva A; pH = 6.7)[60] were used as a simulated leaching fluid for as-received masks. Artificial saliva solutions were mixed in house by dissolving and vortexing the following compounds in Milli-Q water; saliva F contained NaCl (0.4 g/L), KCl (0.9 g/L), $CaCl_2 \cdot 2H_2O$ (0.795 g/L), NaH_2PO_4 (0.69 g/L), and urea (1 g/L), and saliva A contained NaCl (0.7 g/L), KCl (1.2 g/L), Na_2HPO_4 (0.26 g/L), $NaHCO_3$ (1.5 g/L), KSCN (0.33 g/L), and urea (1 g/L). All compounds had a minimum purity of 99.0% (by mass) with a certified metal analysis reporting no detectable copper or silver. While Fusayama solution is the most used media in the evaluation of dental implants, the composition of human saliva is known to vary widely. Thus, two saliva solutions were used for the mask leaching experiments with the calcium component in Fusayama tempering the oxidant nature of the more pro-oxidant Anfor solution[43]. 2 cm square mask samples were soaked in 10 mL of each artificial saliva solution for 8 h to simulate a typical workday.

Analysis of total metal content and leached metals

DI water soak, wash/rinse, and artificial saliva soak solutions were analyzed (undiluted) for the presence of metal nanoparticles using UV–Vis spectrophotometry. Measurements were carried out using a Shimadzu UV–Vis Spectrophotometer in absorbance mode. Spectra were recorded across a wavelength range of 250 nm to 600 nm with a 1 cm sample depth and a 1 nm spectrometer slit width.

To prepare the mask samples for ICP-MS analysis, 0.01 g of as-received and treated masks (after 1 h DI water, detergent wash cycles, and artificial saliva exposure) were digested in 2 mL 70% trace metal grade nitric acid at 70 °C for 16 h, centrifuged, and the resulting supernatant extracted and filtered through a 20 μm hydrophilic cellulose acetate syringe filter. Aliquots of the soaking solutions were mixed 1:1 with 70% trace metal grade nitric acid at 65 °C for 2 h then centrifuged and the resulting supernatant extracted. Prior to ICP-MS analysis all digested samples were diluted to 2% nitric acid using Milli-Q water. Diluted solutions were analyzed for metal concentration using a Shimadzu Inductively Coupled Plasma Mass Spectrometry (ICP-MS-2030). Analysis was done in quantitative mode using an internal standard and a 9-point calibration curve. The tuning solution, calibration solution and internal standard were all purchased from High Purity Standards (USA). Additional ICP-MS details are available in the online Supplemental Information.

Statistical analysis

All mask-soaking experiments were run in (at least) duplicate and analyzed independently. The Shimadzu UV–Vis Spectrophotometer and Shimadzu Inductively Coupled Plasma Mass Spectrometer analyze samples in triplicate. The means and standard deviations are reported of the triplicate measurements of duplicate runs.

Supplementary Information

Supplementary Information. (777K, docx)

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Author contributions

Z.P. is responsible for methodology, sample preparation, data collection and analysis (ICP-MS), and manuscript drafting and revisions. M.K. is responsible for data collection and analysis (UV–Vis). J.G. is responsible for conceptualization, writing, supervision and resources.

Data availability

The masks used in this study are available for commercial purchase. All data used in this paper has been included in the Supplemental Information in graphical and/or tabular form.

Competing interests

The authors declare no competing interests.

Footnotes

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Supplementary Information

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Opposition to new masking regulation

Jeff LeBlanc <jleblanc141516@gmail.com>
Fri 3/15/2024 9:52 AM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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To those who value freedom,

I write this not only as a free American, but also as a proud father of three boys 10 years and under. To say I simply oppose the proposed masking regulation would be a massive understatement. I am truly insulted by the continued arrogance of the RIDOH to even be considering anything but a genuine apology to the children and parents of RI. An apology that is years overdue.
Currently there is a lack of trust in both state and federal agencies, some of which caused by the unjustified mandates, regulations and best "guidance " issued by the DOH. Doubling down on something like future mask mandates for children will only exacerbate the lack of trust. Now should be the time to rebuild the trust in our health institutions, but that would require the ability to genuinely look back, weighing both pros and cons and most importantly respecting everyone's autonomous freedom, not dictating what is "best"for them.
For those of us who suffered, and watched our children suffer under the thumb of unelected bureaucrats I can say honestly that never again will we fall victim to your will. I was an outspoken advocate for mask choice when in-person learning resumed in my town of Smithfield. At a local school committee meeting I said that I was raising " rule followers" and my children will follow whatever masking decision was made at the time. It was my job as a father to advocate for what I thought was right for my children, but I can tell you that never again will I mask any of my children. The state will have to deny my children their right to a public education if another mask mandate ever is issued. I will not sit back and watch as they become victims of what has become a COVID cult mentality.
After all we have gone through and all the residual mental, emotional and physical damage we still see with children from the COVID era, how can this proposal even be considered?
Information , including peer reviewed studies regarding masking is now public knowledge. It is there to be seen and learned from, if only it was the will of the DOH to step outside of the narrative that has been disproven, after following it for far too long.

Respectfully,

Jeff LeBlanc
Smithfield resident/father

Mask

pattipie1961@gmail.com <pattipie1961@gmail.com>

Fri 3/15/2024 10:01 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Please do not have children wear masks again. I am so against , these children are dealing with so much already . Please allow them to be free to breathe and learn normally. If u feel like u have to do something let it be voluntary if that's what the parents want. Thank you or your time, let wisdom guide you and not fear.

Thank you patricia corcoran

Sent from my iPhone

Mask Mandate

John Monroe <jmonroe@oceanstateacademy.com>

Fri 3/15/2024 10:06 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Dear Mr. Garceau,

My name is John Monroe and I am a citizen of Westerly, RI. I currently work as a teaching assistant at Ocean State Academy in Cranston, RI. I am writing to you to please oppose and mask mandating within the schools. We have discovered that masking the students and staff has not prevented the spread of covid. We all wore masks and still everyone was exposed to covid multiple times. If someone is concerned about germs and wants to wear a mask that is perfectly fine but it does not make sense for someone who doesn't want to wear a mask to be forced to wear a mask. We tried the masks and it was not effective at preventing the spread of viruses. Masking the students also had a negative effect on people socially. Please hear our concerns and do not allow for a mask mandate. Thank you very much and I wish you the best!

Sincerely,
John Monroe

Re: Opposition of the Proposed Policy of 216-RICR-30-05-04-Masking in School

Denise Miller <millerddo13@gmail.com>

Fri 3/15/2024 1:04 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:Denise Miller <millerddo13@gmail.com>

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I would like to add to my written testimony:

My name is Denise Miller. Like I stated before I have two children who attend Tiverton public schools. Olivia who is a 5th grader at TMS and Owen who is a 2nd grader at Ranger.

The irreparable harm that masks have caused my children is not reversible. You cannot take back the 4 years of education loss, the mental and emotional detriment it has caused.

When my son first started kindergarten in 2021-2022 he had never had to wear a mask - not even at daycare. Thankfully the daycare we attended at the time did not impose a mask mandate on their children. At least they had children's best interest in mind. But when he started kindergarten - he had to wear a mask for 6 hours + a day. He struggled significantly. He would come home with holes bitten in his mask. I asked him why he had holes in his mask and he said "because mommy I can't breath! And when I try to take a mask break the teacher made me pull my mask back up."

This policy has no business being implemented. If you implement this policy, can you reassure that our children will not suffer? Can you assure that irreparable harm will not be caused on healthy children?? Will you allow parents choice? Can you guarantee that our children will not be bullied by adults?

I am Veteran of the US Air Force. I served a six month tour in Afghanistan, and a 4 month tour in Saudi Arabia. I fought for other countries to have the basic human right to be free of oppression.

I refuse to allow this to happen in my country. I sacrificed 9 years to serve my country and I refuse to let anyone to take away my freedom and my children's freedom on US soil. This proposed policy should stop here....and never be brought back again.

Denise Miller
Tiverton, RI

On Thu, Mar 14, 2024 at 4:44 PM Denise Miller <millerddo13@gmail.com> wrote:

> I am writing in opposition of the proposed policy of 216-RICR-30-05-04-Masking in School. They are harmful to children and unsupported by scientific data. A medical intervention should never be forced on anyone, let alone healthy children. Masks should always be a choice and nothing more.
>
> Denise Miller
> Tiverton, Rhode Island

Masking in Public schools

Kimberly Parker <kimparker419@gmail.com>

Fri 3/15/2024 1:54 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Good afternoon,

Is it true that the DOH is trying to bring back the requirement for masking in public schools? How do I go about voting AGAINST that?

Thank you,

Kimberly Parker
RI Resident

Testimony in opposition to proposed RI DOH regulation "Masking In School"

Joe Daley <joepdaley@gmail.com>
Fri 3/15/2024 4:45 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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To Whom It May Concern,
I am writing to submit my testimony in opposition to the proposed RI Department of Health regulation for a masking requirement in school. As both a parent and an educator I saw firsthand the negative impact of school mask mandates during the 2020-2022 school years.

Two of my children attended public school in 2020-2021. To our great disappointment, our son spent his first year of school attempting to socialize, interact, and learn from behind a mask. It was a miserable experience for a kindergartener. He developed an unnatural fear that he had never displayed before being forced to mask all day long. He complained of headaches, not being able to breathe, discomfort and distress. Both of our children were bullied by teachers. Students were not given breaks and had to fully mask during gym or when outside for recess. Even when the temperatures soared into the 80s and 90s, they sat sweating without mask breaks in an un-air conditioned building. As parents we were extremely concerned and continually raised the alarm with our principal and school administration. Each time, we were told there was nothing the schools could do. There was no room for accommodation nor was the mandate's impact on individual students considered relevant. It was one size fits all directly from the Governor, the Department of Education and the Department of Health.

When the mask mandates continued into the 2021-2022 school year, our family took drastic action. We would not subject our children to another year of learning loss and distorted socialization for an intervention that doesn't work, for a disease that they're not at significant risk from. Instead, we made the decision to homeschool our children. It was a major challenge for our family, but well worth it. Despite the ongoing in-school mandates, our children continued regular social experiences with their peers outside of the school day when all the kids took their masks off and just played together like normal. The mandates were a form of theater, and even the kids saw through it. When our children finally returned to public school after the mandate was lifted in March 2022, they were well above their peers in terms of academics. Unfortunately, it was easy to see that learning through a mask had significant negative effects on education outcomes for all students.

As an elementary school teacher, I often think about my experience pre- and post- Covid. If in 2019 I had forced a student to strap a piece of cloth over their nose and mouth for an hour, I'm sure it would have resulted in a very serious meeting with my principal and superintendent, not to mention an angry phone call from the parents. If I had done the same during gym class in 85 degree heat, it would probably would have been considered child abuse. Yet for the 2020-2021 school year and two-thirds of the 2021-2022 school year, we did this to school children all day, every day. No exceptions. Not only was the forced masking of school children an abusive health policy, it was a terrible educational policy.

The early years of education are critical for development, and the face, especially the mouth and eyes are the primary way we transmit and convey information. The forced masking of both students and staff crippled this natural process. Oral and auditory learning went out the window. Social and emotional learning were turned on their head. The impact of masking on phonemic awareness, phonics, vocabulary development, reading fluency, etc... resulted in significant learning loss for all students. English Language Learners and English as a Second Language students faced even greater obstacles to learning. But none of this mattered. To my knowledge, no study was ever done to assess the impact of masking in schools on educational outcomes. What's more important? A disease that has not killed a single child in RI and from which children easily recover, or a year and half of learning loss?

Before any further regulation is considered, the Department of Health must address how a mask requirement would impact the social, emotional, and educational outcomes of all students in grades K-12. Does learning loss impact the short or long-term health of students? What are the unintended consequences of wearing a face mask all day long? What is the long-term impact of a particular infectious disease on a student compared to the long-term impact of required face masking in school? The Department of Health must answer these questions with valid scientific evidence for any proposal requiring masking in schools.

Thank you,

Joe Daley
South Kingstown

Mask mandate opposition testimony

Jennifer Moore <j_mo516@yahoo.com>

Sat 3/16/2024 7:38 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Please accept my written opposition to any and all mask mandates in schools in Rhode Island. As a mother of two young children who has been fighting alongside countless parents since 2020, We will not be complying with any future mandates.

Our two children will NOT under any circumstance wear a mask to attend school. Wearing something that is considered a "medical device" is a medical decision that can only be made by parents-not the government, not RIDOH, RIDE or anyone else who thinks they have the authority to enforce this medical decision. I think about all the families who knew it was wrong to allow the children to be masked but didnt have a choice because they had to work. We struggled financially in order for me to stay home so I could homeschool my children but there was no way I was sending them in masks. My son who has special needs with a significant speech delay and sensory issues and an IEP suffered immensely by not being able to receive walk in services. They would not let him in the building with out a mask. Now, hes almost 7 and struggles with speech from missing the assistance he needed from schools speech therapist. RIDOH should be both ashamed and held accountable.
Jennifer Hall

Mask mandate proposal

Suzanne Gagnon <suzanneg904@icloud.com>

Sat 3/16/2024 8:14 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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Good morning,

I'm Nathaniel and I'm 8 years old. Your mask mandates hurt me. They made it hard to breathe and I couldn't hear anyone. For first and second grade, I couldn't understand my teachers and they couldn't understand me. I never got breaks from hours of masking and I was bullied by adults when I tried to give myself one. I hated school.

I couldn't make friends because I couldn't even see my friend. You forced us to cover our faces.

I had to exercise in a mask. It hurt my body and it made it even harder to breathe.

Have you tried to have gym in a mask when it's 95 degrees out?

I do not ever want to have to wear a mask again. Now I can never trust you because you hurt children.

I oppose your horrible mask mandates.

Nathaniel
Sent from my iPhone

One more story:

Tara Mellow <tmellow@mpsri.net>

Sat 3/16/2024 9:55 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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At work I just had to get huffy about masks last week..... making us wear them for 10 days if we weee in contact with someone who was out sick with Covid

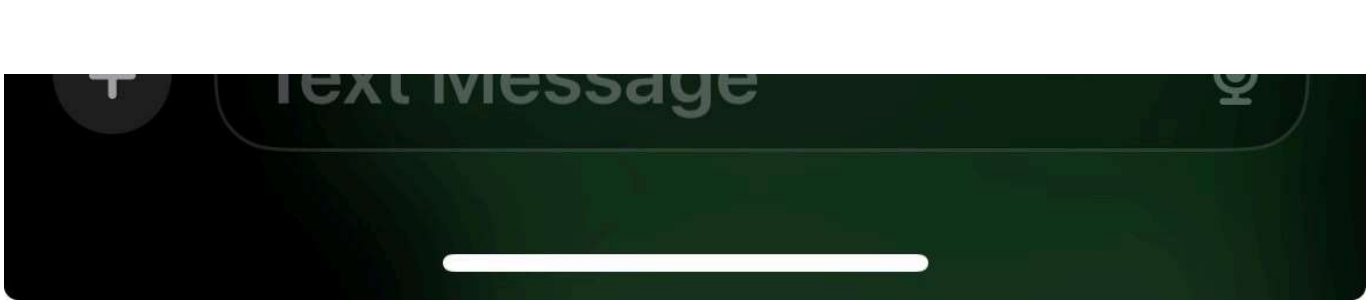
They still had the old protocol... we didn't even have Covid , tested twice negitive and still an n95 doe 10 days!!!!

Me and a mother called to complain, so they changed it to 5 days! Still wrong!!!!

M

Subject

Text Message


Text Message

OPPOSE - Proposed School Mask Regulation

Richard Southwell <rcsouthwell@yahoo.com>

Sat 3/16/2024 10:09 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

5 attachments (2 MB)

Southwell Testimony - 2024-03-15.pdf; Pima AZ Study.pdf; The CDC's Flawed Case for Wearing Masks in School - The Atlantic.pdf; Pima AZ Study - Chandra + Hoeg.pdf; Rhode Island Breaks Ground on $82 Million State-of-the-Art Public Health Laboratory.pdf;

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Good morning.

Attached is a document that outlines the reasons for my opposition to the proposed school mask mandate along with suggested revisions if RIDOH decides to move forward with it. Supporting documents are also attached to this email for you reference.

In short, RIDOH lacks credible scientific evidence that support its long held ***belief*** that "masks work". In yesterday's hearing you came face to face with the damage that your Covid era policies caused. The risk/benefit ratio for masking school children is woefully out of balance and if RIDOH didn't know it before, they most certainly know it now.

Sincerely,

Rich Southwell
(401) 339-0907

Good morning. My name is Richard Southwell and I am the lead plaintiff in the Southwell v. McKee lawsuit.

Before providing my feedback on the proposed school mask regulation, I thought it would be useful to walk through a timeline of key events.

March 16, 2020
15 days to flatten the curve. RI school children were sent home to learn remotely and did not return to school for the remainder of the school year.

September, 2020 - 5 months after 15 days to flatten the curve
After a summer of contentious debate, the decision is made to reopen schools for in-person learning with strict Covid protocols, including mandatory masking for all children throughout the school day.

Summer, 2021 - 16 months after 15 days to flatten the curve
Concerned parents began engaging with school committees to adopt “mask optional” policies for the upcoming school year. There was a growing recognition of the physical and psychological harm that Covid protocols generally and mask requirements specifically were causing among school children. There was also growing skepticism about the efficacy of masking children while they are in school. The skeptics note that despite being nearly a year and a half into the pandemic, there has been little to no scientific research on the benefits or harms that masking school children may cause. There is no historical research that supports the use of masks to reduce the spread of airborne illness. Despite the lack of evidence, public health officials continued to insist that “masks work”.

September, 2021 -
The Centers for Disease Control (CDC) releases a study with the title:

Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021

This will come to be known as “The Pima AZ Study”

The stunning conclusion reached in the Pima AZ Study was that school districts WITHOUT mask mandates were nearly 3X as likely to have an outbreak of Covid. This soundbyte was aggressively pushed by public health officials and major media outlets as THE scientific proof that “masks work”.

October, 2021 -
The Pima Study was entered into evidence by the Rhode Island Department of Health as part of their defense in the Southwell v. McKee lawsuit.

November, 2021 -
The CDC awards Rhode Island an $81.7 million grant for the construction of a new public health laboratory.

December, 2021 -
An article titled **The CDC's Flawed Case for Wearing Masks in School** was published in The Atlantic magazine. Based on discussions with several research scientists, the author raised legitimate questions about the data set and underlying methodology in the Pima study.

The science was being questioned

The CDC, which published the Pima AZ study in its Morbidity and Mortality Weekly Report (MMWR) responded to the article's author by stating *"MMWR is committed to quickly correcting errors when they are identified. We reviewed the specific items that you describe below and found no errors."*

American author, Upton Sinclair was right when he said "It is difficult to get a man to understand something when his salary depends on him not understanding it."

February 1, 2022 - nearly 2 years after 15 days to flatten the curve
The General Assembly held committee hearings on extending the Governor's emergency powers. Concerned parents testified en masse to oppose the measure based on the implications that it could have on continued school masking. Dr. James McDonald submitted written testimony to the committees and cited the findings of The Pima Study as justification for continued school masking.

March, 2022
Rhode Island's school mask mandate ends.

September 30, 2022
One year after the Pima AZ study was published, researchers Chandra and Hoeg released a study titled **Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort**. It was published in the Journal of Infection.

Objectives: To expand upon an observational study published by the Centers for Disease Control (CDC) showing an association between school mask mandates and lower pediatric COVID-19 cases. We examine whether this association persists in a larger, nationally representative dataset over a longer period.

Conclusions: The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are prone to multiple biases and provide insufficient evidence for recommending mask mandates.

The study was a direct challenge to “the science” that RIDOH had been relying on to support its school masking policies. What did they do? Did they look into it? No. They did not. Why? Could it have something to do with what was scheduled to happen on December 9, 2022?

December 9, 2022
Rhode Island Department of Health breaks ground on its new, $81.7 million CDC funded health lab.



To paraphrase Upton Sinclair, “It is difficult to get the public health bureaucracy to understand something when its funding depends on them not understanding it.”

The Rhode Island Department of Health has failed to provide credible scientific evidence to support masking school children as an effective intervention for stopping the spread of airborne disease. The best science that they have been able to muster thus far is the now highly suspect Pima AZ study.

Yet, here we are discussing a proposed regulation that would allow them to “require face masks for students in school to prevent the spread of an infectious disease”.

A few thoughts on the current DRAFT of the regulation:

**** The rationale described in section 4.3.A needs to be significantly more detailed than a statement that “Masks Work”. At a minimum, it should address in detail, the items listed in 4.3.B.9, which reads

Scientific evidence of the effectiveness, disadvantages and side-effects of masks on the pathogen including an assessment of the quality and availability of such evidence.

4.3.A should be expanded to require a more detailed statement and rationale should a school mask mandate be implemented.

**** Section 4.3.B provides a list of factors to be considered in deciding whether to require students to wear masks at school.

Items 6, 7 and 8 are an indirect reference to vaccines. The availability of a vaccine and/or the rate at which people choose to take that vaccine should have no bearing on the decision to mask school children. These items should be removed from the final regulation.

Item 10 indicates that parents or guardians MAY be included as stakeholders who provide input into the decision to mask students. This language should be changed to “Parents and guardians MUST be included as stakeholders from whom input will be sought.”

Item 13 is part of the “layered approach to stopping the spread” argument that we heard during Covid. Masking either provides a significant and measurable benefit on its own or it doesn’t. This item should be removed from the final regulation.

**** Section 4.3.C provides significant latitude to RIDOH in the selection, weighting and interpretation of scientific evidence used to make a decision on whether or not to mask K-12 students. It reads in part *“this balancing of evidence requires the exercise of judgment based on the facts and circumstances that exist at any given time as well as the experience and expertise of those engaged in the decision making process.”*

This much discretion requires significant transparency and accountability. RIDOH must disclose publicly all of the individuals who reviewed the scientific evidence, their credentials and what specific evidence they relied upon to reach their conclusions. This basic information should be included in the statement described in 4.3.A.

In closing, I will note one more time that RIDOH should not implement this regulation until it can provide credible scientific evidence that masking school children is an effective method for preventing the spread of airborne disease.



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort

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SUMMARY

Objectives: To expand upon an observational study published by the Centers for Disease Control (CDC) showing an association between school mask mandates and lower pediatric COVID-19 cases. We examine whether this association persists in a larger, nationally representative dataset over a longer period.
Method: We replicated the CDC study and extended it to more districts and a longer period, employing seven times as much data. We examined the relationship between mask mandates and per-capita pediatric cases, using multiple regression to control for observed differences.
Results: We successfully replicated the original result using 565 counties; non-masking counties had around 30 additional daily cases per 100,000 children after two weeks of schools reopening. However, after nine weeks, cases per 100,000 were 18.3 in counties with mandates compared to 15.8 in those without them ($p = 0.12$). In a larger sample of 1832 counties, between weeks 2 and 9, cases per 100,000 fell by 38.2 and 37.9 in counties with and without mask requirements, respectively ($p = 0.93$).
Conclusions: The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are prone to multiple biases and provide insufficient evidence for recommending mask mandates.
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Introduction

There is ongoing scientific debate around mask requirements in schools in the United States and other countries during the COVID-19 pandemic. To date, there have been no randomized controlled trials of mask requirements in children. All analyses of the effectiveness of school mask mandates have relied on observational studies. Some of these studies report a negative association between mask wearing and case rates, while others fail to identify any association.

Studies of this subject face the challenge of controlling for fundamental differences between districts and communities that choose to require or not require masking in schools. For example, a study released by the U.S. Centers for Disease Control (CDC) from Arizona found that mask requirements were associated with a reduction in COVID-19 outbreaks whilst another multi-district U.S. study reported lower in-school transmission associated with universal masking[1,2]. It has, however, been difficult to rule out the possibility that these associations were a result of confounding variables rather than an effect of the masks themselves, as some authors have suggested[3,4].

Importantly, too, the findings of these studies were inconsistent with more rigorously designed observational studies[5–7] including a study using a regression discontinuity design which reported no significant effect of masking on SARS-CoV-2 transmission in Catalonian schools[8]. Furthermore, one randomized study in adults found no impact of community cloth masking and only a marginal impact of surgical masking, though only in those over 50 years of age[9]. Another randomized study in adults failed to find a 50% reduction in acquisition of SARS-CoV-2 by the wearer of surgical cloth masks in community settings and was not powered to find smaller reductions[10]. The scientific literature prior to the COVID-19 pandemic also found low certainty evidence on the effectiveness of masks in various settings[11].

Considering millions of schoolchildren have been required to comply with mask mandates since the start of the pandemic and may be required to do so again in the future, it is incumbent upon society to determine if there is any effectiveness of masking children in schools against COVID-19 or other respiratory illnesses and, if so, that the benefits outweigh the harms.

Our study has two goals: First, we replicate and then extend, a highly cited observational study by the CDC on school mask

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mandates by Budzyn et al.[12]. The second goal is to identify possible sources of statistical bias in observational studies, particularly those that are limited in population size, diversity, and duration[13]. This is important because studies identifying rather than rejecting an association are more likely to be published[14] and consequently inform public health interventions despite a potential lack of true efficacy.

In their study, Budzyn et al. found that, following school openings in the Summer of 2021, pediatric COVID-19 case rates increased faster in U.S. counties that did not have mask mandates in schools, compared to those that did. While the results do not show a causal relationship, the study has been cited by the CDC in its policy recommendations and in the news media as evidence that mask mandates in schools can lower community spread.[1] Our study replicates the same analysis and then extends it, using a larger sample of school districts and a longer study duration.

Methods

We follow the methodology from Budzyn et al.[12] as closely as possible. Data on pediatric and adult COVID-19 case rates, by county, were obtained from the October 25 release of the CDC's Restricted Case Dataset. Data on school enrollments and mask policies were obtained from the data company MCH, the same source used by Budzyn et al. County level demographic variables and school district to county mappings were obtained from the U.S. Census Bureau.

Following Budzyn et al., counties that met the following criteria were selected for the analysis: (1) a valid school start date and a known mask requirement for at least one school district in the county, (2) in districts that have made mask policies available, such policies apply uniformly to all students (counties containing districts with conflicting mask policies were discarded), (3) at least three weeks of data were available with seven full days of case data since the start of the 2021—22 school year (the median school start date across districts within a county was used).

Using September 4, 2021 as the cut-off, as chosen by Budzyn et al., these criteria resulted in the inclusion of 565 counties. Using the more recent data release of November 30, 2021 resulted in a larger sample of 1832 counties. This study uses the smaller sample to compare with Budzyn et al, and the larger sample to evaluate robustness.

As in Budzyn et al., we conducted a multiple linear regression of per-capita pediatric case rates for these 1832 counties, including the following controls: median age, race and ethnicity, and population density; pediatric COVID-19 vaccination rates; adult transmission rates in the corresponding county and week; percentage uninsured and percentage living in poverty; social vulnerability index (SVI) score; Covid-19 community vulnerability index (CCVI) score; and fixed-effects for each week after school opening.

Demographic variables were obtained from the U.S. Census Bureau. The SVI score was obtained from the CDC and the CCVI score from Surgo Ventures. Community transmission is defined as the per-capita rate of adult cases in the county in the corresponding week. The pediatric vaccination rate is defined as the fraction of children in the county ages 12—18 who received two doses of a Covid-19 vaccine. Per-capita pediatric case rates are defined as the weekly sum of confirmed cases in the 0—19 age group that was reported to the CDC for the corresponding county, divided by the county population in that age group.

[1] The CDC cites the Budzyn et al study, among many other observational studies, at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html. The New York Times cited this study repeatedly, using causal language to describe the effectiveness of masks, for example at: https://www.nytimes.com/2021/09/24/health/schools-mask-mandate-outbreaks-cdc.html

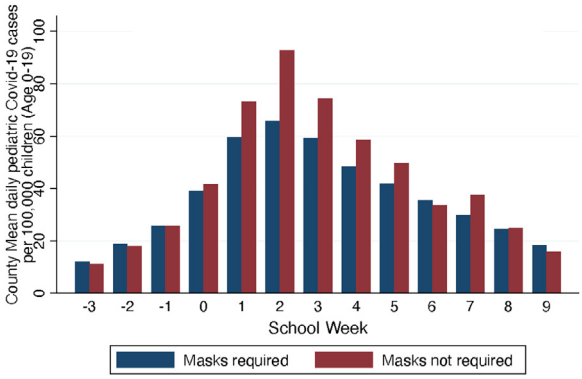


Fig. 1. Pediatric COVID-19 case rates and school mask requirements: 565 counties.

Following the empirical analysis, we use statistical methods to reconcile the difference between our results and those of Budzyn et al., We note various biases that can arise when using observational data on jurisdictions that choose whether to adopt particular public health recommendations. We explore potential cross-sectional and temporal biases that can affect observational studies of this nature.

Results

We examine the relationship between school mask requirements and pediatric cases of COVID-19, replicating the analysis of methods of Budzyn et al., as closely as possible. We identified 565 counties that met the criteria, compared to 520 counties in the original study. The discrepancy occurred for at least two reasons. First, MCH obtains data on school start dates and mask policies from phone surveys of school districts and updates this information frequently. This study uses MCH data that were current as of October 15, 2021. Budzyn et al., used information from earlier, which was likely to have been different as school district information changes regularly. Second, Budzyn et al., selection criteria for counties is ambiguous about districts that cross county lines.[2]

Fig. 1 displays results from 565 counties that fit the criteria used in the original study and analyzes data from three weeks prior to schools opening to nine weeks following opening. After two weeks of schools being open, which was the endpoint for Budzyn et al., the results align with the findings of the original study: non-masking counties had, on average, around 30 additional daily pediatric cases per 100,000 children, compared to counties with mask mandates.

Thus, during August—September 2021, mask mandates were associated with lower pediatric cases of Sars-CoV-2 in districts where schools started by August 15. However, Fig. 1 also shows that cases quickly declined in later weeks and did so faster in counties without mask mandates. In fact, the Budzyn et al., study ended at exactly the peak of school case numbers for this sample of counties. By the end of the ninth week after reopening average daily pediatric case rates in counties without mask mandates were 15.8 per 100,000 while counties with mandates averaged 18.3 per 100,000; the difference was not statistically significant ($p = 0.12$).

Fig. 2 shows a larger sample of 1832 counties, including counties which were not included in Budzyn et al., analysis due to later school district start dates. Note that there are 3142 counties in the United States, but many cannot be classified with regard to school

[2] We attempted to resolve the discrepancy by contacting the lead author of that study, but they did not provide assistance and declined to share the code used to construct their sample.

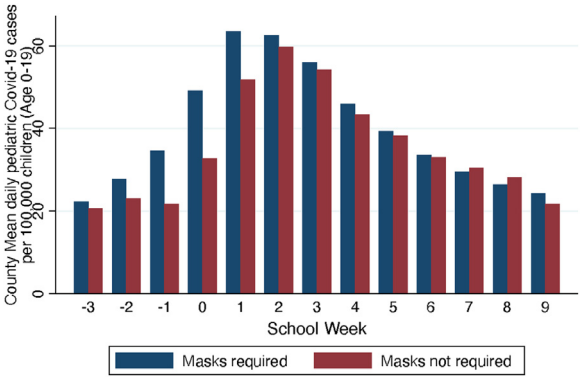


Fig. 2. Pediatric COVID-19 case rates and school mask requirements: 1832 counties.

mask policies, due to either insufficient data from MCH or the specific criteria used by Budzyn et al.

The larger sample of counties enables us to employ a much broader geographical representation of districts, in addition to increasing the population size of the study. This is important for full geographic representation as southern states are more likely to have early start dates. The figure shows the lack of a clear relationship between mask mandates and pediatric cases. Counties that required masks in schools saw slightly larger increases in cases in the weeks immediately before and after school opening, but by the second week after the start of school there was no statistical difference. At the end of week 9, cases per 100,000 capita were 21.8 in counties without mask mandates and 24.3 in counties with mandates; the difference was not statistically significant ($p = 0.057$).

Fig. 2 also shows that the change in case rates, across various weeks, was virtually identical for counties with and without school mask mandates. From three weeks prior to the start of school to two weeks after school opening, average daily cases rose by 39.0 per 100,000 in counties without mask requirements, and by 40.2 per 100,000 in counties with mask mandates. The difference was not statistically significant ($p = 0.74$). Similarly, between weeks 2 and 9, cases per 100,000 fell by 38.2 and 37.9 in counties with and without mask requirements, respectively. This difference was also not statistically significant ($p = 0.93$).

Next, we estimated a multiple regression of pediatric case rates controlling for observable differences across counties (Table 1). The first column of that Table uses the same specification as Budzyn et al. and confirms the lack of association between school mask mandates and case rates: after accounting for covariates, pediatric cases in counties with mask mandates were slightly higher, by 1.27 weekly cases per 100,000, though the effect was not statistically significant ($p = 0.058$).

In column 2 of Table 1, we show the effect of removing the COVID-19 community vulnerability index (CCVI). The CCVI is derived from, and is highly correlated with, the social vulnerability index. Omitting this variable results in a significant positive association ($p < 0.0001$) between school mask requirements and pediatric case rates (see Supplementary Appendix for additional details).

Table 1
Regression of pediatric COVID-19 case rates per 100 K.

	From Budzyn et al (1)	From Budzyn et al minus CCVI (2)
School Mask Requirement	1.279	3.507
	(0.058)	(0.000)
Adult Cases per 100K	1.194	1.196
	(0.000)	(0.000)
Percent Uninsured	-0.558	-0.353
	(0.000)	(0.000)
Percent in Poverty	0.531	0.312
	(0.000)	(0.000)
Population Density	-0.001	0.001
	(0.162)	(0.329)
Social Vulnerability Index	-13.558	8.911
	(0.000)	(0.000)
Community Vulnerability Index	27.154	
	(0.000)	
Percent Non-Hispanic White	-0.892	-1.836
	(0.667)	(0.380)
Median Age	0.768	0.738
	(0.000)	(0.000)
Pediatric Vaccination Rate	1.320	-1.352
	(0.546)	(0.540)
Intercept	-40.113	-35.973
	(0.000)	(0.000)
R^2	0.673	0.666
Observations	12824	12824

Notes: Values in the table are coefficient estimates obtained from a regression of county level reported per-capita pediatric cases of Sars-Cov-2 on the control variables listed in the table. *p*-values are in parentheses. Regressions also include week fixed effects, that are not reported. The specification in Column 1 follows Budzyn et al. The specification in Column2 omits the CCVI index due to its high correlation with the Social Vulnerability Index. See text for sample construction and other details.

Discussion

The study by Budzyn et al. examined 520 U.S. counties and found that counties without mask requirements in school experienced larger increases in pediatric COVID-19 case rates following the start of school compared with those that had school mask requirements. Specifically, the increase in pediatric case rates per 100,000 children starting from one week prior to school opening until one week afterwards was 16.32 for the former group and 34.85 for the latter.

We successfully replicated the main result of the original study by Budzyn et al. Further analysis, however, shows that the results do not hold in a larger sample of school districts, or even in the original sample of districts when extended to a longer time interval. Specifically, when we extend the sample to districts that began later in Autumn 2021, which encompasses a much larger portion of the country, we find no association between mask requirements and pediatric cases.

Thus, using the same methods and sample construction criteria as Budzyn et al., but a larger sample size and expanded time frame for analysis, we fail to detect a significant association between school mask mandates and pediatric COVID-19 cases. The discrepancy between our findings and those of Budzyn et al. is likely attributable to the inclusion of more counties, a larger geographic area and extension of the study over a longer time period. By ending the analysis on September 4, 2021, Budzyn et al. excluded counties with a median school start date later than August 14, 2021. According to the MCH data, this heavily over-samples regions that open schools by mid-August including Florida, Georgia, Kentucky and other southern states. The original study would not have incorporated data from New York, Massachusetts, Pennsylvania, and other states that typically start schools in September. While this does not necessarily bias the results, it calls into question whether the results of that study can be representative of the entire country and suggests at least one important geographic confounding variable affects observational studies of school-based mask mandates in the United States.

If mask wearing were assigned or promoted at random, as, for example, in the Bangladesh cluster-randomized trial by Abaluck et al.[9], then the relationship between these mandates and case outcomes may have a causal interpretation[15]. However, school mask mandates in the United States are not only non-random, but

likely to be correlated with unobserved factors in systematic ways, making it inappropriate to infer causality.

First, school districts that mandate masks are likely to invest in other measures to mitigate transmission and may differ by testing rates and practices. Second, the choices made by school districts reflect the attitudes and behavior of their community. Communities that are concerned about the spread of SARS-CoV-2 are also likely to implement other measures, even outside of schools, that may eventually result in lower spread in the community and including within schools. Finally, the timing of public health interventions is likely to be correlated with that of private behavioral changes. Public health measures are typically introduced when case counts are high, which is precisely when community members are likely to react to media coverage and change their own behavior.

Our study also uses observational data and does not provide causal estimates either. However, there is an important difference: while the presence of correlation does not imply causality, the absence of correlation can suggest causality is unlikely, especially if the direction of bias can be reasonably anticipated[16].

In the case of school mask mandates, the direction of bias can be anticipated quite well. Past research suggests that behavioral changes are likely to be positively correlated with public health measures to reduce cases, both cross-sectionally and temporally[17]. If so, the bias in the estimated coefficient from a naïve regression of case outcomes on public health measures will be negative. In other words, an analysis that omits the extent and timing of private behavioral changes, even one that controls for covariates, will tend to overstate the effect of mask mandates, and run the risk of a spurious correlation between mask mandates and declines in case rates.

To see this, consider estimating the following linear regression:

$$y_{it} = b_0 + b_1 x_{it} + b_2 u_{it} + e_{it}$$

where y_{it} denotes case rates in community i at time t, x denotes observed public-health measures such as mask mandates, and u denotes variables that can affect case rates, but are unobserved or difficult to measure, such as private behavioral changes in the population. If we expect that x and u have a correlation $\delta > 0$, but that u is negatively correlated with y, the bias in the estimated coefficient from a naive regression of case outcomes on observed public-health measures is $b_2\delta$ which is negative[16].

In principle, it is possible for the bias to operate in the other direction. One mechanism for this would be if districts that require masks in schools implement fewer other mitigations, perhaps because they believe that mask mandates are sufficient to decrease the risk of infection. However, evidence from some large school districts does not support this hypothesis. For example, during the 2021-22 school year, New York City Public schools—by far the largest school district in the country—required masks for all students from September 2021 until March 2022, both indoors and outdoors. During this time, both the school district and the city imposed some of the strictest mitigation measures in the country. Additional measures in New York schools included daily symptom screening checks, contact tracing of exposed students in conjunction with whole or partial class quarantines, staggered lunch and recess times, and an extensive ventilation system with two HEPA filters in every classroom.[3] New York City had mask and vaccine requirements for most places, monetary incentives to encourage adult and child vaccinations and many other interventions.[4] Regardless of their individual efficacies, these interventions could have lowered infection rates in areas with mask mandates, confounding the data in such a way that would give the false appearance of high mask effectiveness.

Importantly, too, districts with mask mandates were more likely to have higher vaccination rates which, at the time of the Budzyn study during the Delta variant wave, might have had more of an effect on infection and transmission rates[18] than later on, with the emergence of the more transmissible and immune-evasive omicron variant[19]. Higher vaccination rates at the time of the initial analysis by Budzyn et al. could have been conflated with the effect of masks. This would further support the hypothesis that the correlation between school mask mandates and other interventions is likely to create a spurious negative, rather than positive, bias in the estimated effect of mask policies on case rates, as explained above.

An additional possible confounder in our study may be differences in testing rates across counties with and without school mask requirements, especially as research suggests that Republican-led states have historically had lower testing rates[20]. This limitation would have affected the Budzyn et al study as well. In the Supplementary appendix, however, we present both cross-state and within-state data which suggest that differences in test rates do not affect our results.

We also demonstrated that removing redundant socioeconomic data from the regression analysis actually resulted in a significant positive association between school mask mandates and COVID-19 cases. No causality can be inferred with the increased cases, but this demonstrates how controlling multiple times for similar variables can alter results and including the CCVI appears to strengthen the association identified by Budzyn et al. As shown in the Supplementary appendix, removing CCVI from Budzyn et al. initial analysis would have rendered their initial finding insignificant. Indeed, it is unclear what the purpose was of including CCVI in the regression analysis when it contains redundant information to the social vulnerability index (SVI) which the authors also controlled for.

An important caveat to our study is that it does not exclude some effectiveness of mask usage or school mask mandates. We do, however, show why relying on observational studies can be misleading. Such studies will tend to systematically overstate, rather than understate, the effectiveness of interventions for two reasons: selection bias caused by particular jurisdictions choosing to implement interventions; and omitted variable bias, due to such jurisdictions also being likely to implement other, unobserved interventions.

Furthermore, studies with significant findings are more likely to be published than those with non-significant or negative findings[14]. This is particularly important in the context of the current pandemic where publishing studies that fit a certain narrative can become a self-fulfilling prophecy rather than an unbiased pursuit of truth.

In summary, expanding upon a widely cited CDC study, and employing the same methodology but with a larger, more representative dataset over a longer time period, we fail to find the same evidence that school mask mandates are associated with a reduction in county pediatric COVID-19 cases. We demonstrate how observational studies can be misleading when used to guide public health policy.

[3] https://www.nytimes.com/2021/08/26/nyregion/new-york-city-schools-reopening.html

[4] https://www.usnews.com/news/best-states/new-york/articles/2021-12-16/with-omicron-in-full-force-nyc-to-hand-out-masks-tests

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jinf.2022.09.019.

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Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021

Megan Jehn, PhD[1,*]; J. Mac McCullough, PhD[2,*]; Ariella P. Dale, PhD[3,4]; Matthew Gue[1]; Brian Eller[5]; Theresa Cullen, MD[5]; Sarah E. Scott, MD[4]

On September 24, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

CDC recommends universal indoor masking by students, staff members, faculty, and visitors in kindergarten through grade 12 (K–12) schools, regardless of vaccination status, to reduce transmission of SARS-CoV-2, the virus that causes COVID-19 (*1*). Schools in Maricopa and Pima Counties, which account for >75% of Arizona's population (*2*), resumed in-person learning for the 2021–22 academic year during late July through early August 2021. In mid-July, county-wide 7-day case rates were 161 and 105 per 100,000 persons in Maricopa and Pima Counties, respectively, and 47.6% of Maricopa County residents and 59.2% of Pima County residents had received at least 1 dose of a COVID-19 vaccine. School districts in both counties implemented variable mask policies at the start of the 2021–22 academic year (Table). The association between school mask policies and school-associated COVID-19 outbreaks in K–12 public noncharter schools open for in-person learning in Maricopa and Pima Counties during July 15–August 31, 2021, was evaluated.

A school was considered to have a mask requirement if all persons, regardless of vaccination status, were required to wear a mask indoors in school. An early mask requirement was one that was in place when the school year began, and a late mask requirement was one that was implemented any time after school began. Mask policies were abstracted from publicly available school COVID-19 mitigation plans, which must be posted online per Executive Order 2020–51.† A school-associated outbreak was defined as the occurrence of two or more laboratory-confirmed COVID-19 cases§ among students or staff members at the school within a 14-day period and at least 7 calendar days after school started, and that was otherwise consistent with the Council for State and Territorial Epidemiologists 2020 outbreak definition¶ and Arizona's school-associated outbreak definition.** In Arizona, school-associated outbreaks are required to be reported to the local public health agency within 24 hours; data are stored in Arizona's Medical Electronic Disease Surveillance Intelligence System. School characteristics, including county of location, grade levels present,†† enrollment, and Title I status§§ (a measure of a school population's socioeconomic status) were obtained from the Arizona Department of Education. Crude and adjusted logistic regression analyses with 95% confidence intervals (CIs) were performed in Stata (version 15; StataCorp) and adjusted for school county, enrollment size, grade levels present, Title I status, and 7-day COVID-19 case rate in the school's zip code during the week school commenced. Schools with late mask requirements were excluded from these analyses because of their mixed exposure status during the sampling time frame (e.g., schools might have enacted mask requirements after an outbreak). Vaccination coverage for staff members and students was not available at the school level.

Data were available for 1,020 of 1,041 (98.0%) K–12 public noncharter schools in Maricopa and Pima counties. Twenty-one (2.0%) schools had outbreaks reported <7 days after school began and were excluded from the analyses. Among the 999 (96.0%) schools included in the analysis, 210 (21.0%) had an early mask requirement, 309 (30.9%) had a late mask requirement enacted a median of 15 days after school started (interquartile range = 9–17 days), and 480 (48.0%) had no mask requirement (Table). During July 15–August 31, 2021, 191 school-associated outbreaks occurred, 16 (8.4%) in schools with early mask requirements, 62 (32.5%) in schools with late mask requirements, and 113 (59.2%) in schools without a mask requirement.

In the crude analysis, the odds of a school-associated COVID-19 outbreak in schools with no mask requirement were 3.7 times higher than those in schools with an early mask requirement (odds ratio [OR] = 3.7; 95% CI = 2.2–6.5). After adjusting for potential described confounders, the odds of a school-associated COVID-19 outbreak in schools without a mask requirement were 3.5 times higher than those in schools with an early mask requirement (OR = 3.5; 95% CI = 1.8–6.9).

CDC recommends universal indoor masking in K–12 schools (*1*); however, masking requirements in K–12 schools vary by school district, county, and state. In the two largest Arizona counties, with variable K–12 school masking policies at the onset of the 2021–22 academic year, the odds of a school-associated COVID-19 outbreak were 3.5 times higher in schools with no mask requirement than in those with a mask requirement implemented at the time school started. Lapses in universal masking contribute to COVID-19

* These authors contributed equally to this report.
† https://azgovernor.gov/sites/default/files/executive_order_2020-51.pdf
§ Defined as a SARS-CoV-2–positive reverse transcription–polymerase chain reaction or nucleic acid amplification test or antigen test.
¶ https://preparedness.cste.org/wp-content/uploads/2020/08/Educational-Outbreak-Definition.pdf
** Emergency Measure 2020–03. https://www.azdhs.gov/covid19/documents/emergency-measure-2020-03.pdf

†† The variable for grade levels present was included within the model as three separate indicator variables, corresponding to elementary, middle, and high school.
§§ https://www2.ed.gov/programs/titleiparta/index.html

TABLE. School-associated COVID-19 outbreaks and school characteristics among K–12 public noncharter schools, by school mask policy — Maricopa and Pima Counties, Arizona, July–August 2021

Characteristic	All schools no. (%) (N = 999)	School mask requirements no. of schools (%) None* (n = 480)	Early* (n = 210)	Late* (n = 309)	p-value*
School-associated outbreak†					<0.001
No	808 (81)	367 (76)	194 (92)	247 (80)	
Yes	191 (19)	113 (24)	16 (8)	62 (20)	
County					<0.001
Maricopa	782 (78)	444 (93)	100 (48)	238 (77)	
Pima	217 (22)	36 (8)	110 (52)	71 (23)	
Grades present§					NC§
Elementary (K–5)	678 (68)	296 (62)	136 (65)	246 (80)	
Middle (6–8)	656 (66)	336 (70)	110 (52)	210 (68)	
High (9–12)	251 (25)	160 (33)	58 (28)	33 (11)	
7-day case rate in school zip code¶					0.002
<10	3 (0.3)	3 (0.6)	0 (—)	0 (—)	
10 to <50	4 (0.4)	4 (0.8)	0 (—)	0 (—)	
50 to <100	36 (4)	14 (3)	19 (9)	3 (1)	
>100	956 (96)	459 (96)	191 (91)	306 (99)	
Title I status**					<0.001
Not Title I	359 (36)	216 (45)	45 (21)	98 (32)	
Title I eligible	81 (8)	48 (10)	5 (2)	28 (9)	
Any Title I participation	559 (56)	216 (45)	160 (76)	183 (59)	
No. of students enrolled					<0.001
<850	243 (24)	60 (13)	109 (52)	74 (24)	
850–1,199	248 (25)	108 (23)	32 (15)	108 (35)	
1,200–1,649	255 (26)	156 (33)	32 (15)	67 (22)	
≥1,650	253 (25)	156 (33)	37 (18)	60 (19)	

Abbreviations: K–12 = kindergarten through grade 12; NC = not calculated.

* Chi-square and Fisher's exact tests were used to calculate p-values between schools with early mask requirements (mask requirement in place at the start of the school year) and those with no mask requirements, which are included in logistic regression analyses. Schools with late mask requirements instituted mask requirements at any time after the start of the school year.

† During July 15–August 31, 2021.

§ Defined as the presence or absence of grades taught at the school. Categories are not mutually exclusive, and p-value was not calculated. Three separate indicator variables were used to capture presence of these grade levels in the multivariate model.

¶ Calculated as all new confirmed and probable COVID-19 cases per 100,000 population occurring in each zip code containing a school included in this analysis during the surveillance week in which the school's academic year started. Categories presented are based on CDC community transmission metrics, included as a continuous variable in the multivariate model.

** Under Title I, financial assistance is provided to local educational agencies and schools with high numbers or high percentages of students from low-income families.

outbreaks in school settings (*3*); CDC K–12 school guidance recommends multiple prevention strategies. Given the high transmissibility of the SARS-CoV-2 B.1.617.2 (Delta) variant, universal masking, in addition to vaccination of all eligible students, staff members, and faculty and implementation of other prevention measures, remains essential to COVID-19 prevention in K–12 settings (*1*).

Acknowledgments

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Rhode Island Breaks Ground on $82 Million State-of-the-Art Public Health Laboratory

A move towards modernizing the state laboratory and integrating genomics sequencing as a standard.



Rhode Island Governor Dan McKee and state leaders breaking ground on a new state-of-the-art laboratory

In late October, Rhode Island state leaders, including Governor Dan McKee, gathered in Providence to celebrate the new construction of the state's public health laboratory. The facility is planned to be more energy efficient and provide a more optimized workspace with capacity to handle surges in response activity. The building will also be home to a new Center for Biological Sciences that will function as a dedicated Genomics Sequencing Core Laboratory, with an estimated space of 2700 square feet. The laboratory will enable the Rhode Island State Health Laboratory (RISHL) to continue providing high-quality scientific testing through genomic sequencing of infectious disease.

RISHL plays a critical role in investigating and mitigating life-threatening diseases, including H1N1, Ebola, Zika, and COVID-19. It performs molecular sequencing of SARS-CoV-2 and other pathogens to detect, respond to, control, and prevent infectious diseases. They also provide essential services for state and municipal agencies to ensure the safety of drinking water, food, local shellfish, and dairy products.

The $81.7 million award comes from CDC's Office of AMD, which provides outreach and funding via the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement, to support public health departments in their efforts to modernize infectious disease laboratories. The total project cost is expected to be $165 million. Rhode Island is one of seven jurisdictions to receive construction awards to improve state laboratory facilities to expand and modernize infectious disease laboratories.

"Genomic surveillance is an increasingly important part of public health work and can be applied to almost any bacterial and viral pathogens," says Duncan MacCannell, Acting Director, Office of Advanced Molecular Detection. "This new lab will provide a significant contribution to outbreak investigations. We're excited to see Rhode Island, and surrounding areas, benefit from this facility."

This funding effort is a part of AMD's efforts to integrate the latest next-generation genomic sequencing technologies. Using bioinformatics and epidemiology expertise across the nation, state and local public health departments are better able to find, track, and stop disease-causing pathogens faster than ever before.

Last Reviewed: December 9, 2022

SCIENCE

The CDC's Flawed Case for Wearing Masks in School

The agency's director has said, repeatedly, that schools without mask mandates have triple the risk of COVID outbreaks. That claim is based on very shaky science.

By David Zweig



Chip Somodevilla / Getty; INA FASSBENDER / Getty; NurPhoto / Getty; SOPA Images; Getty; The Atlantic

DECEMBER 16, 2021

The debate over child masking in schools boiled over again this fall, even above its ongoing high simmer. The approval in late October of COVID-19 vaccines for 5-to-11-year-olds was for many public-health experts an indication that mask mandates could finally be lifted. Yet with cases on the rise in much of the country, along with

anxiety regarding the Omicron variant, other experts and some politicians have warned that plans to pull back on the policy should be put on hold.

Scientists generally agree that, according to the research literature, wearing masks can help protect people from the coronavirus, but the precise extent of that protection, particularly in schools, remains unknown—and it might be very small. What data do exist have been interpreted into guidance in many different ways. The World Health Organization, for example, does not recommend masks for children under age 6. The European Centre for Disease Prevention and Control recommends against the use of masks for any children in primary school.

Seen in this context, the CDC has taken an especially aggressive stance, recommending that all kids 2 and older should be masked in school. The agency has argued for this policy amid an atmosphere of persistent backlash and skepticism, but on September 26, its director, Rochelle Walensky, marched out a stunning new statistic: Speaking as a guest on CBS's *Face the Nation*, she cited a study published two days earlier, which looked at data from about 1,000 public schools in Arizona. The ones that didn't have mask mandates, she said, were *3.5 times* as likely to experience COVID outbreaks as the ones that did.

Read: Parents are not okay

This estimated effect of mask requirements—far bigger than others in the research literature—would become a crucial talking point in the weeks to come. On September 28, during a White House briefing, Walensky brought up the 3.5 multiplier again; then she tweeted it that afternoon. In mid-October, with the school year in full swing, Walensky brought up the same statistic one more time.

But the Arizona study at the center of the CDC's back-to-school blitz turns out to have been profoundly misleading. "You can't learn anything about the effects of school mask mandates from this study," Jonathan Ketcham, a public-health economist at Arizona State University, told me. His view echoed the assessment of eight other experts who reviewed the research, and with whom I spoke for this article. Masks may well help prevent the spread of COVID, some of these experts told me, and there may well be contexts in which they should be required in schools. But the data being touted by the CDC—which showed a dramatic *more-than-tripling* of risk for unmasked students—ought to be excluded from this debate. The Arizona study's lead authors stand by their work, and so does the CDC. But the critics were forthright in their harsh assessments. Noah Haber, an interdisciplinary scientist and a co-author of a systematic review of COVID-19 mitigation policies, called the research "so unreliable that it probably should not have been entered into the public discourse."

This is not the only study cited by Walensky in support of masking students, but it's among the most important, having been deployed repeatedly to justify a policy affecting millions of children—and having been widely covered in the press. The agency's decision to trumpet the study's dubious findings, and subsequent lack of transparency, raise questions about its commitment to science-guided policy.

The Arizona study, published in the CDC's *Morbidity and Mortality Weekly Report*, looked at school-associated outbreaks in Maricopa and Pima Counties, comparing rates across schools with and without mask mandates for students and staff. "The school year starts very early in Arizona, in mid-July, so we had the advantage of being

able to get an early look at data," one of the lead authors, J. Mac McCullough, told *The New York Times*. The early look revealed that just 16 outbreaks had occurred among the 210 schools that had a mask mandate in place from the start of classes, versus 113 among the 480 schools that had no mandates at all. According to McCullough and his colleagues, this amounted to a 3.5-fold increase in incidence of outbreaks for the no-mandate schools.

Yet the study's methodology and data set appear to have significant flaws. The trouble begins with the opening lines of the paper, where the authors say they evaluated the association between school mask policies and school-associated COVID-19 outbreaks "during July 15–August 31, 2021." After reviewing school calendars and speaking with several school administrators in Maricopa and Pima Counties, I found that only a small proportion of the schools in the study were open at any point during July. Some didn't begin class until August 10; others were open from July 19 or July 21. That means students in the latter group of schools had twice as much time—six weeks instead of three weeks—in which to develop a COVID outbreak.

When I brought this issue to Megan Jehn, the study's corresponding author and an epidemiologist at Arizona State University, she acknowledged that exposure times varied across schools. The ones without mask mandates were open longer overall, she told me—but the difference was too small to matter. Their median start date was August 3, versus August 5 for the schools that did have mask mandates. In a follow-up correspondence, Jehn and McCullough wrote, "It is highly improbable that this difference alone could explain the strong association observed between mask policies and school outbreaks."

Yet Ketcham said that a comparison of median start dates is insufficient. "If schools with mask mandates had fewer school days during the study," he told me, "that alone could explain the difference in outbreaks."

Ketcham and others also criticized the Arizona study's use of school-related outbreaks, rather than cases per student per week, as the relevant outcome. The authors defined an outbreak as being two or more COVID-19 cases among students or staff members

at a school within a 14-day period that are epidemiologically linked. “The measure of two cases in a school is problematic,” Louise-Anne McNutt, a former Epidemic Intelligence Service officer for the CDC and an epidemiologist at the State University of New York at Albany, told me. “It doesn’t tell us that transmission occurred in school.” She pointed to the fact that, according to Maricopa County guidelines, students are considered “close contacts” of an infected student—and thus subject to potential testing and quarantine—only if they (or that infected student) were unmasked. As a result, students in Maricopa schools with mask mandates may have been less likely than students in schools without mandates to get tested following an initial exposure. This creates what’s known as a detection bias, she said, which could grossly affect the study’s findings. (Jehn and McCullough called it “highly speculative to make the assumption that identified close contacts are more likely to be tested than other students.”) McNutt believes that masks are an important prevention tool in the pandemic, but she maintained that the Arizona study doesn’t answer the specific question it purports to answer: whether mask mandates for students reduce the spread of SARS-CoV-2.

Read: The pandemic of the vaccinated is here

There are other issues, too. Jason Abaluck, an economics professor at Yale and the lead investigator on a 340,000-person randomized trial of masking in Bangladesh, called the Arizona study “ridiculous” for failing to control for the vaccination status of staff or students. If more people had been immunized at the schools with mask mandates—or if those schools were more likely to have other mitigation measures in place, such as improved ventilation—then they likely would have seen fewer outbreaks regardless. According to the paper, data on vaccination coverage were unavailable on a per-school basis.

Even basic elements of the data set inspire some concerns. According to the paper, 782 of the 999 public, non-charter schools included in the study were in Maricopa County. In response to a public-records request, the Arizona Department of Education sent me what it said was the same list of schools that had been provided to

the researchers, with 891 relevant entries for Maricopa. But closer inspection revealed that about 40 of them were virtual learning academies, about 20 were preschools, and about 90 were vocational programs associated with otherwise-listed schools. That left at most roughly 740 schools for inclusion in the study, not 782. If dozens of entries were inappropriately included in the final data set, were "outbreaks" counted for them too?

Starting at the end of October, I reached out to Jehn and *MMWR* about the number of schools, and repeatedly asked for the list of those included in the study. I also asked about the fact that schools with mask mandates and those without mandates opened at different times. Neither the journal nor the study's authors agreed to share the list of schools, or any other data from the study. The journal replied: "*MMWR* is committed to quickly correcting errors when they are identified. We reviewed the specific items that you describe below and found no errors." This week the authors finally shared their narrowed-down list of Maricopa schools as used for the study. Yet it still included at least three schools in Pima County, along with at least one virtual academy, one preschool, and more than 80 entries for vocational programs that are not actual schools. In response to a follow-up inquiry, they acknowledged having included the online school by mistake, while attributing any other potential misclassifications to the Arizona Department of Education.

A media-relations manager from the lead authors' university told me that "the data used for this study were entirely appropriate for the study's objectives," and that "Drs. Jehn and McCullough stand by the methodology and results from the data analyses of the 999 schools included in the study."

The extent of the benefits of wearing masks for preventing COVID remains uncertain, but it's wrong to say we don't know anything at all. "One thing you can extrapolate well is that masks have some effect," Haber told me. "But the level of effectiveness depends on an enormous array of very important factors, and high-quality direct evidence is difficult to come by, particularly for schools."

Given its apparent flaws, the Arizona study would seem to bear out Haber's point, offering little evidence, one way or another, on whether mask mandates "work" in schools, or to what degree. Even taken at face value, though, its findings don't appear to fit with those from other research. Abaluck's huge, randomized trial of mask use in rural Bangladeshi villages, for example, estimated just an 11 percent reduction in confirmed symptomatic SARS-CoV-2 infection among adults wearing surgical masks (and relatively little evidence of any effect for cloth masks).

Another, more similar study, published in *MMWR* in May, looked at case rates among more than 90,000 students in Georgia, comparing those at schools with and without mask mandates. It found that the incidence of COVID was 37 percent lower in schools where staff were required to wear masks, and 21 percent lower in schools where that rule applied to kids. (The latter difference was not statistically significant, and the authors noted that the data "cannot be used to infer causal relationships.") Now compare those numbers with the headline finding from the Arizona study, touted repeatedly by Walensky: that a lack of school masking mandates *more than tripled* the risk of outbreaks.

A number of the experts interviewed for this article said the size of the effect should have caused everyone involved in preparing, publishing, and publicizing the paper to

tap the brakes. Instead, they hit the gas. Given that data were collected through August 31, the authors had just a few weeks to complete their analysis and finalize their manuscript before *MMWR* put it out on September 24. Walensky tweeted out the research four days later.

As the CDC's outlet for scientific reports, *MMWR* has long been crucial for assessing and documenting outbreaks of disease, up to and including this pandemic. Yet it's also been a source of steady controversy. As *Politico* reported in September 2020, officials in the Trump administration tried to influence *MMWR* releases so that its messaging on COVID would align with the president's. Career staffers expended "great effort" to resist this influence and uphold *MMWR*'s scientific integrity, a former official later told the House Select Subcommittee on the Coronavirus Crisis.

Yet under the Biden administration, the agency has not always been apolitical. In May, it was revealed that the American Federation of Teachers, the nation's second-largest teachers' union, had private exchanges with CDC officials prior to new school guidance being issued under Walensky's tenure, and some of the union's suggestions were added nearly verbatim. In September, on the same day as the Arizona study's publication, Walensky overruled her agency's advisory committee by endorsing the use of COVID-vaccine booster shots for teachers and other workers deemed at high risk of exposure, thereby aligning the CDC more closely with President Joe Biden's position.

Still, the publication and agency endorsement of the Arizona study is especially demoralizing. How did research with so many obvious flaws make its way through all the layers of internal technical review? And why was it promoted so aggressively by the agency's director? I reached out to Walensky's office to ask about the study, noting its evident limitations and outlier result. How, if at all, does this research figure into the agency's continuing guidance for schools around the country? The CDC did not respond to my inquiries.

With Biden in the White House, the CDC has promised to "follow the science" in its COVID policies. Yet the circumstances around the Arizona study seem to show the opposite. Dubious research has been cited after the fact, without transparency, in support of existing agency guidance. "Research requires trust and the ability to verify work," Ketcham, the ASU public-health economist, told me. "That's the heart of science. The saddest part of this is the erosion of trust."

The Atlantic*'s COVID-19 coverage is supported by grants from the Chan Zuckerberg Initiative and the Robert Wood Johnson Foundation.*

David Zweig is a writer based in New York. He is the author of the nonfiction book *Invisibles* and the novel *Swimming Inside the Sun*.

FREEDOM

Deborah Whitman <mrswhit@verizon.net>

Fri 3/15/2024 9:44 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

There is no scientific evidence that masks stop the transmission of viruses. Forcing people to mask/vax/quarantine or anything else is a violation of human rights. Mandating medical products and especially EXPERIMENTAL drugs is unethical,immoral and breaks International Laws set forth in The Nuremberg Code. Masking children has caused actual infection and deaths. People with heart and lung issues should never have the airway obstructed EVER. People with psychological issues such as claustrophobia can not wear masks. Victims of assault cannot have their mouths covered. People unfamiliar with medical issues should not be mandating medical procedures or equipment to others nor performing medical procedures such as temperatures, vital signs and nasal swabs etc. Freedom and bodily autonomy IS THE LAW of the land given by The Creator. Gov't needs to stay out of the business of forced medical procedures including masks and masking in the schools especially of kids who need to breathe. The patient has a right to refuse care. I was taught that in nursing school over 30 years ago. Gov't people you work for us. We decide what happens to ourselves and our kids.

Deborah Whitman, Retired NURSE, wife, mother of 3, concerned human

Oppose mask mandate

emily siemion <emily_siemion@yahoo.com>

Mon 3/18/2024 9:50 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Gregory, and health board,

I'm writing to oppose the mask mandate that is currently being voted on in the upcoming weeks.

Please note that I have a nine-year-old and husband that work and go to school in South Kingstown. I believe strongly in community and connection and masks get in the way of those goals. I wouldn't have known it unless I lived through it. My son was in kindergarten when the first mandates were imposed in his school. The mask mandate was strictly enforced and I saw the Ramath negative ramifications across emotional development and educational development. I also noticed a huge decrease in his water consumption and his health for all these reasons I oppose.

Sincerely,
Emily Rhodes
Mom and resident of SK RI

Sent from Yahoo Mail for iPhone [mail.onelink.me]

RI DOH School Masking Testimony

J <heyjay1971@verizon.net>

Mon 3/18/2024 9:53 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

2 attachments (9 KB)

SchoolMaskSpeechFinal.rtf; SchoolMaskSpeechFinal.txt;

This Message Is From an External Sender

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Report Suspicious

Hi Zachary Garceau,

My name is Jason Romblad. I am writing tonight to voice my opposition to the RI DOH school masking proposal. I am sending my testimony in this email. I will attach my testimony in two file formats, rtf and txt. I will also type it out below, in this email body, not sure which format is best for you. Please let me know if you require extra information, before the deadline to submit testimony.

My Testimony:

Good morning,
My name is Jason Romblad, I am an unaffiliated voter from Woonsocket. I am here today to vehemently oppose the school masking proposal that the RI DOH is proposing today. I want to point out that school masking started during covid era lockdowns using executive orders and supposed emergency powers. There were no studies used as reference when issuing these mandates and there were no studies conducted in this state regarding the effects on the children being forced to inhale their own carbon dioxide for hours at a time. The uncleanliness of these masks, over time, are detrimental to the health of the human body, inhibiting the flow of fresh air and oxygen. Nearly all masks worn, will not stop a virus and states exactly that on the packaging. To issue these authoritative mandates, with no follow-up studies, is negligent and quite frankly, should be criminal.
To this day, not one person under the age of 18 has died from covid, in RI. This is direct information from the RI DOH covid portal. To force masks on healthy children who have no risk of dying from a virus, is inhumane.
The same people, who issued mask mandates in Rhode Island, including this agency, allowed masks to be removed in restaurants, while sitting and consuming food and beverages. Do you expect all of us commonsensical people in this state, to believe that nonsense? Do you expect us to believe, that we are safe from catching a virus while we are sitting but we are not safe while standing? How absurd and insulting. I am still shocked today, that the general public fell for this hoax and that the RI legislature allowed the dictators/governors to rule for so long under supposed emergency powers.
These same people, including this agency, eventually allowed masks to be removed at retail locations, if plexiglass was installed at the cash registers, ignoring the fact that a virus will spread easily around such plexiglass. The lack of science when issuing these mandates, is astounding.
We are here today to discuss school masking, but let's make it clear, this was just one tool used to propagate the greatest medical hoax in world history. Covid. Big Pharma spends hundreds of millions, if not billions, to push their products and that is exactly what these rules and mandates were, a ruse to instill fear in the general public, in order to convince them to take an experimental shot.

This agency, the RI DOH, often referred to using the guidance of the CDC, FDA and NIH. They called for a 6 foot social distancing rule, which closed many schools, setting many children back in their studies. Just recently Anthony Fauci testified that this rule was "likely not based on scientific data". In laymen's terms, they lied. With such an egregious admission how are we to believe any of their recommendations. This agency, the RI DOH, followed along blindly, with the recommendations of these agencies that are heavily intertwined with big pharma. Many top officials at the FDA, CDC & NIH have previously worked for the same pharmaceutical companies who are producing the covid shots being pushed, and vice versa. They also collect royalties from these same pharmaceutical companies. Moderna announced last year, that they alone, paid the NIH, $400 million in royalties, probably to the same people that approved their clot shots.

Covid has more than a 99% survival rate and there are over the counter medications that work against it. For that reason alone, the Emergency Use Authorization, for the covid shots, was both unnecessary and illegal. These shots are not safe and effective and have many adverse reactions, including death. This information was provided in the Pfizer clinical trials, which they tried to get sealed for 75 years.

This RI DOH sent letters to our medical professionals, threatening that they would lose their medical licenses if they spoke out against these lies. This state government also forced many to take these shots and terminated employment to those who did not comply. This is in direct violation of the Nuremburg Codes and people should be held liable.

You should all be ashamed that this agency, resorted to fear, intimidation and control tactics.

So in closing, I again state, that I vehemently oppose the school masking regulation being proposed. Thank you.

End Testimony.

Thank You,

Jason Romblad

Proposed Masking Regulation

P/M Daley <dalfam@hotmail.com>

Thu 3/14/2024 4:17 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4RI@hotmail.com <consent4RI@hotmail.com>

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This message came from outside your organization.

Report Suspicious

Dear Sir,

We are very opposed to, even alarmed by, any regulation empowering the RIDOH to impose mask mandates on our school children. The recent past has shown us how harmful masking has been to school children and their education, without being an effective medical measure. RIDOH seems to want more power over our schools, at the expense of parental authority, by judging for itself when and if to exert more mandates. This Bill will severely weaken the public's confidence in the motives of the Health bureaucracy, and lead us to question the safety of our schools. Please do not allow this to happen.

Sincerely,

Paul Daley, Mary Daley
West Kingston

Provide all Public Comments from Friday's Hearing

Ellen S <ellenstarck.schaffer@gmail.com>

Tue 3/19/2024 10:29 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello Mr. Garceau,

Please respond with immediate access for me to view all public comments, both email and a transcript of spoken testimony, from the hearing for 216-30-05-04 Masking in School this past Friday.

I'm not sure how RIDOH has gotten away with blocking or obscuring public visibility to comments, but given submission ends tomorrow, time is of the essence with regard to this transparency.

I look forward to your immediate compliance.

Thank you,
Ellen

Sent from Gmail Mobile

Provide all Public Comments from Friday's Hearing

Ellen S <ellenstarck.schaffer@gmail.com>

Tue 3/19/2024 10:29 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
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Report Suspicious

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Please respond with immediate access for me to view all public comments, both email and a transcript of spoken testimony, from the hearing for 216-30-05-04 Masking in School this past Friday.

I'm not sure how RIDOH has gotten away with blocking or obscuring public visibility to comments, but given submission ends tomorrow, time is of the essence with regard to this transparency.

I look forward to your immediate compliance.

Thank you,
Ellen

Sent from Gmail Mobile

Masking in School

Vanessa Matteson <vanessajmatteson@gmail.com>

Tue 3/19/2024 1:26 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello Zachary,

I'm writing in regards to the proposed adoption of masking in school. I never contribute to any public forum because generally I agree with decisions that are being made. In this instance, I feel strongly about making kids wear masks in school.

I understand that this wouldn't be a requirement all year long as I'm sure that it would be during peak winter illnesses but I don't believe that the health department should mandate masks in school and that it should be a decision that the parents make for their children.

I currently have 3 children in either middle school or high school and I have a daughter who will be going to kindergarten in 3 years. My teenagers had a tough time through covid and 2 of them now have social anxiety due to all of the strict regulations that were needed to be followed. I don't want that to happen to my youngest who has no memory of the mask wearing. She also has sensory issues and wearing a mask all day in school is something that she wouldn't be able to do. With the availability of vaccines, I don't understand why mask wearing would be a requirement put forth by the DOH. Again, it should be up to the parents to ensure that the children are getting their vaccinations and if they want their children to, to wear masks.Taking the choice away from parents isn't the right way to go.

Vanessa

Mask wearing

tessakheradi <tessakheradi@gmail.com>
Tue 3/19/2024 1:59 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good afternoon Zachary,

I am writing to you to let you know I strongly oppose giving the department of health the ability to enforce mask wearing in schools. Previous mask damage did an enormous amount of damage to children educationally, socially and emotionally. This needs to be kept up to the parents of students. The masks did not help contain Covid and due to improper use of masks or not washing masks, it caused skin infections etc. This is a free country and parents should have the ability to choose if a mask is worn by their children.

Please note my opposition.

Thank you

Tessa Grace
Coventry RI resident
401-474-9186

Sent from my Verizon, Samsung Galaxy smartphone

Mask Mandate Proposal

Kelly Conner <kellyjeanneconner@hotmail.com>

Tue 3/19/2024 5:37 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:Consent4RI@hotmail.com <Consent4RI@hotmail.com>

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Report Suspicious

To whom it may concern:

I am a registered nurse, a mother of four, and a grandmother of eleven children of varying ages. I strongly oppose the harmful practice of forcibly masking children for prolonged durations of time. Our Rhode Island State Health Department should know that Cochran is the *gold star* of science. Why do you continue to ignore Cochran's finding that Masks make no difference in the transmission of respiratory viruses [cochrane.org]? What happened to your mantra "Follow the science?"

Additionally, a Florida grand jury recently concluded, "*We have never had sound evidence of their (masks) effectiveness against SARS-CoV-2 transmission in the form of reliable RCTs that demonstrated statistically significant benefits [flvoicenews.com]*." The jury addressed the, "*flawed observational and laboratory data the CDC has published to justify its Guidance.*" They concluded that, *"This is a "quality" problem, not a "quantity" problem. The number of published studies available cannot serve as a substitute for the quality of the underlying science upon which they are based*" (2/2/24)

Science does not support mask mandates for children.

Additionally, mask mandates are harmful to developing children. Masks impair learning, language acquisition, delay speech, and impair communication. Forcibly masking children isolates them from peers because and markedly impairs their socialization. Isolating children is undeniably harmful to their mental health. Shame on you for even proposing this regulation that would cause additional harm to our children! This is particularly egregious while we are still in the midst of the mental health crisis that you created as a direct result of your previous mandates.

I demand that you withdraw your shameful proposal of a mask mandate regulation and salvage what little credibility you may have left.

Kelly Conner, RN, BSN, CCRN

Kelly Conner RN
Kellyjeanneconner@hotmail.com
iPhone 717-994-8117

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Physical interventions to interrupt or reduce the spread of respiratory viruses (Review)

Jefferson T, Dooley L, Ferroni E, Al-Ansary LA, van Driel ML, Bawazeer GA, Jones MA, Hoffmann TC, Clark J, Beller EM, Glasziou PP, Conly JM

Jefferson T, Dooley L, Ferroni E, Al-Ansary LA, van Driel ML, Bawazeer GA, Jones MA, Hoffmann TC, Clark J, Beller EM, Glasziou PP, Conly JM.
Physical interventions to interrupt or reduce the spread of respiratory viruses.
Cochrane Database of Systematic Reviews 2023, Issue 1. Art. No.: CD006207.
DOI: 10.1002/14651858.CD006207.pub6.

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WILEY

[Intervention Review]

Physical interventions to interrupt or reduce the spread of respiratory viruses

Tom Jefferson[1], Liz Dooley[2], Eliana Ferroni[3], Lubna A Al-Ansary[4], Mieke L van Driel[5,6], Ghada A Bawazeer[7], Mark A Jones[2], Tammy C Hoffmann[2], Justin Clark[2], Elaine M Beller[2], Paul P Glasziou[2], John M Conly[8,9,10]

[1]Department for Continuing Education, University of Oxford, Oxford OX1 2JA, UK. [2]Institute for Evidence-Based Healthcare, Bond University, Gold Coast, Australia. [3]Epidemiological System of the Veneto Region, Regional Center for Epidemiology, Veneto Region, Padova, Italy. [4]Department of Family and Community Medicine, King Saud University, Riyadh, Saudi Arabia. [5]General Practice Clinical Unit, Faculty of Medicine, The University of Queensland, Brisbane, Australia. [6]Department of Public Health and Primary Care, Ghent University, Ghent, Belgium. [7]Department of Clinical Pharmacy, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia. [8]Cumming School of Medicine, University of Calgary, Room AGW5, SSB, Foothills Medical Centre, Calgary, Canada. [9]O'Brien Institute for Public Health and Synder Institute for Chronic Diseases, Cumming School of Medicine, University of Calgary, Calgary, Canada. [10]Calgary Zone, Alberta Health Services, Calgary, Canada

Contact: John M Conly, john.conly@albertahealthservices.ca.

Editorial group: Cochrane Acute Respiratory Infections Group.
Publication status and date: Edited (no change to conclusions), published in Issue 4, 2023.

Citation: Jefferson T, Dooley L, Ferroni E, Al-Ansary LA, van Driel ML, Bawazeer GA, Jones MA, Hoffmann TC, Clark J, Beller EM, Glasziou PP, Conly JM. Physical interventions to interrupt or reduce the spread of respiratory viruses. *Cochrane Database of Systematic Reviews* 2023, Issue 1. Art. No.: CD006207. DOI: 10.1002/14651858.CD006207.pub6.

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ABSTRACT

Background

Viral epidemics or pandemics of acute respiratory infections (ARIs) pose a global threat. Examples are influenza (H1N1) caused by the H1N1pdm09 virus in 2009, severe acute respiratory syndrome (SARS) in 2003, and coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in 2019. Antiviral drugs and vaccines may be insufficient to prevent their spread. This is an update of a Cochrane Review last published in 2020. We include results from studies from the current COVID-19 pandemic.

Objectives

To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses.

Search methods

We searched CENTRAL, PubMed, Embase, CINAHL, and two trials registers in October 2022, with backwards and forwards citation analysis on the new studies.

Selection criteria

We included randomised controlled trials (RCTs) and cluster-RCTs investigating physical interventions (screening at entry ports, isolation, quarantine, physical distancing, personal protection, hand hygiene, face masks, glasses, and gargling) to prevent respiratory virus transmission.

Data collection and analysis

We used standard Cochrane methodological procedures.

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Main results

We included 11 new RCTs and cluster-RCTs (610,872 participants) in this update, bringing the total number of RCTs to 78. Six of the new trials were conducted during the COVID-19 pandemic; two from Mexico, and one each from Denmark, Bangladesh, England, and Norway. We identified four ongoing studies, of which one is completed, but unreported, evaluating masks concurrent with the COVID-19 pandemic.

Many studies were conducted during non-epidemic influenza periods. Several were conducted during the 2009 H1N1 influenza pandemic, and others in epidemic influenza seasons up to 2016. Therefore, many studies were conducted in the context of lower respiratory viral circulation and transmission compared to COVID-19. The included studies were conducted in heterogeneous settings, ranging from suburban schools to hospital wards in high-income countries; crowded inner city settings in low-income countries; and an immigrant neighbourhood in a high-income country. Adherence with interventions was low in many studies.

The risk of bias for the RCTs and cluster-RCTs was mostly high or unclear.

Medical/surgical masks compared to no masks

We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community). Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).

N95/P2 respirators compared to medical/surgical masks

We pooled trials comparing N95/P2 respirators with medical/surgical masks (four in healthcare settings and one in a household setting). We are very uncertain on the effects of N95/P2 respirators compared with medical/surgical masks on the outcome of clinical respiratory illness (RR 0.70, 95% CI 0.45 to 1.10; 3 trials, 7779 participants; very low-certainty evidence). N95/P2 respirators compared with medical/surgical masks may be effective for ILI (RR 0.82, 95% CI 0.66 to 1.03; 5 trials, 8407 participants; low-certainty evidence). Evidence is limited by imprecision and heterogeneity for these subjective outcomes. The use of a N95/P2 respirators compared to medical/surgical masks probably makes little or no difference for the objective and more precise outcome of laboratory-confirmed influenza infection (RR 1.10, 95% CI 0.90 to 1.34; 5 trials, 8407 participants; moderate-certainty evidence). Restricting pooling to healthcare workers made no difference to the overall findings. Harms were poorly measured and reported, but discomfort wearing medical/surgical masks or N95/P2 respirators was mentioned in several studies (very low-certainty evidence).

One previously reported ongoing RCT has now been published and observed that medical/surgical masks were non-inferior to N95 respirators in a large study of 1009 healthcare workers in four countries providing direct care to COVID-19 patients.

Hand hygiene compared to control

Nineteen trials compared hand hygiene interventions with controls with sufficient data to include in meta-analyses. Settings included schools, childcare centres and homes. Comparing hand hygiene interventions with controls (i.e. no intervention), there was a 14% relative reduction in the number of people with ARIs in the hand hygiene group (RR 0.86, 95% CI 0.81 to 0.90; 9 trials, 52,105 participants; moderate-certainty evidence), suggesting a probable benefit. In absolute terms this benefit would result in a reduction from 380 events per 1000 people to 327 per 1000 people (95% CI 308 to 342). When considering the more strictly defined outcomes of ILI and laboratory-confirmed influenza, the estimates of effect for ILI (RR 0.94, 95% CI 0.81 to 1.09; 11 trials, 34,503 participants; low-certainty evidence), and laboratory-confirmed influenza (RR 0.91, 95% CI 0.63 to 1.30; 8 trials, 8332 participants; low-certainty evidence), suggest the intervention made little or no difference. We pooled 19 trials (71, 210 participants) for the composite outcome of ARI or ILI or influenza, with each study only contributing once and the most comprehensive outcome reported. Pooled data showed that hand hygiene may be beneficial with an 11% relative reduction of respiratory illness (RR 0.89, 95% CI 0.83 to 0.94; low-certainty evidence), but with high heterogeneity. In absolute terms this benefit would result in a reduction from 200 events per 1000 people to 178 per 1000 people (95% CI 166 to 188). Few trials measured and reported harms (very low-certainty evidence).

We found no RCTs on gowns and gloves, face shields, or screening at entry ports.

Authors' conclusions

The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions. There were additional RCTs during the pandemic related to physical interventions but a relative paucity given the importance of the question of masking and its relative effectiveness and the concomitant measures of mask adherence which would be highly relevant to the measurement of effectiveness, especially in the elderly and in young children.

There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect. The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use

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of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection. Hand hygiene is likely to modestly reduce the burden of respiratory illness, and although this effect was also present when ILI and laboratory-confirmed influenza were analysed separately, it was not found to be a significant difference for the latter two outcomes. Harms associated with physical interventions were under-investigated.

There is a need for large, well-designed RCTs addressing the effectiveness of many of these interventions in multiple settings and populations, as well as the impact of adherence on effectiveness, especially in those most at risk of ARIs.

PLAIN LANGUAGE SUMMARY

Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?

Key messages
We are uncertain whether wearing masks or N95/P2 respirators helps to slow the spread of respiratory viruses based on the studies we assessed.

Hand hygiene programmes may help to slow the spread of respiratory viruses.

How do respiratory viruses spread?
Respiratory viruses are viruses that infect the cells in your airways: nose, throat, and lungs. These infections can cause serious problems and affect normal breathing. They can cause flu (influenza), severe acute respiratory syndrome (SARS), and COVID-19.

People infected with a respiratory virus spread virus particles into the air when they cough or sneeze. Other people become infected if they come into contact with these virus particles in the air or on surfaces on which they land. Respiratory viruses can spread quickly through a community, through populations and countries (causing epidemics), and around the world (causing pandemics).

Physical measures to try to prevent respiratory viruses spreading between people include:

· washing hands often;

· not touching your eyes, nose, or mouth;

· sneezing or coughing into your elbow;

· wiping surfaces with disinfectant;

· wearing masks, eye protection, gloves, and protective gowns;

· avoiding contact with other people (isolation or quarantine);

· keeping a certain distance away from other people (distancing); and

· examining people entering a country for signs of infection (screening).

What did we want to find out?
We wanted to find out whether physical measures stop or slow the spread of respiratory viruses from well-controlled studies in which one intervention is compared to another, known as randomised controlled trials.

What did we do?
We searched for randomised controlled studies that looked at physical measures to stop people acquiring a respiratory virus infection.

We were interested in how many people in the studies caught a respiratory virus infection, and whether the physical measures had any unwanted effects.

What did we find?
We identified 78 relevant studies. They took place in low-, middle-, and high-income countries worldwide: in hospitals, schools, homes, offices, childcare centres, and communities during non-epidemic influenza periods, the global H1N1 influenza pandemic in 2009, epidemic influenza seasons up to 2016, and during the COVID-19 pandemic. We identified five ongoing, unpublished studies; two of them evaluate masks in COVID-19. Five trials were funded by government and pharmaceutical companies, and nine trials were funded by pharmaceutical companies.

No studies looked at face shields, gowns and gloves, or screening people when they entered a country.

We assessed the effects of:

· medical or surgical masks;

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· N95/P2 respirators (close-fitting masks that filter the air breathed in, more commonly used by healthcare workers than the general public); and

· hand hygiene (hand-washing and using hand sanitiser).

We obtained the following results:

Medical or surgical masks

Ten studies took place in the community, and two studies in healthcare workers. Compared with wearing no mask in the community studies only, wearing a mask may make little to no difference in how many people caught a flu-like illness/COVID-like illness (9 studies; 276,917 people); and probably makes little or no difference in how many people have flu/COVID confirmed by a laboratory test (6 studies; 13,919 people). Unwanted effects were rarely reported; discomfort was mentioned.

N95/P2 respirators

Four studies were in healthcare workers, and one small study was in the community. Compared with wearing medical or surgical masks, wearing N95/P2 respirators probably makes little to no difference in how many people have confirmed flu (5 studies; 8407 people); and may make little to no difference in how many people catch a flu-like illness (5 studies; 8407 people), or respiratory illness (3 studies; 7799 people). Unwanted effects were not well-reported; discomfort was mentioned.

Hand hygiene

Following a hand hygiene programme may reduce the number of people who catch a respiratory or flu-like illness, or have confirmed flu, compared with people not following such a programme (19 studies; 71,210 people), although this effect was not confirmed as statistically significant reduction when ILI and laboratory-confirmed ILI were analysed separately. Few studies measured unwanted effects; skin irritation in people using hand sanitiser was mentioned.

What are the limitations of the evidence?
Our confidence in these results is generally low to moderate for the subjective outcomes related to respiratory illness, but moderate for the more precisely defined laboratory-confirmed respiratory virus infection, related to masks and N95/P2 respirators. The results might change when further evidence becomes available. Relatively low numbers of people followed the guidance about wearing masks or about hand hygiene, which may have affected the results of the studies.

How up to date is this evidence?
We included evidence published up to October 2022.

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Testimony in opposition to RIDOH regulation 216-RICR-30-05-04

Maddalena Cirignotta <lenacirignotta@hotmail.com>

Tue 3/19/2024 9:36 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

For the safety and wellbeing of Rhode Island children, I request that RIDOH withdraw 216-RICR-30-05-04, which would put our children under threat of reckless, harmful mandates.

In the event that RIDOH implements this dangerous regulation, I request that RIDOH include the following language:

"In order to implement a school mask mandate. RIDOH will specify in its regulation how the department will determine what science to disregard when deciding to implement a mask mandate. RIDOH will outline specific criteria that it will use to determine why a particular study or meta-analysis will be disregarded. RIDOH will specify necessary criteria of a particular study, meta-analysis or data set, in order to be included in their analysis of whether or not to impose a mask mandate.

RIDOH will specify the transmission rate threshold necessary in order to trigger the implementation of a mask mandate.

RIDOH will specify which viral outbreaks may trigger the implementation of a mask mandate (Covid, influenza, RSV, whooping cough, chicken pox, etc.)

RIDOH will demonstrate the efficacy of mask mandates via randomized control trials that clearly prove the effectiveness and safety of universal mask use.

RIDOH will demonstrate a lack of correlation between mask use and learning loss.

RIDOH will demonstrate a lack of correlation between mask use and deteriorated mental health in children.

RIDOH will poll the general public for a period of 30 days in order to ascertain how parents feel about forcibly masking their children in order to access public schools. RIDOH will ask how parents feel that mask mandates affect the learning, communication, socialization, mental health, physical health, breathing, viral infection rate and sense of well-being of their children.

RIDOH will send surveys to all public schools asking students, the principle stakeholders, for their input regarding how mask mandates affect their learning, communication, socialization, mental health, physical health, breathing and sense of well-being.

RIDOH will send surveys to all teachers and administrators asking for input regarding how mask mandates affect learning, communication, socialization, mental health, physical

health, breathing, connections and overall sense of well-being of both students and staff.

RIDOH's 216-RICR-30-05-4 regulation will include an analysis of the ways that mask mandates affect developing children. RIDOH's regulation will include a benefit/cost analysis of the following:

How do mask mandates affect mental health?

How do mask mandates affect social development?

How do mask mandates affect social connections to one another and to adults?

How do mask mandates affect language acquisition?

How do mask mandates affect receptive language?

How do mask mandates affect expressive language?

How do mask mandates affect communication?

How do mask mandates affect learning loss?

How do mask mandates affect dental and oral health?

How do mask mandates affect blood oxygen levels during exercise?

How do mask mandates affect resting heart rates?

How do mask mandates affect rates of skin infections?

How do mask mandates affect children with prior facial surgeries?

How do mask mandates affect children with sensory sensitives?

How do mask mandates affect children with asthma?

How do mask mandates affect children with allergies?

How do mask mandates affect children with respiratory conditions?

How do mask mandates affect viral transmission rates?

How do mask mandates affect overall health outcomes of children?"

Sincerely,

Maddalena Cirignotta
South Kingstown, RI

MY CHILDREN WILL NOT COMPLY WITH MASKS

Katie Kelly <kkelly0514@gmail.com>

Wed 3/20/2024 3:41 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Excuse you Zachary,
You CAN NOT tell us to mask our children again. Your crappy government can let millions into a country but try to mask its own people. There must be something seriously wrong with you All!!!! Keep letting millions of illegals into our country while trying to mask children GET THE F OUT OF HERE!!! This is the dumbest shit you people have ever tried to pull. How about no one will listen to you so good so luck!!!! You should be fired for incompetence!!!!! Covid is pretend!!!! Try again with all your lies and BS TRYING TO SCARE PEOPLE!!!! Grow up!!!!!

By the way it's not a damn law it's a mandate so technically as American citizens who are legal to be here have rights to say NO to your rules. I will let everyone I know also know they have rights as Americans to not listen to people like you who have control issues.

Masking in school

Kate Gaudette <kategaudette@icloud.com>

Wed 3/20/2024 8:48 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Hello,

I would like to express my concern for the suggested mandate of masking in schools in RI. As a mother of two school aged children I am extremely against this policy. After seeing the hindrance of language and reading development in my children during the time of masking in 2020, I was extremely relieved when they were allowed to go mask free again.
If my children are forced to wear masks at school again I will remove them from the public school system, this is absolutely outrageous that it would even be considered again especially since it has been proven that masking is not an effective way to stop the spread of germs.

Please reconsider this mandate.

Thank you,
Kate Gaudette

Sent from my iPhone

No to masks

Yulia Avvakumova <yuliamc88@gmail.com>

Wed 3/20/2024 8:55 AM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

Good morning,

This email to confirm that as a mother of two kids I strongly oppose to implementing masks in schools! Children need to feel free without masks and other forced ways to cover their face.

Thank you!

Oppose bill 216-RICR-30-05-4

Evgeniya Steele <estl0174@gmail.com>

Wed 3/20/2024 2:03 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Report Suspicious

To whom it may concern,
I'm writing to oppose proposed bill 216-RICR-30-05-4 Masking at School for students in grades kindergarten through twelve in RI. Masks have negative effects on mental health of children as well as development. Such medical decisions should be made by parents.
Thank you for taking your time reading this email.

Best,
Evgeniya Steele
401-654-3996
64 new rd apt 38
East Providence, RI 02916

No masks in school

Victoria Pogonets <vipogonets@gmail.com>

Wed 3/20/2024 2:33 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

Good morning,

This email to confirm that as a mother of two kids I strongly oppose to implementing masks in schools!
Children need to feel free without masks and other forced ways to cover their face.

Thank you!
Best regards,
Victoria Pogonets

Masking Public Comment

Ellen S <ellenstarck.schaffer@gmail.com>
Wed 3/20/2024 2:59 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

1 attachments (45 KB)
RIDOH Masking Public Comment.pdf;

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Please find attached and below

Hello Mr. Garceau,

Thank you for conducting the in-person portion of Public Comment this past Friday, March 15. Unique from my spoken comments at that meeting, please enter the following into record as my written Public Comment pursuant to the Administrative Procedures Act (APA) and Regular Rulemaking procedures for Rhode Island Executive Agencies:

1. Regarding the mandated step of "Concise Explanatory Statements" described at this link https://health.ri.gov/regulations/ , and excerpt below:

> *Concise Explanatory Statements: When RIDOH files final regulations with the Rhode Island Secretary of State (after the required Public Notice of Proposed Rulemaking described above), it is required to issue a concise explanatory statement which contains an explanation of any changes between the text of the regulations posted for public comment and the text of the final rule, and provides RIDOH's reasons for not accepting revisions suggested during public comment.*

I will provide suggested revisions, and if any are not accepted, I instruct you to please reply back to me with the written explanatory statement.

PROPOSED SUGGESTED REVISIONS - Public Comment

216-RICR-30-05-4
TITLE 216 – DEPARTMENT OF HEALTH CHAPTER 30 – INFECTIOUS DISEASES SUBCHAPTER 05 – INFECTIOUS DISEASES PART 4 – MASKING IN SCHOOL

4.1 Authority and Purpose
A. These Regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws §§ 23-1-17 and 23-1-18, for the purpose of publicly setting forth the rationale for a masking requirement in the event a future masking requirement is promulgated by the Rhode Island Department of Health for students in grades Kindergarten through twelve in Rhode Island.
4.2 Definitions
A. In this Part, the following terms shall mean as stated:
1. "Department" means the Rhode Island Department of Health.
2. "Director'' means the Director of the Rhode Island Department of Health or

designee.
3. “Scientific Evidence” means the results of clinical trials or other studies published in peer-reviewed articles, as well as medical literature generally recognized by the relevant medical specialty community.
4. “School" means any school for students in grades Kindergarten through twelve in Rhode Island.
5. “Student” means any individual who is enrolled in grades Kindergarten through twelve at a school.
4.3 Masking in School
A. In the event that the Department requires face masks for students in school to prevent the spread of an infectious disease, the Department shall set forth the rationale for a masking requirement through a statement. This statement shall be made publicly available on the Department's website.
B. Any decision regarding whether to implement a face mask requirement for students will first demonstrate with respect to a masking requirement, the Department’s full compliance with the Administrative Procedures Act (APA) by providing the complete, requisite Regulatory Analysis including adherence to the Rhode Island Office of Regulatory Reform December 2023 guidance document ANALYZING REGULATORY BENEFITS AND COSTS - A guide for Rhode Island executive agencies. The masking requirement will also be supported by scientific evidence derived from random control trials (RCTs) and will demonstrate direct applicability to students wearing masks in schools for the duration of the school day and during all school-associated activities. The masking requirement will also explain it’s reasoning for feasibility. The factors considered in this decision may include, but not be limited to:
1. The transmissibility and infectiousness of the specific pathogen;
2. Facilitators of the specific pathogen (including how it is spread);
3. Students' ages;
4. Infection control in school, which may include, but not be limited to:
a. The ability to separate students into smaller groups,
b. The availability of other prevention options for similarly situated students (including vaccinations), and
c. The availability of treatment options for similarly situated students;
5. The ability of students with disabilities, as defined by the Americans with Disabilities Act, 42 U.S.C. §§ 12101 et seq., to comply with the requirements;
6. The effectiveness of any available prevention and treatment approaches;
7. Whether the effectiveness referenced in § 4.3(B)(6) of this Part varies among the different ages and age ranges represented by school;
8. Whether the prevention and treatment options are Emergency Use Authorizations (EUA) or FDA-approved;
9. Scientific evidence of the effectiveness, disadvantages, and side effects of masks on the pathogen (including an assessment of the availability and quality of such evidence);
10. Input from various stakeholders which may include, but are not limited to, the Rhode Island Department of Education, the Office of the Governor, school districts, students, and parents or guardians of students, as well as other expert groups and institutions (e.g., Centers for Disease Control and Prevention, Infectious Disease Epidemiology Advisory Committee);
11. The concentration and spread of the disease among students;
12. The immediate discomfort and long-term effects of the disease on students and variations in the effects from those experienced by the general population;
13. How masking could form part of a comprehensive approach to addressing the disease in students;
14. The concentration of the disease in the general population (and any data that correlates estimates/expectations of concentration among students and how that impacts the general population concentration); and
15. The contribution of students to the transmission of the disease to other vulnerable populations.
16. How masking affects children with various conditions, including but not limited to: social and

emotional difficulties, developmental delays, special educational needs, diagnosed medical conditions, diagnosed mental health disorders or conditions.

C. Scientific evidence will be utilized in connection with evaluation of § 4.3(B) of this Part; provided, however, that some evidence may be given more weight than other evidence, and this balancing of evidence requires the exercise of judgment based on the facts and circumstances that exist at any given time as well as the experience and expertise of those engaged in the decision-making process. The Director shall have the final decision within the Department regarding face masking for students.

D. EXEMPTIONS

In the event of a masking requirement, any child, parent or guardian may claim an exemption for any reason, including, but not limited to a medical, philosophical, or religious exemption.

4.4 Severability

A. If any provision of these regulations or the application thereof shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

PROPOSED SUGGESTED REVISIONS - Public Comment

216-RICR-30-05-4

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3. “Scientific Evidence” means the results of clinical trials or other studies published in peer-reviewed articles, as well as medical literature generally recognized by the relevant medical specialty community.
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2. Facilitators of the specific pathogen (including how it is spread);
3. Students' ages;
4. Infection control in school, which may include, but not be limited to:

a. The ability to separate students into smaller groups,

b. The availability of other prevention options for similarly situated students (including vaccinations), and

c. The availability of treatment options for similarly situated students;

5. The ability of students with disabilities, as defined by the Americans with Disabilities Act, 42 U.S.C. §§ 12101 et seq., to comply with the requirements;

6. The effectiveness of any available prevention and treatment approaches;

7. Whether the effectiveness referenced in § 4.3(B)(6) of this Part varies among the different ages and age ranges represented by school;

8. Whether the prevention and treatment options are Emergency Use Authorizations (EUA) or FDA-approved;

9. Scientific evidence of the effectiveness, disadvantages, and side effects of masks on the pathogen (including an assessment of the availability and quality of such evidence);

10. Input from various stakeholders which may include, but are not limited to, the Rhode Island Department of Education, the Office of the Governor, school districts, students, and parents or guardians of students, as well as other expert groups and institutions (e.g., Centers for Disease Control and Prevention, Infectious Disease Epidemiology Advisory Committee);

11. The concentration and spread of the disease among students;

12. The immediate discomfort and long-term effects of the disease on students and variations in the effects from those experienced by the general population;

13. How masking could form part of a comprehensive approach to addressing the disease in students;

14. The concentration of the disease in the general population (and any data that correlates estimates/expectations of concentration among students and how that impacts the general population concentration); and

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Healthcare Worker Regulations Comment

Philip Chan <philip_chan@brown.edu>

Wed 3/20/2024 3:17 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Hi Zach,

Thank you for your work on these regulations. I have one small comment.

In “Definitions” section, I would propose the follow amendment:

“Scientific evidence” means published guidelines from the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), or other major scientific organizations. In rapidly evolving emergent outbreaks of respiratory disease, the results of clinical trials or other studies published in peer-reviewed articles, as well as medical literature recognized by the relevant medical specialty community, will also be regarded as evidence to drive policy.”

Thank you again!

Philip A. Chan, M.D., M.S. (*he/him/his*)
Associate Professor, Brown University

Please terminate RIDOH proposed regulation 216-RICR-30-05-4

Christine Waldeck <christine.fhwaldeck70@yahoo.com>

Wed 3/20/2024 4:00 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Christine Healy Waldeck

29 Nelson Street

Providence , RI 02908

March 15, 2024

Mr. Zachary Garceau

Rhode Island Department of Health

3 Capitol Hill

Providence, RI 02908

Mr. Garceau:

My name is Christine Waldeck. My family and I live in Providence RI. I am also a co founder of Rhode Island Wellness Society, which is a group of local families and professionals, and we advocate for choice, informed consent, and consumer protections in health policy, particularly concerning the medical procedure of vaccination. I am writing to you today because I am so deeply troubled about RIDOH's proposed facemask regulation 216-RICR-30-05-4, especially since the original proposal stated : "*an absence of scientific evidence regarding the effectiveness of face masks against a specific pathogen will not prevent the department from considering a face mask requirement*". I strongly OPPOSE this dangerous regulation, and I urge RIDOH to cancel 216-RICR-30-05-4 as soon as possible.

As a member of RI Wellness Society and many other parent groups in RI, I have seen, heard, and talked with many families statewide whose children have suffered terribly from being forced to wear a face covering for six or more hours per day at school. According to testimony from other parents, children across the state have suffered from migraine headaches, sensory dysregulation, face acne and skin fungal infections, dips in oxygen saturation levels, speech delays, regression of receptive language skills, anxiety, claustrophobia, lethargy, developmental regression, depression, and regression in academic skills and school work. Most disturbingly, so many parents have shared that when their children wore these coverings across their mouths, the masks inhibited their desire to speak out and communicate during class discussions, and even when socializing with their peers.

My biggest concerns lie with our RI children who have learning and developmental disabilities, physical disabilities, health challenges, are non -verbal, have speech and language delays, and delays in social skills. All Rhode Island School children who have disabilities, whether it be developmental, physical or learning disabilities, negotiate an Individual Education Program, also known as an "IEP" which is a personalized legal contract between a child's parents, the school district, and the government. An IEP states all of a child's educational goals, and describes to all parties about who, what, when, where, why and how, a child with disabilities will be educated. Very often these IEPs include goals that will help a child

develop their speech and communication skills, and social skills, particularly for students with Autism and are non- speakers, like my daughter. I have heard from numerous families that speech and communication goals were not even being addressed, because so many teachers and service providers were under enormous pressure to make sure students were wearing their mouth coverings all day. **IEP speech and communication goals were essentially ignored for so many students for multiple years in RI!! I have literally cried for these young children between 2 -7 who are non verbal, preverbal, non speakers, or speech delayed, and were ROBBED of their speech therapy during those years because of the Governors mask mandate. These children missed the "developmental window" of learning to speak and communicate effectively! Why won't RIDOH and the Governor acknowledge these children and this horrific reality???**

Although Many RI schools implemented a policy that granted "mask exemptions" to children with disabilities who met a certain criteria, many districts were NOT proactive in seeking out, and offering students mask exemptions. At one Providence School Board meeting, I was sad and furious to hear the testimony from a single Mom from the Dominican Republic. **She stated how her son, who is non verbal, uses a wheelchair, has limited arm movement and oral motor challenges, comes home from school each day with a sopping wet facemask because he drools in his facemask all day.** I was also angered by a story from a teacher whose classroom is directly across the hall from a special education classroom. She witnessed her colleagues repeatedly touch and adjust the facemask of a young girl who is also non verbal, also uses a wheelchair, and is immobile from the neck down. **The Teacher and TA's would keep touching her face and moving the mask so that it completely covered her nose and mouth. How can the behavior of multiple people repeatedly touching another persons face and facemask be a healthy practice?** It became quite evident during that time, that **school districts were simply NOT being proactive in offering students with disabilities mask exemptions.** Sadly, many families in Providence were not even aware that facemask exemptions existed! Why were the school districts so unmotivated to protect these vulnerable children??? If RIDOH wishes to implement this policy, HOW will RIDOH ensure that school districts are properly investigating and seeking out students who can be grievously harmed from this practice?

My own 2 children were in high school during those years, and they, too, were very negatively impacted by the Mask mandate. My son went back to school in person as soon as the state allowed it. His school followed the Governor's Mask Mandate very seriously, and a few times, I witnessed well- intentioned teachers constantly remind the students to wear "mask up and over the nose!!!." Soon after returning to school, my son started breaking out in an itchy, scaly, red angry rash across the bridge of his nose and across his cheeks, all on the skin that lied beneath his face mask. After trying numerous remedies as well switching up different varieties of face masks that did not help quell his rash, we took him to our pediatrician. Our Dr said she saw this before and even has a name, that it's called "maskne" (rhymes with "acne") She suggested that we try a few lotions, but unfortunately those lotions did not work, either. he tried numerous medications and lotions, none of them worked, and many even made his rash worse. He tried wearing different kinds of facemasks with varying fiber content, but to no avail. He would change his facemask multiple times per day. And still, his rash persisted. For a teenager who is shy and introverted, dealing with this new unsightly and extremely uncomfortable skin condition was very, very hard on him. The severe itchiness was extremely distracting for him, and the rash was painful. Nonetheless, he did not want to cause any trouble and be the only student not wearing a mask. Sometimes he had to wear a mask for 13 hours straight because he was involved in before AND after school activities. I struggled allowing him to wear his mask because we were having such a hard time treating his rash. It was his senior year, and he was so happy to be back amongst his friends and favorite activities. We finally found a remedy that helped, but unfortunately, his skin condition, which is called **seborrheic dermatitis**, never fully went away. To this day, 2 years later, he is still struggling with flares, even though he doesn't wear a mask anymore. He requires a consistent and strict skin cleansing and treatment protocol with multiple, expensive products in order for his condition to stay under control. **It angered me to my core** when I recently discovered multiple studies that documented how prolonged mask wearing can trigger facial seborrheic dermatitis. This skin condition is **nothing** like typical acne. It is extremely painful, incredibly itchy, very unsightly, and very difficult to control! The rash can spread to other parts of the body and can cause pain, and embarrassment. **It angers me so much that my sons condition started AFTER he started wearing a mask for 6 + hours and day and now there is documentation and per reviewed published studies that show how face masks can cause this condition.** If RIDOH wishes to implement this regulation, will RIDOH be transparent and disclose that some people may suffer severe, permanent skin infections from prolonged face masking??? HOW will RIDOH help???

My daughter, who was born with Down syndrome, and diagnosed with autism at 10 years old, is essentially non verbal, and has multiple sensory challenges, was **very negatively impacted from the Governor's mask mandate**. At the time of the implementation of the Mandate, she was enrolled in a private school for children with significant disabilities. (My daughter was referred "out of district" by Providence Public Schools in Middle School, so her private schooling was paid for by PPSD). Fortunately, this school understood how difficult and dangerous prolonged facemask wearing can be for children with disabilities, especially children with autism and sensory processing issues, so this school **DID NOT** require the children to wear a facemask.

However, my daughter had a very difficult time ***being around people who were wearing facemasks.*** My daughter would try to pull the facemasks off people who wore them. I believe it was so she can hear them, as she is hard of hearing in one ear, and so she can see their facial expressions. Her school required ALL teachers, support staff and employees to wear a mask. Many teachers even wore goggles, head protection, and gloves. A few trachers tried wearing clear facemasks, however, EVERY adult was unrecognizable, and the sight of all the teachers with their faces and bodies covered in protective equipment was a frightening sight. Unrecognizable masked teachers, coupled with the fact that my very strong, very determined, non verbal daughter would try to pull the facemasks off of the adults, gave me pause about sending her back to school all day. We decided to try a hybrid school day where I teach her at home, and then bring her to school for in person speech and occupational therapy. Unfortunately, My daughter had a very difficult time connecting with, and communicating with, the speech and occupational therapists whole they were donned in their facemasks and protective equipment. It was painfully obvious that my daughter could not understand what they were saying, and the sessions were difficult. We tried ZOOM Occupational Therapy and speech sessions, however, my daughter would not pay attention and loose interest Eventually, Providence Schools decided to stop paying for her tuition to attend the school because she was unable to attend every day. **It angers me tremendously that my daughter missed out on her educational programming and vital speech and occupational therapies during those years because of the Governors Mask Mandate, and extreme Covid restrictions.**

I ask our Department of Health to consider the following regarding the proposed Mask Mandate regulation:

RIDOH is now fully aware that there are children who were "irreparably harmed" by the Governor's Mask Mandate. In addition, RIDOH refuses to provide any data that proves the practice of masking children for 6+ hours per day is actually safe or effective for all students. **Will the Department acknowledge and apologize to the children and their families for the harm this horrific mask mandate policy caused?** How will RIDOH HELP the children who were harmed?

If RIDOH refuses to acknowledge or help the families that were harmed by the UNSAFE and INEFFECTIVE Mask Mandate, then this regulation must be terminated immediately!!! Will RIDOH pay for all of the medical bills and medicines for students who suffer headaches, skin infections, psychological trauma, and other negative effects from prolonged mask wearing? Will RIDOH PAY FOR all compensatory speech therapy, occupational therapy, and social skill therapy sessions for students?? **Rhode Island children, and ALL RI'ers, deserve public health policy that is TRULY safe and effective for all**. Acknowledging and HELPING RI'ers who were harmed will help build trust and confidence.

RIDOH MUST become accountable for the harm caused by their mandates. Please help protect your fellow RI'ers and advocate for the reformation of the Public Readiness and Emergency Preparedness Act, which shields manufacturers, policymakers, and others from all liability for harms caused by Covid 19 (and other public health emergency) countermeasures (such as masks and vaccines). **The time has come for our Government Health Agencies to STOP catering to industry and START PROTECTING THE PEOPLE. Our Government bodies must STOP implementing all potentially harmful medical mandates of any kind. Where there is risk of harm, there must be CHOICE.**

In lieu of imposing ineffective, unsafe, unscientific, medically dangerous, and abusive "public health" **mandates** upon RI'ers, please consider safer and more effective alternatives such as these:

- **Advocate for robust and comprehensive PAID SICK LEAVE** for all RI working families so that RI'ers can stay home when sick, and keep their sick children home from school without losing wages/income.

- **Advocate for investments for renovation of ALL SCHOOLS IN RI to ensure that dangerous toxins are removed from the environment**. These would be toxins such as **lead** paint, lead water pipes, **asbestos** in floors and walls, **formaldehyde** in building materials, **radon**, which can enter schools through cracks or other openings in their foundations, **polychlorinated biphenyls (PCBs)** which is found in building materials, **mercury** in gym floors and classroom materials.

- **Advocate for investments for renovation of ALL SCHOOLS to ensure that proper hand hygiene protocols are accessible**. This includes making sure that there is SOAP in ALL dispensers in all bathrooms , and making sure that ALL bathroom sinks are working properly.

- **Advocate for investments for renovations of ALL schools to ensure that there is proper air ventilation in all rooms**. This can be accomplished easily by just making sure that ALL windows are working properly and be easily opened and closed.

- **Advocate for low cost and diversified health care for all Rhode Islanders.**

- **Acknowledge publicly that good nutrition and exercise is critical in our journey towards optimal health. Develop programs to educate RI'ers about the importance of eating foods that nourish the body.**

-

Thank you for your time.

Sincerely,

Christine Healy Waldeck

Providence RI

Sources:

PREP ACT https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx [aspr.hhs.gov]

Seborrheic dermatitis and anti-COVID-19 masks (WITH IMAGES) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7436393/ [ncbi.nlm.nih.gov]

Masks trigger facial seborrheic dermatitis and psoriasis: evidence from a multicenter, case-control study during COVID-19 pandemichttps://pubmed.ncbi.nlm.nih.gov/35829673/#:~:text=Background%3A%20Wearing%20masks%20is%20an,PsO)%20flares%20due%20to%20masks [pubmed.ncbi.nlm.nih.gov].

"Face mask dermatitis" due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care and non-health care workers in Germany "Face mask dermatitis" due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care and non-health care workers in Germany - PubMed (nih.gov) [pubmed.ncbi.nlm.nih.gov]

Fungal contamination of medical masks among forensic healthcare workers in the COVID19 era https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10132829/ [ncbi.nlm.nih.gov]

"Mask" Tinea: An Increasing Infection during COVID-19 Pandemic: https://link.springer.com/article/10.1007/s11046-021-00612-7 [link.springer.com]

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Public Readiness and Emergency Preparedness (PREP) Act

Update

Eleventh Amendment to the Declaration under the PREP Act for COVID-19 Medical Countermeasures

On May 9, 2023, Secretary Becerra signed the 11th amendment to the declaration under the PREP Act for COVID-19 Medical Countermeasures. The Secretary issues this amendment to clarify that COVID-19 continues to pose a credible risk of a future public health emergency, add two new limitations on distribution, extend the time period of coverage for certain Covered Countermeasures and Covered Persons, clarify the time period of coverage for Covered Persons authorized under the Declaration, and extend the duration of the Declaration to December 31, 2024.

Read the Federal Register Notice (https://www.federalregister.gov/documents/2023/05/12/2023-10216/eleventh-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for)

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims:

- of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions
- determined by the Secretary to constitute a present, or credible risk of a future public health emergency
- to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures

A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

COVID-19 PREP Act Declarations

The end of the COVID-19 Public Health Emergency Declaration does not automatically terminate PREP Act coverage. To learn more, **view our COVID-19 PREP Act FAQs (/legal/PREPact/Pages/PREP-Act-Question-and-Answers.aspx#COVID).**

Declaration and Amendments

- **Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (March 17, 2020) (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures)**
- **First Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (April 15, 2020) (https://www.federalregister.gov/documents/2020/04/15/2020-08040/amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical)**
- **Second Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (June 8, 2020) (https://www.govinfo.gov/content/pkg/FR-2020-06-08/pdf/2020-12465.pdf)**
- **Third Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (August 24, 2020) (https://www.govinfo.gov/content/pkg/FR-2020-08-24/pdf/2020-18542.pdf)**
- **Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (December 3, 2020) (https://www.federalregister.gov/documents/2020/12/09/2020-26977/fourth-amendment-to-the-declaration-under-the-public-readiness-and-emergency-preparedness-act-for)**
- **Fifth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 2, 2021) (https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02174.pdf)**
- **Sixth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 16, 2021) (https://www.federalregister.gov/documents/2021/02/16/2021-03106/sixth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical)**
- **Technical Correction to Fifth and Sixth Amendments to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (February 22, 2021) (https://www.federalregister.gov/documents/2021/02/22/2021-03526/sixth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical)**
- **Seventh Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (March 11, 2021) (https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf)**
- **Eighth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (August 4, 2021) (https://www.federalregister.gov/public-inspection/2021-16681/eighth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for)**
- **Ninth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (https://www.federalregister.gov/public-inspection/2021-19790/ninth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical) (Fact Sheet (https://www.phe.gov/Preparedness/legal/prepact/Pages/PREPact-NinethAmendment.aspx) | PDF Presentation (https://www.phe.gov/Preparedness/legal/prepact/Documents/PREP-Act-Declaration-Amendment-9-Stakeholder-Presentation-Sept2021.pdf))**
- **Technical Correction to Ninth Amendment to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (October 4, 2021) (https://www.federalregister.gov/documents/2021/10/04/2021-21652/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures)**
- **Tenth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (January 7, 2022) (https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical)**
- **Eleventh Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (May 12, 2023) (https://www.federalregister.gov/documents/2023/05/12/2023-10216/eleventh-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for)**

Advisory Opinions of the General Counsel +

HHS Guidance +

Other Current PREP Act Declarations

Smallpox, Mpox, and Other Orthopox −

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- **Notice of Amendment to the January 1, 2016 Republished Declaration Under the Public Readiness and Emergency Preparedness Act (https://www.federalregister.gov/documents/2022/10/03/2022-21412/notice-of-amendment-to-the-january-1-2016-republished-declaration-under-the-public-readiness-and)**
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Seborrheic dermatitis and anti-COVID-19 masks

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1.

Dear Editor

In Milan, Italy, after the end of the lockdown period (March and April 2020), we observed several patients with seborrheic dermatitis (SD) who showed a more or less important worsening of their disease. In a group of 43 patients with SD who had been visited from December 2019 to February 2020, a worsening in 20 of them (46.5%) was seen. They were 15 males (75%) and 5 females (25%), with an age ranging from 23 to 48 years (mean age: 36.7 years). All patients used anti-coronavirus-19 (COVID-19) face mask for 6-10 hours per day; 7 out of 20 patients (35%) were physicians, obstetricians, or nurses. According to the clinical point of view, the worsening was characterized by increased erythema and desquamation (Figures 1 and 2). Fourteen out of 20 patients (70%) stated that also itching worsened.

Feedback



FIGURE 1

Worsening of SD associated with long-time mask wearing



FIGURE 2

Worsening of SD associated with long-time mask wearing

In the last few weeks, some articles have been published on cases of dermatitis of the face associated with the use of anti-COVID-19 masks.[1], [2], [3], [4], [5] In a Chinese study, it was observed that 49% of subjects reported skin reactions on the face related to mask. Itch (14.9% of patients), erythema (12.6%), and dryness (11.6%) were the most frequent manifestations. Furthermore, 43.6% of patients with acne, 100% of patients with rosacea, and 37.5% of patients with SD reported exacerbation of their diseases.[1] A Polish study demonstrated that itching associated with the use of face mask was present in 19.6% of subjects. In particular, subjects with atopic dermatitis, SD, and acne were at significantly higher risk of itching development. Furthermore, subjects who wore masks for many hours per day reported itching more frequently.[2] A case of occupational allergic contact dermatitis caused by formaldehyde and 2-bromo-2-nitropropane-1,3-diol (bronopol) contained in a polypropylene surgical mask was published.[3] In another Chinese study, it was observed a significant increased flare of acne in individuals with long-time mask wearing (>4 hours per day over 2 months). The authors hypothesized that this condition is due to high temperature of the face covered by the mask that induces an increased sebum excretion rate: The latter increases by 10% for each 1°C rise.[4]

In our patients with SD, it is possible that high temperature of the face induces abnormalities of microbiota (proliferation of *Malassezia* spp.?) and permeability of skin barrier and increases sweating with irritant action and worsening of itching.

CONFLICT OF INTEREST

The authors declare there are no conflicts of interest—financial or otherwise—related to the material presented herein.

INFORMED CONSENT

Informed consent and permission for publication of medical images were taken from the patient.

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Multicenter Study Ital J Dermatol Venerol. 2022 Oct;157(5):419-423.
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Masks trigger facial seborrheic dermatitis and psoriasis: evidence from a multicenter, case-control study during COVID-19 pandemic

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Abstract

Background: Wearing masks is an optimal preventive strategy during COVID-19 pandemic, but it may increase facial sebum production. However, few case reports have described seborrheic dermatitis (SeBD) and psoriasis (PsO) flares due to masks. Hence, we conducted a multicenter study to clarify the possibility of increased SeBD and PsO flares in association with mask wearing during the COVID-19 pandemic.

Methods: This multicenter study enrolled patients with a diagnosis of facial SeBD and PsO. All dermatological consultations were conducted in teledermatology at baseline (T0) and after 1 month (T1) Of >6 hours/day wearing mask. PsO patients were assessed using PsO Area and Severity Index (PASI) and self-administered PASI (SAPASI), whilst SeBD patients with symptom scale of seborrheic dermatitis' (SSSD) and seborrheic dermatitis area and severity index (SEDASI).

Results: A total of 33 (20 males, 13 females, average age 43.61±9.86) patients with PsO and 33 (20 males, 13 females, average age 44.00±8.58) with SeBD were enrolled. After 1 month, PsO patients displayed higher values of both PASI and SAPASI ($P<0.0001$), while SeBD patients experienced a flare, as testified by the increment of both SSSD and SEDASI ($P<0.0001$). Mask type did not seem to influence the flare severity.

Conclusions: Masks remain an optimal preventive strategy during COVID-19 pandemic, but patients with PsO and SeBD may experience facial flares. Thus, therapeutic approach should be more aggressive in these groups of patients to counteract the triggering effect of masks.

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Eur J Dermatol. 2021 Apr 1;31(2):199-204. doi: 10.1684/ejd.2021.4007.

"Face mask dermatitis" due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care and non-health care workers in Germany

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Abstract

Background: During the COVID-19 pandemic, wearing face masks is mandatory not only for health care workers (HCWs) but also for the general population in many countries around the globe.

Objectives: The aim of the study was to investigate the onset of adverse facial skin reactions due to compulsory face masks during the COVID-19 pandemic in HCWs and non-HCWs, and draw awareness of this new dermatological condition and its preventive measures.

Materials & methods: A questionnaire was distributed to 550 patients and HCWs from the Department of Dermatology and Allergy of the University Hospital Munich (LMU), Germany. Participants were surveyed regarding mask type, duration of usage and adverse facial skin reactions. Information on symptoms and the use of skin care products and topical drugs were retrieved.

Results: The duration of wearing masks showed a significant impact on the prevalence of symptoms ($p < 0.001$). Type IV hypersensitivity was significantly more likely in participants with symptoms compared to those without symptoms ($p = 0.001$), whereas no increase in symptoms was observed in participants with atopic diathesis. HCWs used facial skin care products significantly more often than non-HCWs ($p = 0.001$).

Conclusion: Preventive and therapeutic measures should be established in order to avoid "face mask dermatitis", especially for people with underlying risk factors.

Keywords: COVID-19; SARS-CoV-2 pandemic; adverse skin reactions; face mask dermatitis; health care workers.

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Fungal contamination of medical masks among forensic healthcare workers in the COVID19 era

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Abstract

Background

Medical masks are widely used in health care settings to protect healthcare workers from respiratory infections, particularly in the context of the recent Covid-19 disease.

Methods

A cross-sectional study of 52 used masks collected from 52 forensic healthcare practitioners was conducted to culture for fungal isolation and identification. A study of fungal contamination was conducted by making an impression of the mouth mask cut piece on Sabouraud agar for selective isolation; each health worker completed a questionnaire, which included age, sex, type of mask, and duration of mask use.

Results

Twenty five of the 52 used masks tested positive for fungal contamination (48,08%). A total of 44% of the contaminated masks belong to health workers between the ages of 21–30 years. Surgical masks (80%), KN95 (8%), and N95 (4%) were the most contaminated protective devices. Usage duration of 1–2 h was associated with 4% of fungal contamination, while a usage duration

Feedback

of 5–6 h was associated with 36% of fungal contamination. *Alternaria* sp (32%), *Penicillium* sp (20%), *Aspergillus* sp (16%) were the most predominant isolated fungi discovered on the inside areas of the masks.

Conclusion

Because fungi are known to cause allergies and serious adverse health effects following recommendations to properly wear a medical mask is critical to preventing fungal contamination, especially among health care workers who are wearing the same mask for a long period during the pandemic.

Keywords: Mask contamination, Facemasks, Covid-19 protection, Fungal contamination, Forensic workers

1. Introduction

Because healthcare workers (HCws) are particularly vulnerable to Sars-Cov-2 exposure, wearing a facemask has become essential in the health care setting. According to the CDC guidelines, a surgical mouth mask is a personal protective barrier [1], and HCWs must wear them while performing their duties. Fungi are ubiquitous microorganisms that can be found in all parts of the world and can cause a wide range of diseases. Fungi that cause disease can enter the body through wounds, cuts, and burns, as well as the respiratory route. In addition to rhinitis, allergic bronchopulmonary mycosis, allergic fungal sinusitis, and asthma, fungus exposure has been linked to a number of other illnesses, the majority of which affect the nails or skin, causing rashes of skin conditions [2]. Manuscript (without author details) Click here to view linked References Various fungi including *Alternaria* sp*, Cladosporium* sp*,* and *Penicillium* sp [2], are traditionally associated with decay in an outdoor environment. Morbidity rates associated with fungal infections are a major public health concern. Medical masks were originally developed to filter droplets containing microorganisms expelled from the mouth [3]. In the health care setting, the most commonly worn are either the N95 mask or the surgical mask. This preliminary study aims to assess the fungal contamination of the internal part of facemasks used by forensic HCWs. Materiel and methods This cross-sectional study was carried out for one month (April 2020) in the forensic department of the university hospital of Sidi-Bel-Abbès, Algeria, to estimate the fungal contamination on used masks worn by the forensic HCWs. The subjects were recruited voluntarily for the study. An epidemiological survey was conducted during contact screening to collect information on all HCWs participants wearing masks, including gender, age, comorbidities, type of mask used, and duration of wearing. The subjects were permitted to carry out their normal work activities, but eating and physical exertion were not permitted. The study of fungal contamination was carried out by making an impression of the mouth mask cut piece on Sabouraud agar for selective isolation, blank medium were used to eliminate an environmental fungal contamination All samples were inoculated on SDA medium and incubated at 30°C for 7 to 14 days, to allow filamentous fungi and yeasts to grow. Identification of fungal contaminant species was based on macroscopic and microscopic features of growing colonies. Data were managed and analyzed using statistical software 17.0 (SPSS, Inc., Chicago, IL) Results A total of 52 participants were recruited, with 10 males and 42 females (

Table 1). Out of the 52 used masks collected, 25 were positive for fungal presence, the overall fungal contamination of used masks is 48,08%, and the majority of contaminated masks belong to males (80%). The age distribution is shown in Table 1.

Table 1

Prevalence and factors associated with fungal contamination of facemasks.

	Variable	fungal-	fungal +	%
Gender	Female	5	5	20,0%
	Male	22	20	80,0%
Age	21–30	12	11	44,0%
	31–40	11	9	36,0%
	41–50	3	3	12,0%
	51et +	1	2	8,0%
Type of mask	Surgical mask	27	22	88,0%
	KN95	0	1	4,0%
	N95	0	2	8,0%
Mask duration usage	1–2	4	1	4,0%
	3–4	9	8	32,0%
	5–6	3	9	36,0%
	7 et +	11	7	28,0%

Fungal contamination of used masks was demonstrated on the inside area of the used mask. The prevalence of fungal masks carriage was determined between the ages of 21 and 30 years old, as summarized in Table 1, and as further displayed in Table 1, the prevalence of masks fungal carriage is significant among young health workers. Table 2 shows the different fungi isolated from the medical mask, with *Alternaria* sp (32%), *Penicillium* sp (20%), *Aspergillus* sp (16%) being the most common.

Table 2

Fungal species isolated from used masks Identification.

Identification	N	%
Alternaria sp	8	32,0%
Penicillium sp	5	20,0%
Aspergillus flavus	2	8,0%
Aspergillus niger	2	8,0%
Trichophyton mentagrophytes	2	8,0%
Lichtheimia sp	1	4,0%
Candida non albicans	1	4,0%
Rhodotorula sp	1	4,0%
Fusarium sp	1	4,0%
Cladosporium sp	1	4,0%
non identified	1	4,0%
Total	25	100,0%

2. Discussion

This study was done during the pandemic of Covid-19 (Sars-Cov-2). Sidi Bel Abbes HCWs were advised to wear facemasks at work. Because mask protection is the most effective device against the Sars-CoV-2 pandemic, mask reuse and extended use are common in many parts of the world, particularly during outbreaks and pandemics [4,5]. Furthermore, due to mask shortage, patients were compelled to wear the same mask for several days. According to studies, proper use of medical masks and adherence to hygiene measures are associated with lower microorganism contamination. Fungal infections can occur anywhere there is warm, moist, and creased skin. The acceptance of a mask is influenced by the air, temperature, and humidity inside the mask [6]. The majority of infections are caused by inhaling droplet nuclei ranging from 1 to 5 μm [7,8]. The current study found that the high fungal contamination on the inside area of the used surgical masks was most likely related to mask-wearing duration, environmental contamination, or HCWs habits (handling masks in white coat pockets or their instrument trays). Fungi diseases are a persistent threat, with serious diseases caused by filamentous fungi constantly emerging or re-emerging. Numerous fungi were isolated from the used masks, implying that airborne fungi accumulated on the used masks [3]. The high prevalence of masks fungal carriage among young health workers can be attributed to the occlusive effect of the mask, to the physical activity, and high breathing rate which, creates a humid environment. The stress of working with dead bodies from Covid-19 is an additional source of high breathing rate in the forensic department, additionally, the resulting sweat can make the mask wet more quickly, making breathing difficult and promoting the growth of microorganisms. It is important to remember that in such situations, HCWs are more likely to wear

masks for an extended period of time and tend to re-use them, particularly in developing countries. This suggests a higher risk of masks contamination. Nonetheless, the difference in protective efficacy between facemasks and N95 respiratory is undeniable. These differences can be attributed to different material properties of the masks, such as lower air permeability, and water vapor permeability in the N95 respirator [9], moreover, N95 masks are more uncomfortable to wear compared to surgical masks and this may affect the contamination levels noted.

After 3 h of wearing, we noticed an increase in fungal contamination, which we believe was caused by temperature and humidity fluctuations. Wearing a facemask for a certain period may raise the temperature inside the oral cavity by reducing heat convection and evaporation from the mouth to the surrounding environment [10]. A fungal infection can thrive in the moist environment provided by the mask. During an outbreak of infectious diseases, like SARS and Sars-CoV-2 HCWs may be required to wear a mask for several hours, if not a day [10]. Furthermore, HCWs are wearing masks during their activities and even at home to avoid familial contamination, such reactions are reminiscent of behavior during the 2003 SARS outbreak, when not only the general public, but even close family members were afraid of being infected by HCWs exposed to the disease [11]. In addition, unsanitary re-use of face masks, particularly during the prevailing hot and humid weather was responsible for increasing the risk of Mucormycosis in India [12], and the genera Lichtheimia recovered in this study is considered as a proven Mucormycosis pathogen among immunosuppressed individuals. Additionally, an invasive mucormycosis due to *Lichtheimia* sp following tooth implants has already been reported in our medical center [13].

In all epidemiologic studies, mold exposure and dampness are considered together, with dampness is defined as sufficient moisture on or a substrate to support fungal growth [2]. The humidity content of the mask air was only significant when the mask air was warm [6]. Moreover, microorganisms can spread easily in spaces such as hospital wards. Furthermore, keeping the mouth mask in white coat pockets or instrument trays, as well as regular handling of the masks for adjustments and during a conversation, can be considered risk factors for masks contamination [14]. According to previous studies, the majority of the organisms isolated from the mouth-masks in this study were potentially pathogenic [12,[15], [16], [17]], 32% of all the colonies were identified as Alternaria, which are also considered to be outdoor airborne fungi. Along with the four most abundant isolated species, *Penicillium* sp*, Aspergillus flavus, Aspergillus niger*, and *Trichophyton mentagrophytes*. Likewise, Alternaria, and Cladosporium are known to cause allergies [2]. A link between fungi exposure and the risk of respiratory symptoms has already been established, regardless of sensitization [2]. Furthermore, in a study of adults with asthma, 76% of patients with multiple hospital admissions had at least one positive fungal skin test to Aspergillus, Alternaria, Cladosporium, and Penicillium genera [2], which were recovered in our study, and are considered as common outdoor fungi.

Recent studies in our hospital are suggesting a possible infectious role of these species among HIV, psychiatric and oncology inpatient [[17], [18], [19], [20]]. Moreover, most of these fungi were also isolated from patients wearing earmolds, and cockroaches trapped in several medical departments [15,21].

In several studies, the use of face masks has been linked to acne caused by an accumulation of *S. aureus*, moreover, acne, rosacea, and seborrheic dermatitis conditions can either be more prevalent or worsened [22,23]. *Trichophyton mentagrophytes* is linked to tinea and sycosis, and this finding may indicate a potential skin disorder in HCW mask wearers, which is supported by previous research [23]. It is also possible that face masks induce abnormalities of both local microbiota and skin barrier permeability [23]. Most common fungi, however, are frequently found indoors because they enter through open doors and windows and can be carried inside. While wearing a medical mask may have little or no clinical impact, however, it can be a source of fungal contamination in health care settings, particularly among immunosuppressed patients. What is still unknown is how much exposure is required (amount and duration), whether there is a dose-response, whether specific fungi genera are responsible for the effect, and whether intervention to reduce exposure would prevent health-related adverse effects. The microbial counts in indoor air are affected by a variety of factors, including velocity, humidity, temperature, ventilation, the number of occupants, people's activities, particulate matter or dust concentration, and the outdoor air quality [[24], [25], [26]]. To reduce the fungal contamination on the used masks, hospital environments should be improved, particularly microbial air quality in working wards. Wards in the unit should be cleaned regularly to prevent the growth of moisture-borne pathogens. To prevent microbial growth, avoid wet surfaces, keep relative humidity levels below 70%, use effective particulate filtration, good housekeeping, and operate and maintain HVAC system properly [27,28].

There are some limitations in this study that must be addressed, particularly the small sample size. Another issue is the source of fungal contamination, mycological results were based solely on the mask contamination not on the environment contamination, which may have probably influenced the findings. This would be more accurately estimated if PCR technique were applied on both masks and environment. In addition, in addition, we didn't investigate mask-wearing behavior at an individual level. More research is needed to evaluate the efficacy of mask-wearing in various settings. We are unable to confirm the source of contamination because other factors associated with fungal exposure may also influence any observed health effects. The Ethics Committee of the institution approved this study, and all participants provided informed consent. In this paper, we present an observational cross-sectional analysis of data collected from HCWs masks in April 2020.

3. Conclusion

In this study on fungal masks contamination, a wide variety of fungi were recovered. Wearing a mask for extended periods, especially on hot, humid summer days, can thus promote fungal contamination. The interesting findings in our study probably could be explained by the fact that wearing the same facemask for an extended period may promote fungal overgrowth. The establishment and implementation of health and safety standards, as well as monitoring of the work environment, should be considered.

4. Learning points

What is already known about this subject?

- Healthcare workers are on the front lines of the fight against covid19 pandemic. They are frequently at high risk of infection in the workplace and must wear mask protection for a long time.
- When assessing the risk of microbial mass contamination in healthcare workers, it is critical to understand when and how masks become infected in the hospital, whether by the environment or health workers.
  What this study adds:
- To the best of our knowledge, this is the first study on fungal contamination of face masks among HCWs so far.
- Healthcare workers may underestimate the risk of dermatophytes and airborne fungi and disregard protective measures during mask usage.
- Mask fungal carriage is significant and may have a substantial impact on fungal transmission in hospital settings. Although it was not a large-scale study, our findings may provide some hints on this issue.

What impact this may have on practice or policy:

- Our findings may raise worker awareness on the importance of using additional protective measures when wearing masks.
- Strengthening administrative control measures, improving mask quality, working environment, and limiting the duration of mask‘s wearing could have a significant impact on reducing its fungal load and some fungal adverse effects on health such as rhinitis.

CRediT authorship contribution statement

Yassine Merad: contributed in collecting, Formal analysis, the results, Writing – review & editing. **Zoubir Belmokhtar:** contributed in collecting, Formal analysis, the results, Writing – review & editing. **Malika Belkacemi:** contributed in collecting, Formal analysis, the results, Writing – review & editing. **Derouicha Matmour:** contributed in collecting, Formal analysis, the results, Writing – review & editing. **Zakaria Merad:** contributed to writing, Writing – review & editing. **Adila Bassaid:** contributed to writing, Writing – review & editing. **Ouziane Megherbi:** contributed to writing, Writing – review & editing.

Declaration of competing interest

We have no conflict of interest to declare.

Notes

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MYCOPATHOLOGIA IMAGE

"Mask" *Tinea*: An Increasing Infection during COVID-19 Pandemic

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Since the onset of Coronavirus Disease-19 (COVID-19) pandemic, our lifestyle habits have changed dramatically. The use of face masks for many hours per day, necessary to limit the risk of virus transmission, is surely one of them. It has been reported that, because of occlusive effects of masks on the skin, some dermatitis of the face, such as acne, rosacea and seborrheic dermatitis, often worsen. In addition to these diseases, we also observed an increased number of cases of *tinea faciei*, a very rare infection among adults in the metropolitan area of Milan, with only 19 diagnosed cases in the decade 2005–2015. We report seven patients (5 males and 2 females, with an age ranging from 33 to 71 years; mean age: 54 years) with *tinea faciei* involving the area of the face covered by masks, collected in the period from October 2020 to September 2021. All patients used face masks for more than 6 h a day and they wore the same mask for up to ten days (mean usage of the same mask: 6 days). Clinical picture was superimposable in all patients: unilateral, erythematous-squamous lesions, with raised and well-defined borders, involving the area of the face covered by mask (Fig. 1). All patients complained of mild pruritus. After the diagnosis with direct microscopical examinations using 20% potassium hydroxide, fungal identification was performed both with fungal culture on Sabouraud Dextrose Agar and chloramphenicol (SDA + CAF) and with matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS). The causative agent was *Trichophyton mentagrophytes* in 3 patients, *Trichophyton rubrum* in 3 patients and *Microsporum canis* in one case. In five patients the skin of the feet and toenails were also involved by the same agent found in the lesions of the face (*Trichophyton rubrum* in 3 patients and *Trichophyton mentagrophytes* in 2 patients). In one case the suspected source of infection was the patient's pet (a recently bought dog). In the last patient the possible cause was not found. All cases were successfully treated with a combination of topical antifungals (azoles or allylamines) daily for 4 weeks, and terbinafine 250 mg/day for 2 weeks. Follow-up (1–12 months) was negative in all patients.

Face masks induce an increase of temperature of the epidermis: this increases sweating, with irritant action and worsening of pruritus. Furthermore, breath creates a humid environmental. Taken together, these two conditions create the best growth environment for the dermatophytes responsible for *tinea faciei*. It is also possible that face masks induce abnormalities of both local microbiota and permeability of the skin barrier: the latter allows the penetration of fungi. Poor personal hygiene and the use of the same mask for many days can promote the infection. To our



Fig. 1 Erythematous-squamous lesions, with raised, well-defined borders, involving the area of the face covered by masks: "mask" *tinea faciei*

knowledge, only one report of *tinea faciei* associated with the use of face masks has been published so far; however, it is possible that this infection will be observed more frequently in the next future, due to the almost worldwide obligation to wear face mask against COVID-19. We suggest a complete mycological investigation to find all possible reservoirs. It is also important to insist on the necessity of a face mask daily change and careful cleaning of face, hands and feet.

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Declarations

Conflict of interest We declare that we have no conflicts of interest.

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Masking Mandates

Kl2 <kljohnson.2@gmail.com>
Wed 3/20/2024 6:43 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

To the Rhode Island Department of Health,

I am sending this letter in regards to the mask mandates. I am opposed to any mandate this state wants to implement. Having said that, I will leave a short note about myself and my reasoning. I am a long life resident of R.I., born and raised in Providence and attended the Providence public school systems as well. I am a grandmother of four who all attend public school in R.I., all of them under the age of 10. All of my grandchildren have been greatly affected by the disturbances of the school closures and then the mask having to be worn. Two of my grandchildren have speech difficulties to begin with and having the mask on them and their teachers was extremely unproductive to their learning. The grades suffered and so did their self esteem. Never again will the state of R.I. be able to put these stipulations on them, I will pull them from the public sector and homeschool them myself. Instead of carrying on here on paper, I will end this note with this short document I was able to find recently. Lesson #6, has to do with masking and just how wrong our government behaved. I also sent the link, in case you all like to educate yourselves with the real science.
In closing, I wanted to state, this hearing should have been held at a time where most working parents and grandparents would be able to attend. Having the hearing at 0900 on any workday is extremely insensitive to the people that you actually work for.

Lesson #6: Masks Were of Little or No Value and Possibly Harmful There was no high-quality evidence in support of community masking for respiratory viruses in spring 2020; in fact, the randomized clinical trials regarding masking for influenza found it to be ineffective for protecting the wearer and for preventing spread. Unfortunately, rather than commission cluster randomized controlled trials to produce high-quality evidence on masking with respect to SARS-CoV2, global and US public health authorities overstated the benefits of masking and persisted even as evidence to the contrary accumulated. Mask mandates were likely imposed as a way to calm people's fears and help them re-engage in society. But they ended up doing the opposite – amplifying fears by creating the irrational belief that an unmasked face presented a threat, causing conflict and division among citizens, and giving high-risk people the mistaken impression that masks were protective, potentially resulting in some people risking exposure who otherwise may not have. The CDC continues to recommend, contrary to evidence, masking for respiratory viruses, undermining its credibility.

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COMMITTEE TO UNLEASH PROSPERITY



March 2024

COVID Lessons Learned

A Retrospective After Four Years

By Scott W. Atlas, Steve H. Hanke, Philip G. Kerpen, and Casey B. Mulligan

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Executive Summary

This report reviews the major policy errors and lessons learned during the COVID pandemic from a balanced perspective that includes health, economic, educational, and civil liberty considerations.

We outline ten key lessons that must be learned to avoid mistaken policy responses to future pandemics and other crises.

Lesson #1: Leaders Should Calm Public Fears, Not Stoke Them

Conventional wisdom pre-COVID was that communities respond best to pandemics when the normal social functioning of the community is least disrupted. During COVID, the public health establishment followed the opposite principle: they intentionally stoked and amplified fear, which overlaid enormous economic, social, educational, and health harms on top of the harms of the virus itself.

Non-COVID excess deaths from lockdowns and societal panic are estimated at about 100,000 per year in the United States and zero in non-lockdown Sweden.

Lesson #2: Lockdowns Do Not Work to Substantially Reduce Deaths or Stop Viral Circulation

Most lockdown measures were realized around the time when hospitalizations peaked, which due to the time-lag between infection and severe disease, necessarily occurs well after the infective peak. They were timed to claim credit for declining waves, but rarely had any discernible causal impact.

A comprehensive literature review was conducted by Herby, Jonung, and Hanke and published in an authoritative, peer-reviewed book by the Institute of Economic Affairs in London. The Herby-Jonung-Hanke Johns Hopkins research found: "lockdowns in the spring of 2020 had a negligible effect on COVID-19 mortality. This result is consistent with the view that voluntary changes in behavior, such as social distancing, did play an important role in mitigating the pandemic."

A much wiser strategy than issuing lockdown orders would have been to tell the American people the truth, stick to the facts, educate citizens about the balance of risks, and let individuals make their own decisions about whether to keep their businesses open, whether to socially isolate, attend church, send their children to school, and so on.

Lesson #3: Lockdowns and Social Isolation Had Negative Consequences that Far Outweighed Benefits

According to the World Bank, "Mobility restrictions, lockdowns, and other public health measures... produced the largest global economic crisis in more than a century."

In a comprehensive and authoritative review of lockdown harms, Kevin Bardosh concludes:

"The promotion of lengthy social distancing restrictions by governments and scientific experts during the Covid crisis had severe consequences for hundreds of millions of people. Many original predictions are broadly supported by the cumulative research data presented above: a rise in non-Covid excess mortality, mental health deterioration, child abuse and domestic violence, widening global inequality, large increases in debt, food insecurity, lost educational opportunities, unhealthy lifestyle behaviours, increased loneliness and social polarization, democratic backsliding and human rights violations… The pandemic response leaves behind a legacy of poverty, mental health illness, learning loss, debt, food insecurity, social polarization, erosion of respect for human rights and elevated excess mortality for non-Covid health conditions."

The employment impact in the United States was staggering, with lockdowns putting over 49 million Americans out of work according to Bureau of Labor Statistics (BLS) survey data, and over two million remaining out of work due to COVID closures as recently as July 2022.

This enormous unemployment shock has health as well as economic consequences. An NBER study found that the lockdown unemployment shock is projected to result in 840,000 to 1.22 million excess deaths over the next 15 to 20 years, disproportionately killing women and minorities.

In contrast, Jonung and Andersson compare the health and economic outcomes in Sweden, commonly viewed as an outlier relying more on recommendations and voluntary adjustments than on strict lockdowns, to the United States and comparable European OECD countries. Their results suggest that the Swedish policy of advice and trust in the population to reduce social interactions voluntarily was relatively successful. Sweden combined low excess death rates with relatively small economic costs. In future pandemics, policymakers should rely on empirical evidence rather than panicking and adopting extreme measures.

Lesson #4: Government Should Not Pay People More Not to Work

Congress authorized $600 per week unemployment bonuses early in the pandemic, despite warnings that the consequences would be substantial, prolonged unemployment and associated economic underperformance. The evidence shows conclusively that bonuses for not working increased unemployment rates, which plunged rapidly when the original $600 bonus ended, before stalling when a $300 bonus took effect.

Lesson #5: Shutting Down Schools Was a Major Policy Mistake With Tragic Effects on Children, Especially the Poor

The case for opening schools was widely known throughout the world by spring/summer 2020, but teacher unions pressured authorities to close schools.

The harms to children of closing in-person schooling are dramatic and irrefutable. The shutdowns caused serious harm to children, including poor learning, school drop-out, social isolation, mental illness, drug abuse, suicidal ideation, and 300,000 cases of child abuse unreported in spring 2020.

These harms were most severe for lower income and minority students.

The original round of global school closures is estimated by the United Nations to result in $17 trillion in lost lifetime earnings for students, equal to about 14 percent of current world GDP.

Lesson #6: Masks Were of Little or No Value and Possibly Harmful

There was no high-quality evidence in support of community masking for respiratory viruses in spring 2020; in fact, the randomized clinical trials regarding masking for influenza found it to be ineffective for protecting the wearer and for preventing spread. Unfortunately, rather than commission cluster randomized controlled trials to produce high-quality evidence on masking with respect to SARS-CoV2, global and US public health authorities overstated the benefits of masking and persisted even as evidence to the contrary accumulated.

Mask mandates were likely imposed as a way to calm people's fears and help them re-engage in society. But they ended up doing the opposite – amplifying fears by creating the irrational belief that an unmasked face presented a threat, causing conflict and division among citizens, and giving high-risk people the mistaken impression that masks were protective, potentially resulting in some people risking exposure who otherwise may not have.

The CDC continues to recommend, contrary to evidence, masking for respiratory viruses, undermining its credibility.

Lesson #7: Government Should Not Suppress Dissent or Police the Boundaries of Science

A poisonous interplay between America's media, Big Tech, and the academic science and public health community has severely harmed the public. Scientists used the media to bully others, and the media gave them the imprimatur of "the experts" to disparage the opposing views.

Censorship took many forms, including legacy media, social media, preprint servers, and university campuses. Scientific journals published character smears and social media actively suffocated voices that dissented from the accepted COVID narrative.

Anthony Fauci, the head of the largest federal grantmaking entity, created an environment in which it was very difficult for most medical experts to break with the dominant narratives on lockdowns, masks, or overwhelmed hospitals. The National Institutes of Health (NIH) became the principal advocate of lockdown policies, but failed to run high-quality trials of repurposed drugs and non-pharmaceutical interventions.

Lesson #8: The Real Hospital Story Was Underutilization

The tragedy of the non-COVID death pandemic was in large part driven by record-low hospital utilization - with very few exceptions - throughout the entire pandemic period. This was a result of public health messaging and political orders canceling medical procedures and intentionally stoking fear, causing people to cancel their own appointments for serious medical care.

The U.S. Department of Health and Human Services (HHS) data show that COVID waves rarely moved topline inpatient utilization, and that the total number of staffed beds steadily declined during the pandemic. The COVID utilization numbers from HHS are overstated because the agency has refused to differentiate causal from incidental COVID.

This underutilization was likely a significant contributor to non-COVID excess deaths in the United States.

Lesson #9: Protect the Most Vulnerable

One of the most striking features of the earliest COVID morbidity and mortality data was a profound differential in risk between the old and the young.

When specific populations are known to have a high risk for death or serious illness, a strategic use of resources to heighten their protection and awareness should be employed. Specific steps might include: prioritized testing to nursing homes and senior centers; high-frequency testing of all nursing home staff and visitors; extra infection control standards in nursing homes, in alliance with hospitals; frequent monitoring and alert outreach to high-risk seniors in communities and nursing homes when infections are high.

Lesson #10: Warp Speed: Deregulate But Don't Mandate

Project Warp Speed developed multiple highly effective monoclonal antibody treatments and vaccines in record time, but there were multiple failures.

NIH failed to conduct randomized trials of low-cost repurposed drugs, and government monopoly purchasing and distribution of monoclonal antibodies created chronic shortages and politicized distribution decisions, which led to the announcement that Regeneron would be rationed in the South, where it was needed, due to concerns for "equitable distribution, both geographically and temporally."

The vaccines were a deregulatory triumph, because they were developed quickly and had a favorable risk/benefit profile for high-risk populations.

However, the safety of new drugs should have been prioritized and assessed in a far more detailed and thorough manner. This is especially critical in new technologies like the mRNA vaccines. Beyond a failure to assess safety, the failures regarding vaccines included a lack of transparency on what endpoints were assessed, overstatement of benefits, and an all-out "vaccinate everyone" pressure campaign, including mandates, that undermined informed consent.

Conclusion: Limit Government Emergency Powers and Earn Back Public Trust

One result of the government's error-ridden COVID response was that Americans have justifiably lost faith in public health institutions. Lockdowns, school closures, and mandates were catastrophic errors, pushed with remarkable fervor by public health authorities at all levels.

We recommend that Congress and the states define by law "public health emergency" with strict limitations on powers conferred to the executives and time limits that require legislation to extend. Additionally, term limits should be established for all senior health agency positions.

Grantmaking should be independent of policy-making and public communication, and NIH funding itself should be decentralized or block-granted to the states.

Congress should require full transparency of all Food and Drug Administration (FDA), CDC, and NIH discussions with immediate posting to public forums. In addition, statements from all advisors in those meetings should be made widely visible to the public.

It should be definitively restated that CDC guidance is strictly advisory and the CDC does not have power to set laws or mandates.

The U.S. should halt all binding agreements with the World Health Organization until satisfactory transparency and accountability is achieved.

Unless and until key institutions openly acknowledge that lockdowns, school closures, and mask/vaccine mandates were catastrophic errors that will not be repeated in the future, the American people will – and should – withhold their trust.

Lesson #1: Leaders Should Calm Public Fears, Not Stoke Them

SARS-CoV2 was a dangerous virus, but a calm, proportionate response would have applied the lessons from past influenza pandemics and used existing pandemic response plans. Instead, from the moment the virus was detected in America, the public health community and politicians spread an outsized message of fear and doom.

Conventional wisdom pre-COVID was best summarized in a 2006 paper co-authored by the legendary Johns Hopkins professor of public health D.A. Henderson, who led the global campaign for smallpox eradication:

> *"**An overriding principle**. Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted. Strong political and public health leadership to provide reassurance and to ensure that needed medical care services are provided are critical elements. If either is seen to be less than optimal, a manageable epidemic could move toward catastrophe."*[1]

During COVID, the U.S. and most other countries followed for the most part the precisely opposite principle: Rather than calm fears, public health authorities, political leaders, and media stoked and amplified fear out of all proportion. This fundamental misstep set the stage for other substantial errors. It overlaid enormous economic, social, educational, and health (including substantial non-COVID excess mortality) harms on top of the virus itself, which nonetheless worked its way through substantially all of the population.

Francis Collins, the director of the National Institutes of Health until his 2023 retirement, acknowledged this stunning failure in a surprisingly frank statement:

> *"As a guy living inside the Beltway, feeling a sense of crisis, trying to decide what to do in some situation room in the White House… weren't really considering the consequences in communities that were not New York City or some other big city… If you're a public health person and you're trying to make a decision, you have this very narrow view of what the right decision is, and that is something that will save a life. It doesn't matter what else happens. So you attach infinite value to stopping the disease and saving a life.* ***You attach a zero value to whether this actually totally disrupts people's lives, ruins the economy, and has many kids kept out of school in a way that they never quite recovered****… This is a public health mindset. And I think a lot of us involved in trying to make those recommendations had that mindset, and that was really unfortunate. It's another mistake we made. Okay."*[2]

Collins had been warned early – but he and the rest of the key public health leaders ignored the warnings. In March 2020 three nationally visible publications called for "targeted protection:" Ioannidis in *Stat*[3], Atlas in

1 Inglesby, T., Nuzzo, J., O'Toole, T., & Henderson, D. A. (2006). Disease Mitigation Measures in the Control of Pandemic Influenza. Biosecurity and Bioterrorism, 4(4). https://doi.org/10.1089/bsp.2006.4.366

2 Braver Angels. (2023, July 10). A Deplorable and an Elitist Walk into a Bar: Francis Collins and Wilk Wilkinson [Video]. YouTube. https://youtu.be/W1eAvh1sWiw?si=9aHC4JMkFFlJlXnC

3 Ioannidis, J. P. A. (2020, March 17). A fiasco in the making? As the coronavirus pandemic takes hold, we are making decisions without reliable data. Stat News. https://www.statnews.com/2020/03/17/a-fiasco-in-the-making-as-the-coronavirus-pandemic-takes-hold-we-are-making-decisions-without-reliable-data/

Washington Times[4], and Katz in the *New York Times*.[5] In testimony to the Senate on May 6, 2020, Ioannidis, Atlas, and Katz independently in the same session testified that intentional societal disruption via lockdown was both scientifically wrong and destructive.[6]

The results were tragic. Casey Mulligan and Rob Arnott examined two years of death certificates and found a second man-made pandemic imposed on top of COVID by the "panic" response:

> "It should be no surprise that a widespread disruption to patient circumstances would degrade health and even elevate mortality from chronic conditions… During the pandemic, elective procedures were canceled, including colonoscopies and lung cancer CT screenings, and many other procedures, which have saved countless lives through early detection…
>
> "From April 2020 through the end of 2021, Americans died from non-Covid causes at an average annual rate of 97,000 in excess of previous trends for a cumulative total of 52 per 100,000 population through the end of 2021. Presumably excess mortality continues into calendar year 2022.
>
> Summing our estimates across causes and age groups, we estimate 171,000 excess non-Covid deaths through the end of 2021."[7]

Mulligan and Arnott note that Sweden, which followed traditional pandemic response principles with a focus on maintaining calm and a normally functioning society and health care system, experienced no non-COVID excess death.

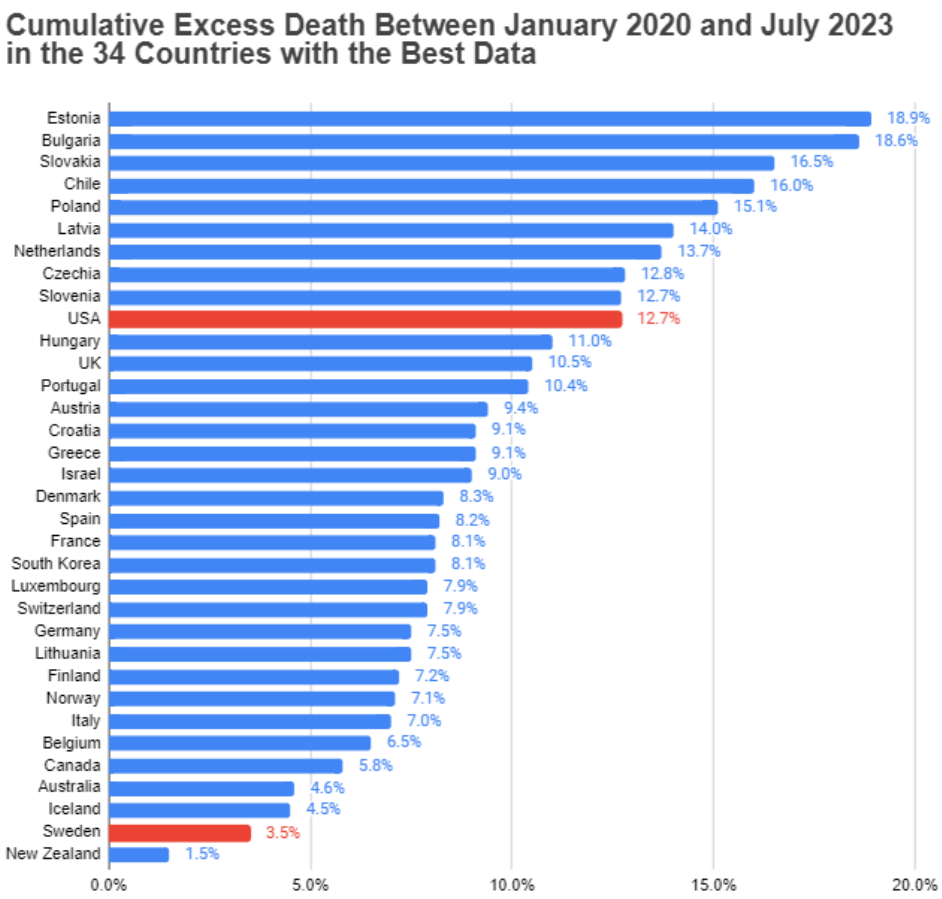
Indeed, Sweden, which rejected lockdowns, experienced cumulative excess mortality during the pandemic period that according to some calculations was among the lowest in the world:

4 Atlas, S. W. (2020, March 26). Widespread isolation and stopping all human interaction will not contain the COVID-19 pandemic. The Washington Times. https://www.washingtontimes.com/news/2020/mar/26/widespread-isolation-and-stopping-all-human-intera/

5 Katz, D. L. (2020, March 20). Is Our Fight Against Coronavirus Worse Than the Disease? New York Times. https://www.nytimes.com/2020/03/20/opinion/coronavirus-pandemic-social-distancing.html

6 Senate Committee on Homeland Security and Government Affairs. (2020, May 6). COVID-19: How New Information Should Drive Policy. https://www.hsgac.senate.gov/hearings/covid-19-how-new-information-should-drive-policy/

7 Mulligan, C., & Arnott, R. (2022). The Young were not Spared: What Death Certificates Reveal about Non-Covid Excess Deaths. INQUIRY: The Journal of Health Care Organization, Provision, and Financing. https://doi.org/10.1177/00469580221139016



Source: Ioannidis, J. P. A., Zonta, F., & Levitt, M. (2023). Variability in excess deaths across countries with different vulnerability during 2020–2023. Proceedings of the National Academy of Sciences of the United States of America, 120(49). https://doi.org/10.1073/pnas.2309557120

Ioannidis, Zonta, and Levitt note: "The United States of America would have had 1.60 million fewer deaths if it had the performance of Sweden, 1.07 million fewer deaths if it had the performance of Finland, and 0.91 million fewer deaths if it had the performance of France."[8]

Jonung and Hanke found that Sweden's exceptionalism rests on both its formal written constitution and the high degree of trust infused in the country's customs and habits. The Swedish constitution (the Regeringsform of 1634), insulates Sweden's public institutions from political meddling to a much greater degree than most other democracies. Furthermore, the Regeringsform protects Swedes against the depravations of personal liberty and guarantees their freedom of movement within the realm.[9]

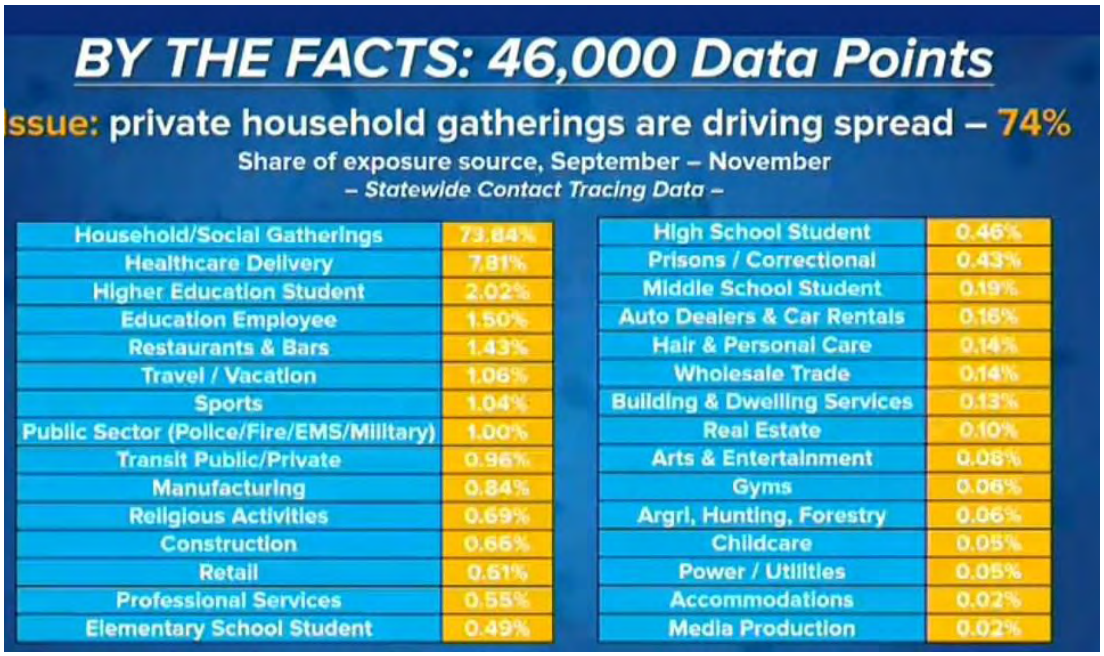
8 Ioannidis, J. P. A., Zonta, F., & Levitt, M. (2023). Variability in excess deaths across countries with different vulnerability during 2020–2023. Proceedings of the National Academy of Sciences of the United States of America, 120(49). https://doi.org/10.1073/pnas.2309557120

9 Jonung, L., & Hanke, S. H. (2020). Freedom and Sweden's Constitution. The Wall Street Journal. https://www.wsj.com/articles/freedom-and-swedens-constitution-11589993183

Lesson #2: Lockdowns Do Not Work to Substantially Reduce Deaths or Stop Viral Circulation

The wholesale suspension of fundamental civil and human rights – to move freely, to engage in commerce, recreation, worship, etc. – was unthinkable in the United States prior to COVID, and with good reason. We should have known that suspension of rights, which has commonly become known as "lockdowns," would be ineffective, because infectious disease response is no exception to the usual rule that freedom produces better outcomes than central planning. Businesses have strong incentives and efficiencies to reduce transmission that people cannot replicate in their own homes.[10]

Ironically, Governor Andrew Cuomo showed this slide indicating that 74 percent of transmission in New York was in private homes – two minutes before ordering a second closure of New York restaurants.[11]



Source: Daily Mail. (2020, December 11). 'The final nail in the coffin for NYC restaurants': Indoor dining will STOP on Monday despite it causing less than 1.34% of new COVID cases. https://www.dailymail.co.uk/news/article-9044211/Indoor-dining-New-York-City-STOP-Monday.html

10 Mulligan, C. B. (2021). The Backward Art of Slowing the Spread? Congregation Efficiencies during COVID-19. University of Chicago, Becker Friedman Institute for Economics Working Paper No. 2021-51. https://ssrn.com/abstract=3832326 or http://dx.doi.org/10.2139/ssrn.3832326

11 Daily Mail. (2020, December 11). 'The final nail in the coffin for NYC restaurants': Indoor dining will STOP on Monday despite it causing less than 1.34% of new COVID cases. https://www.dailymail.co.uk/news/article-9044211/Indoor-dining-New-York-City-STOP-Monday.html

Moreover, most lockdown measures came around the time when hospitalizations peaked, which due to the time-lag between infection and severe disease, necessarily occurs well after the infective peak. They were timed to claim credit for declining waves, but rarely had any discernible causal impact.

A comprehensive literature review and meta-analysis was conducted by Herby, Jonung, and Hanke and published in an authoritative, peer-reviewed book by the Institute of Economic Affairs in London. The Herby-Jonung-Hanke Johns Hopkins research found that:

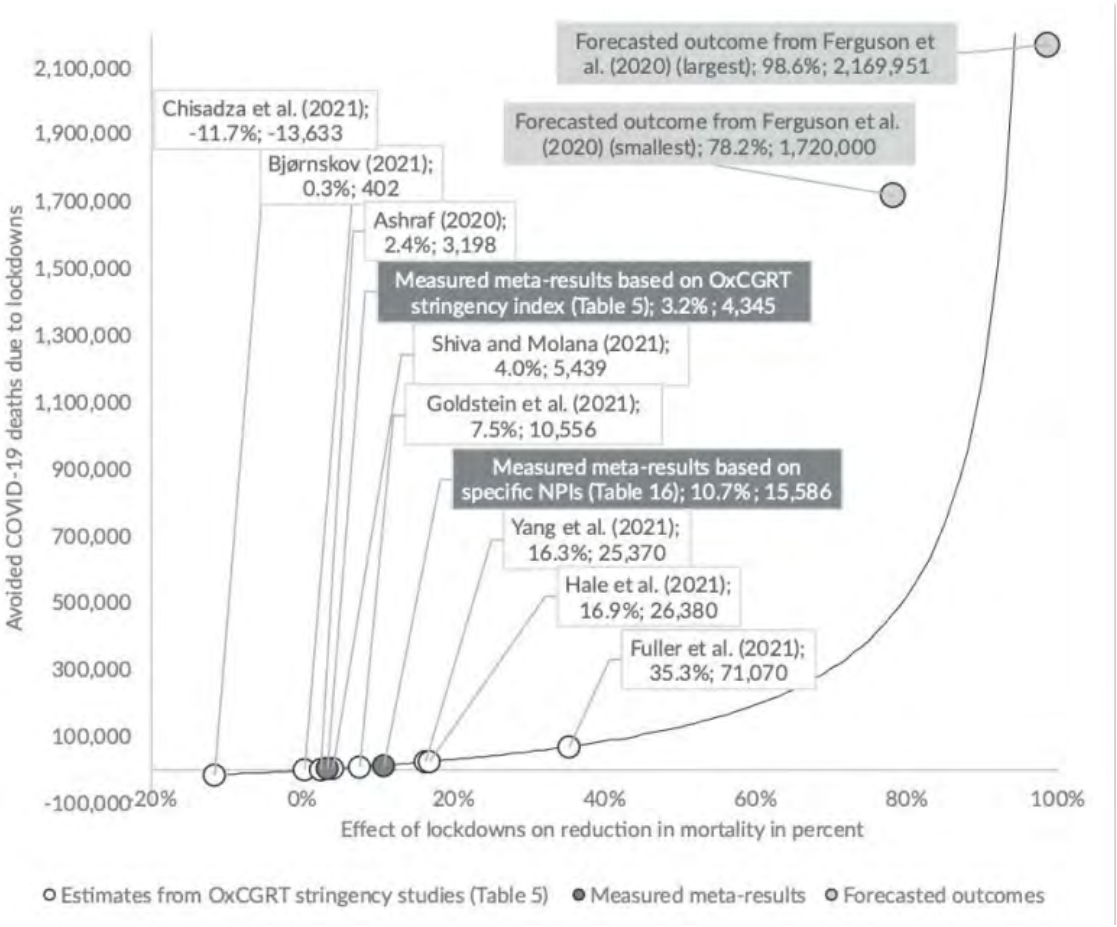
> Stringency index studies find that the average lockdown in Europe and the United States in the spring of 2020 only reduced COVID-19 mortality by 3.2 per cent. This translates into approximately 6,000 avoided deaths in Europe and 4,000 in the United States. SIPOs [shelter-in-place orders] were also relatively ineffective in the spring of 2020, only reducing COVID-19 mortality by 2.0 per cent. This translates into approximately 4,000 avoided deaths in Europe and 3,000 in the United States. Based on specific NPIs [non-pharmaceutical interventions], we estimate that the average lockdown in Europe and the United States in the spring of 2020 reduced COVID-19 mortality by 10.7 per cent. This translates into approximately 23,000 avoided deaths in Europe and 16,000 in the United States. In comparison, there are approximately 72,000 flu deaths in Europe and 38,000 flu deaths in the United States each year. When checked for potential biases, our results are robust. Our results are also supported by the natural experiments we have been able to identify. The results of our meta-analysis support the conclusion that lockdowns in the spring of 2020 had a negligible effect on COVID-19 mortality. This result is consistent with the view that voluntary changes in behaviour, such as social distancing, did play an important role in mitigating the pandemic.[12]

Figure 10 from the Herby-Jonung-Hanke book presents the effect of lockdowns on mortality in the United States based on the measured estimates from all stringency studies included in the Herby-Jonung-Hanke meta-analysis as well as Herby-Jonung-Hanke's two central measured estimates for the effect of lockdowns in the spring of 2020 (the precision-weighted average from the stringency studies and the estimate based on specific NPIs). In addition, and importantly, Herby, Jonung, and Hanke have included the maximum and minimum forecasted estimates from the epidemiological modeling exercises conducted by Ferguson et al. at Imperial College London (ICL). Even if the most extreme empirical estimate of the effects of lockdowns on mortality is picked, the measured effect of lockdowns is orders of magnitude less than those generated by ICL and their epidemiological modeling exercises.[13]

12 Herby, J., Jonung, L., & Hanke, S. H. (2023, June). Did Lockdowns Work? The verdict on Covid restrictions. IEA Perspectives 1. https://iea.org.uk/wp-content/uploads/2023/06/Perspectives-_1_Did-lockdowns-work__June_web.pdf

13 Ibid.

Divergence between avoided number of deaths in the United States as measured by the meta-results, studies based on the OxCGRT stringency index, and the forecasted outcome from Imperial College London



Source: Herby, J., Jonung, L., & Hanke, S. H. (2023, June). Did Lockdowns Work? The verdict on Covid restrictions. IEA Perspectives 1. https://iea.org.uk/wp-content/uploads/2023/06/Perspectives-_1_Did-lockdowns-work__June_web.pdf

The importance of the fatality estimates generated by the ICL's epidemiological models can't be overstated. It was those estimates of between 1.7 and 2.2 million deaths in the United States that sent officialdom into a state of panic. It is also worth noting that the ICL's flawed epidemiological models have a long track record of generating hair-raising predictions of disaster that have missed the mark, set off panic, and motivated officialdom to implement a variety of ill-conceived lockdown policies.

That dreadful record started with the U.K. foot-and-mouth disease epidemic in 2001, during which the ICL modelers persuaded the government to adopt a policy of mass animal slaughter. Their model predicted that daily case incidences would peak at about 420. At the time, the number of incidences had already peaked at just over 50 and was falling. The prediction missed its mark, and as many as 10 million animals, most of which could have been vaccinated, were needlessly killed.

Shortly thereafter, in January 2002, the ICL's epidemiological models suggested that up to 150,000 people in the U.K. could die from mad cow disease. As it turned out, the total number of U.K. deaths was 178 – another miss for the ICL team.

Then, in 2005, ICL's Ferguson suggested that "up to around 200 million" could die from bird flu globally. He justified this claim by comparing the lethality of bird flu to that of the 1918 Spanish flu outbreak, which killed 40 million. By 2021, bird flu had killed 456 people worldwide, making it ICL's biggest miss yet.

The ICL team was back at it again in 2009 when they claimed that 65,000 people could die of swine flu in the U.K. By the end of March 2010, the outbreak had killed fewer than 500 people before petering out – yet another big miss.[14]

The computer models that scared most of the world into lockdown were wildly wrong by any reasonable measure, but lockdowns were one of the principal causes of the panic and fear that drove non-COVID health harms, as well as imposing massive economic and social harms. It's clear that in future planning and reactions to the onset of pandemics, policymakers should view epidemiological models with a great deal of skepticism. In the past, these models have been nothing more than fear machines that generate alarming fantasy numbers.

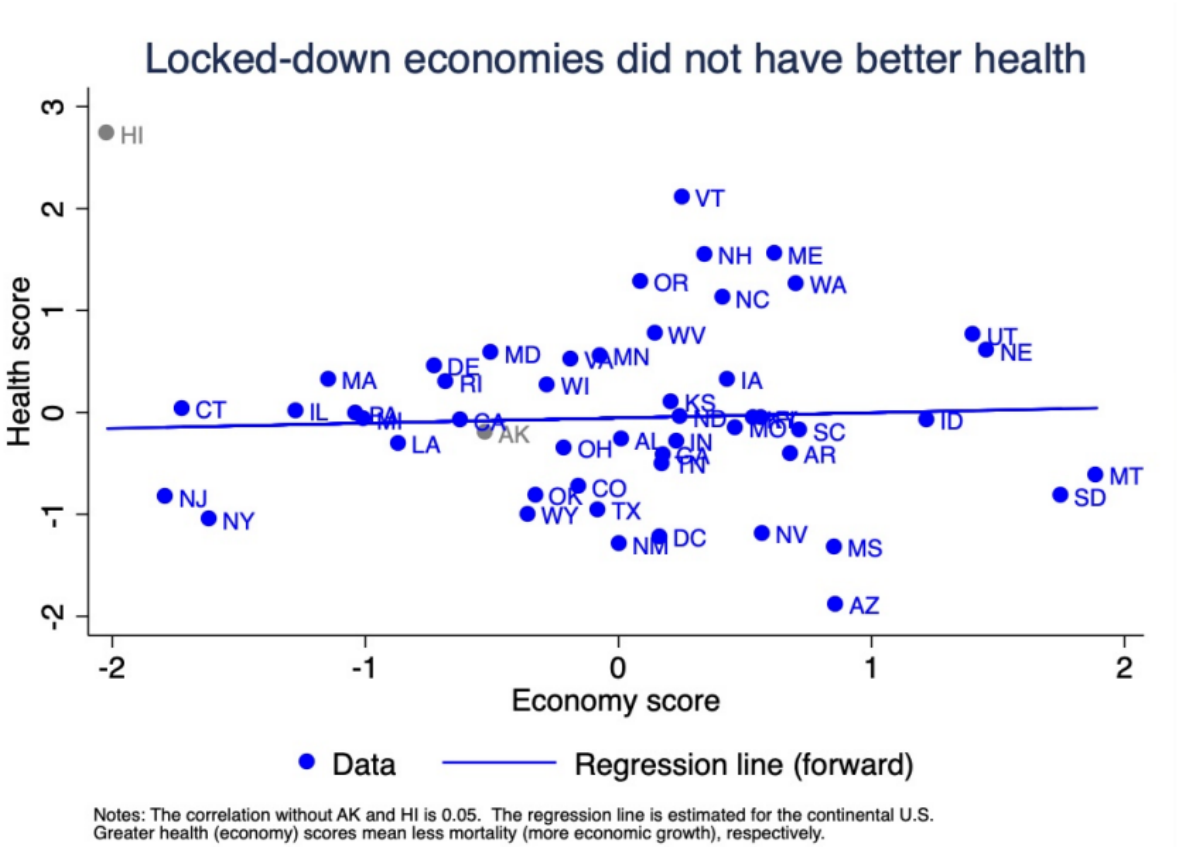
In the US context specifically, Committee To Unleash Prosperity analysis of state economic and health performance during the pandemic analysis found no correlation between withdrawing from economic activity and mortality, indicating lockdowns were all pain and no gain.[15]

14 Hanke, S. H., & Dowd, K. (2022). Imperial College's Fear Machine. National Review. https://www.wsj.com/articles/freedom-and-swedens-constitution-11589993183

15 Kerpen, P., Moore, S., & Mulligan, C. (2022, April). A Final Report Card on the States' Response to COVID-19. National Bureau of Economic Research Working Paper Series No. 29928. https://doi.org/10.3386/w29928

The Relationship Between Mortality, Education, and Economy Scores

Excluding the geographically unusual cases of Hawaii and Alaska to focus on the continental U.S., there is no apparent relationship between reduced economic activity during the pandemic and our composite mortality measure.



Notes: The correlation without AK and HI is 0.05. The regression line is estimated for the continental U.S. Greater health (economy) scores mean less mortality (more economic growth), respectively.

Source: Kerpen, P., Moore, S., & Mulligan, C. (2022, April). A Final Report Card on the States' Response to COVID-19. National Bureau of Economic Research Working Paper Series No. 29928. https://doi.org/10.3386/w29928

It's noteworthy that one of the most prominent US lockdown advocates has admitted error. University of Minnesota epidemiology professor Michael Osterholm, who in November 2020 recommended a hard national lockdown[16] concluded in October 2023: "There is actually no role for lockdowns."[17]

The UK COVID Inquiry recently concluded lockdowns worked by suppressing the best available evidence. The Inquiry refused to include the Herby-Jonung-Hanke book despite it being an authoritative assessment of

16 Feuer, W. (2020, November 14). Biden Covid advisor says U.S. lockdown of 4 to 6 weeks could control pandemic and revive economy. CNBC. https://www.cnbc.com/2020/11/11/biden-covid-advisor-says-us-lockdown-of-4-to-6-weeks-could-control-pandemic-and-revive-economy.html

17 Nocera, J., & McLean, B. (2023, October 30). COVID lockdowns were a giant experiment. It was a failure. New York Magazine. https://nymag.com/intelligencer/article/covid-lockdowns-big-fail-joe-nocera-bethany-mclean-book-excerpt.html

lockdown effectiveness. U.K. COVID Inquiry Secretary Ben Connah asserted that Thomas Hale covered the material in the book.[18] Hale, however, includes studies that do not answer the question about the effectiveness of lockdowns, confuses statistical significance with significance in size (As seen in Herby-Jonung-Hanke's Figure 10, his own study only finds that lockdowns avoided approximately 26,000 deaths during the first wave), and does not refer to or engage the findings of Herby-Jonung-Hanke. Only by excluding the best available evidence did the U.K. COVID Inquiry reach the incorrect conclusion that lockdowns were effective and that the only mistake was that lockdowns should have been imposed earlier than they were.

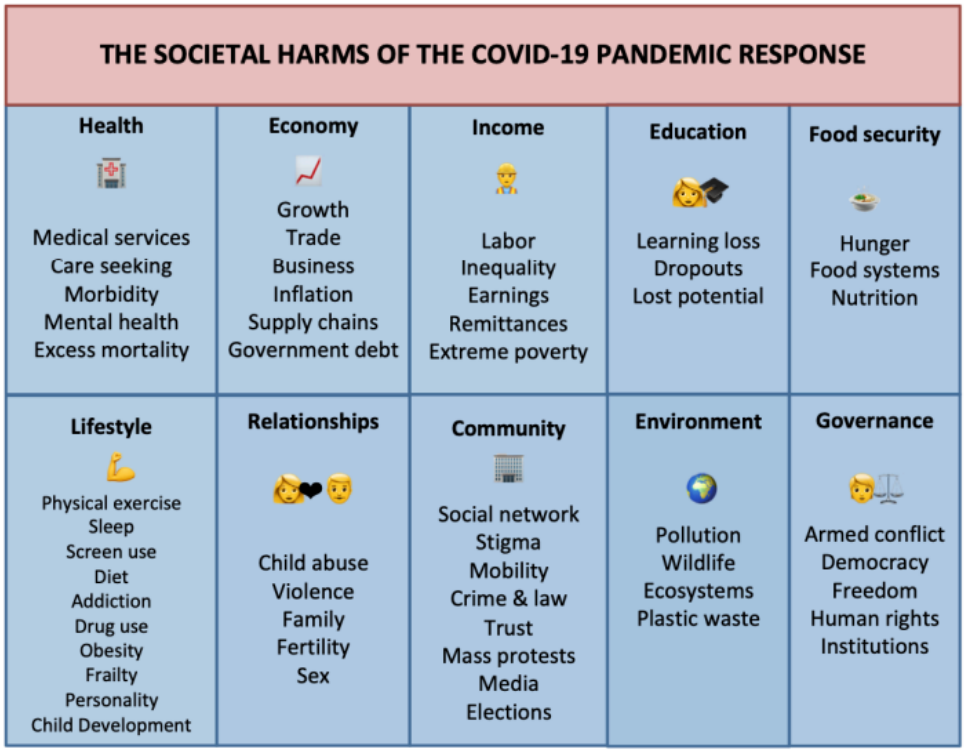
A much wiser strategy than issuing lockdown orders would have been to tell the American people the truth, stick to the facts, educate citizens about the balance of risks, and let individuals make their own decisions about whether to keep their businesses open, whether to socially isolate, attend church, send their children to school, and so on.

18 Connah, B. (2024, January 16). Letter from Ben Connah, UK Covid Inquiry Secretary, to Steve Baker MP, Member of Parliament for Wycombe, House of Commons.

Lesson #3: Lockdowns and Social Isolation Had Negative Consequences that Far Outweighed Benefits

As explained in Lesson #1, the lockdown/panic response overlaid a human-induced pandemic on top of the viral pandemic, causing hundreds of thousands of additional deaths. It also caused vast economic and social harms. The catastrophic economic damage was confirmed by no less than the International Monetary Fund's deputy managing director and Harvard professor Gita Gopinath, who said, "... the Great Lockdown [was] the worst recession since the Great Depression, and far worse than the Global Financial Crisis."[19]

A comprehensive and authoritative framework for analyzing lockdown harms was developed by Kevin Bardosh of the group Collateral Global, a group that was created to address this question.[20]



Source: Bardosh, K. (2023, May 14). How Did the COVID Pandemic Response Harm Society? A Global Evaluation and State of Knowledge Review (2020-21). https://ssrn.com/abstract=4447806 or http://dx.doi.org/10.2139/ssrn.4447806

19 Gopinath, G. (2020, April 14). The Great Lockdown: Worst Economic Downturn Since The Great Depression. IMF Blog. https://www.imf.org/en/Blogs/Articles/2020/04/14/blog-weo-the-great-lockdown-worst-economic-downturn-since-the-great-depression

20 Bardosh, K. (2023, May 14). How Did the COVID Pandemic Response Harm Society? A Global Evaluation and State of Knowledge Review (2020-21). https://ssrn.com/abstract=4447806 or http://dx.doi.org/10.2139/ssrn.4447806

He found studies quantifying some of these harms:

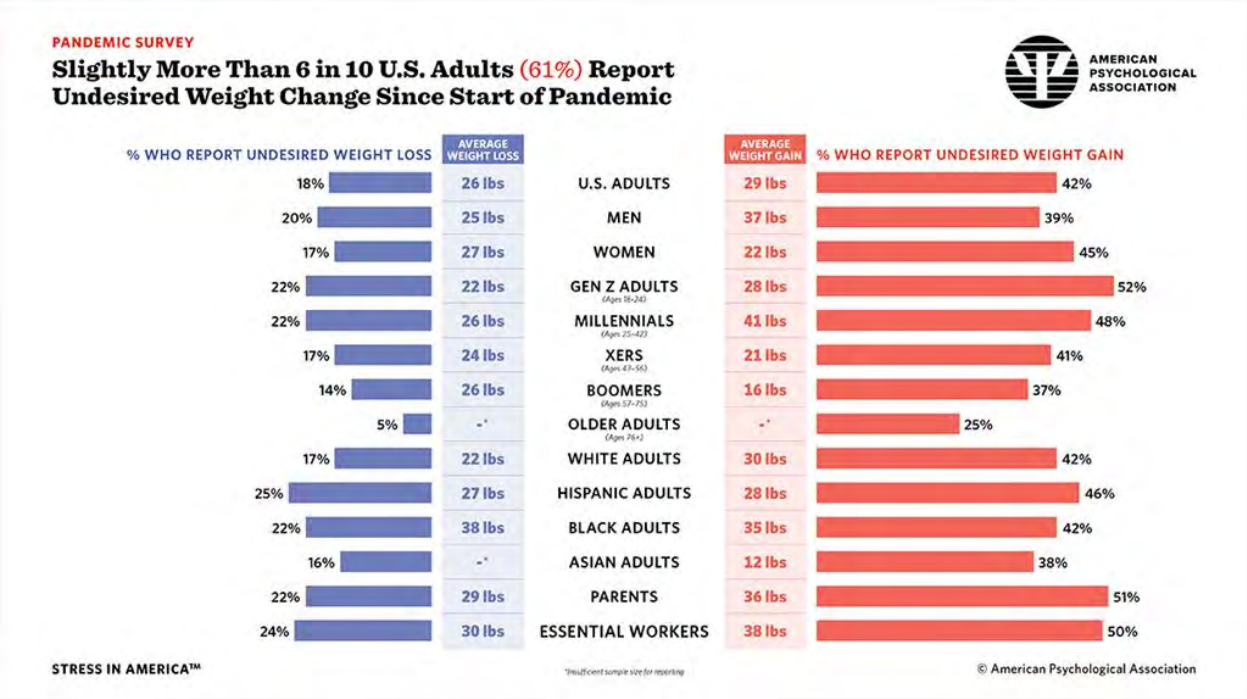
- In North America, non-COVID deaths accounted for about 20% of excess mortality, rising to 70% for people less than 45 years old.
- In low- and middle-income countries, non-COVID child deaths rose sharply, with an estimated 113,962 excess deaths under age 5, compared to 4,480 deaths with COVID in the same age group.
- A 61-country study found that "15% of patients in regions with full lockdowns did not receive elective cancer surgery."
- Multiple studies found skyrocketing rates of anxiety and depression.
- According to the World Bank, "Mobility restrictions, lockdowns, and other public health measures... produced the largest global economic crisis in more than a century."
- Government fiscal stimulus dramatically increased public debt and unleashed inflation, lowering living standards.

Bardosh concludes:

> *"The promotion of lengthy social distancing restrictions by governments and scientific experts during the Covid crisis had severe consequences for hundreds of millions of people. Many original predictions are broadly supported by the cumulative research data presented above: a rise in non-Covid excess mortality, mental health deterioration, child abuse and domestic violence, widening global inequality, large increases in debt, food insecurity, lost educational opportunities, unhealthy lifestyle behaviours, increased loneliness and social polarization, democratic backsliding and human rights violations… The pandemic response leaves behind a legacy of poverty, mental health illness, learning loss, debt, food insecurity, social polarization, erosion of respect for human rights and elevated excess mortality for non-Covid health conditions. These consequences are unequally distributed: the younger generation, individuals and countries with lower socioeconomic status, women and those with pre-existing vulnerabilities were hit hardest and will bear the brunt of future consequences."*

One of the starkest health harms from lockdowns was the rise in obesity. Even college-aged children now face an obesity crisis – more than half reported an unwanted weight gain during the 2020 lockdowns, and it averaged 28 pounds, according to the American Psychological Association.[21]

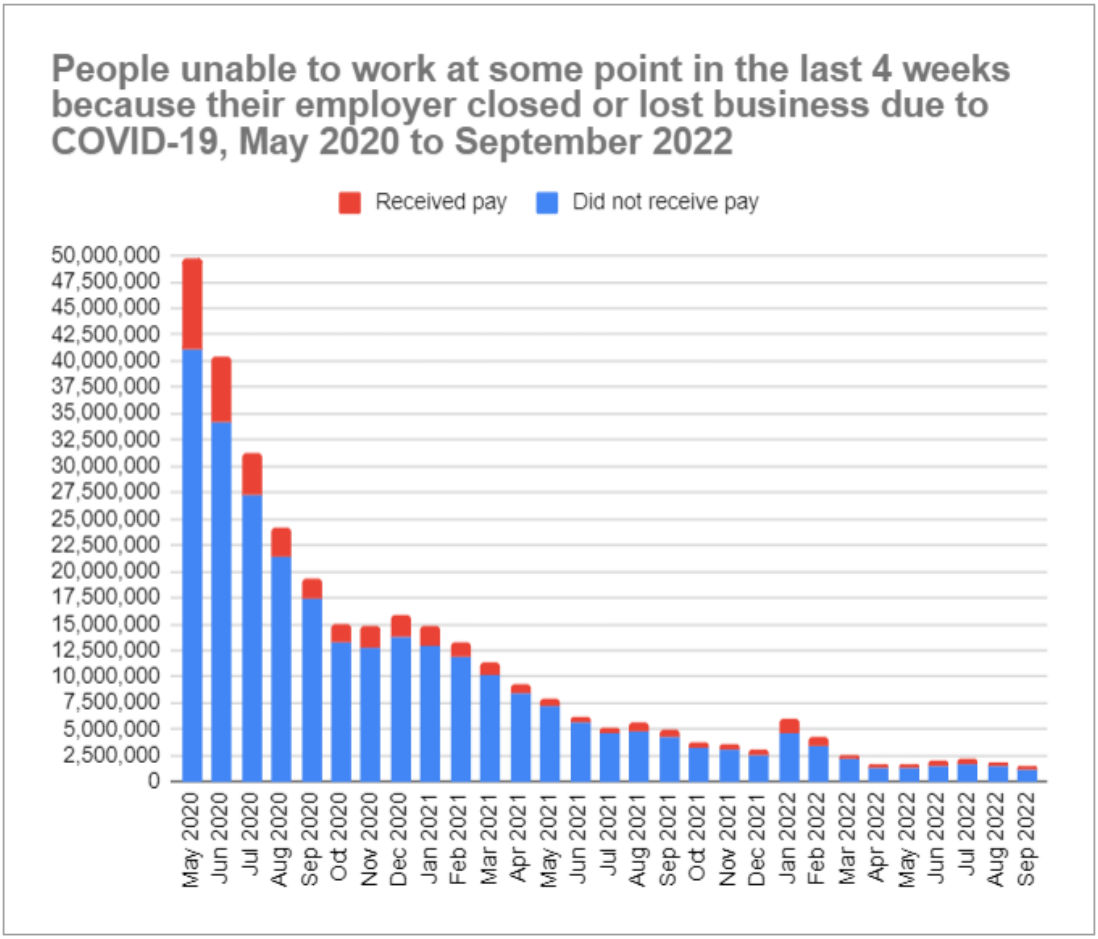
21 American Psychological Association. (2021). 2021 Stress in America Graphs. https://www.apa.org/news/press/releases/stress/2021/infographics-march



Source: American Psychological Association. (2021). 2021 Stress in America Graphs. https://www.apa.org/news/press/releases/stress/2021/infographics-march

The employment impact in the United States was staggering, with lockdowns putting over 49 million Americans out of work according to BLS survey data, and over two million remaining out of work due to COVID closures as recently as July 2022.[22]

22 U.S. Bureau of Labor Statistics. (2024, January 17) May 2020 to September 2022 supplemental data tables. https://www.bls.gov/cps/covid-may2020-sept2022-data-tables.htm



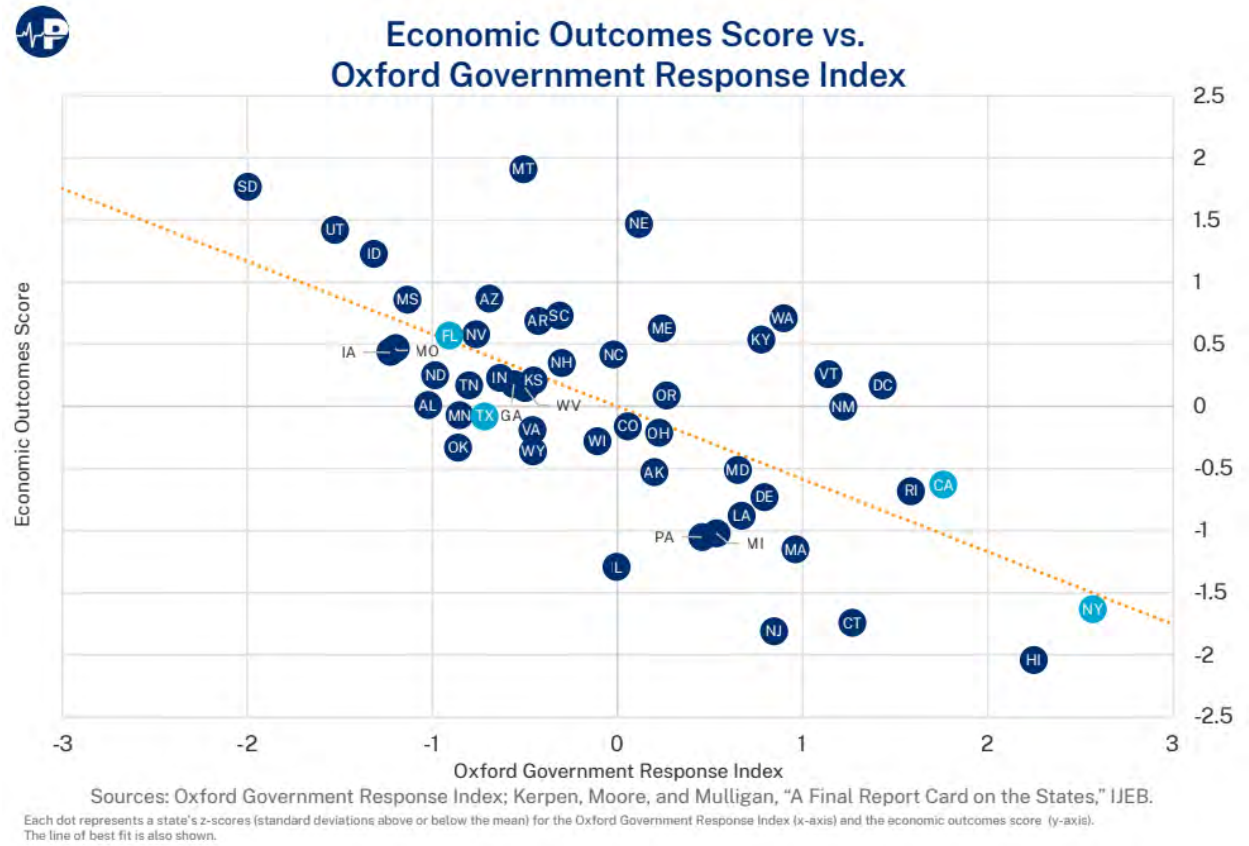
Source: U.S. Bureau of Labor Statistics. (2024, January 17) May 2020 to September 2022 supplemental data tables. https://www.bls.gov/cps/covid-may2020-sept2022-data-tables.htm

This enormous unemployment shock has health as well as economic consequences. An NBER study found that the lockdown unemployment shock is projected to result in 840,000 to 1.22 million excess deaths over the next 15 to 20 years, disproportionately killing women and minorities.[23]

While there is no quantifiable relationship between lockdown severity and a reduction in COVID health harms as demonstrated in Lesson #2, states with more severe lockdowns suffered significantly worse economic outcomes according to an analysis by the Paragon Institute:[24]

23 Bianchi, F., Bianchi, G., & Song, D. (2021, September). The Long-Term impact of the COVID-19 unemployment shock on life expectancy and mortality rates. https://doi.org/10.3386/w28304

24 Zinberg, J. M., M. D. ,. J. D., Blase, B. C., PhD, Sun, E., Mulligan, C. B., PhD, & Paragon Health Institute. (2023). Freedom Wins: States with Less Restrictive COVID Policies Outperformed States with More Restrictive COVID Policies. Paragon Health Institute. https://paragoninstitute.org/wp-content/uploads/2023/02/freedom-wins-policy-paper.pdf



Source: Zinberg, J. M., M. D. ,. J. D., Blase, B. C., PhD, Sun, E., Mulligan, C. B., PhD, & Paragon Health Institute. (2023). Freedom Wins: States with Less Restrictive COVID Policies Outperformed States with More Restrictive COVID Policies. Paragon Health Institute. https://paragoninstitute.org/wp-content/uploads/2023/02/freedom-wins-policy-paper.pdf

In closing Lesson #3, it is worth noting that Jonung and Andersson compared the health and economic outcomes in Sweden, commonly viewed as an outlier relying more on recommendations and voluntary adjustments than on strict lockdowns, to the United States and comparable European OECD countries. They found that the Swedish policy of advice and trust in the population to reduce social interactions voluntarily was relatively successful. Sweden combined low excess death rates with relatively small economic costs. In future pandemics, policymakers should rely on empirical evidence rather than panicking and adopting extreme measures.[25]

25 Andersson, F.. N. G. & L. Jonung. (2024, February). The Covid-19 lesson from Sweden: Don't lock down.Economic Affairs. https://doi.org/10.1111/ecaf.12611

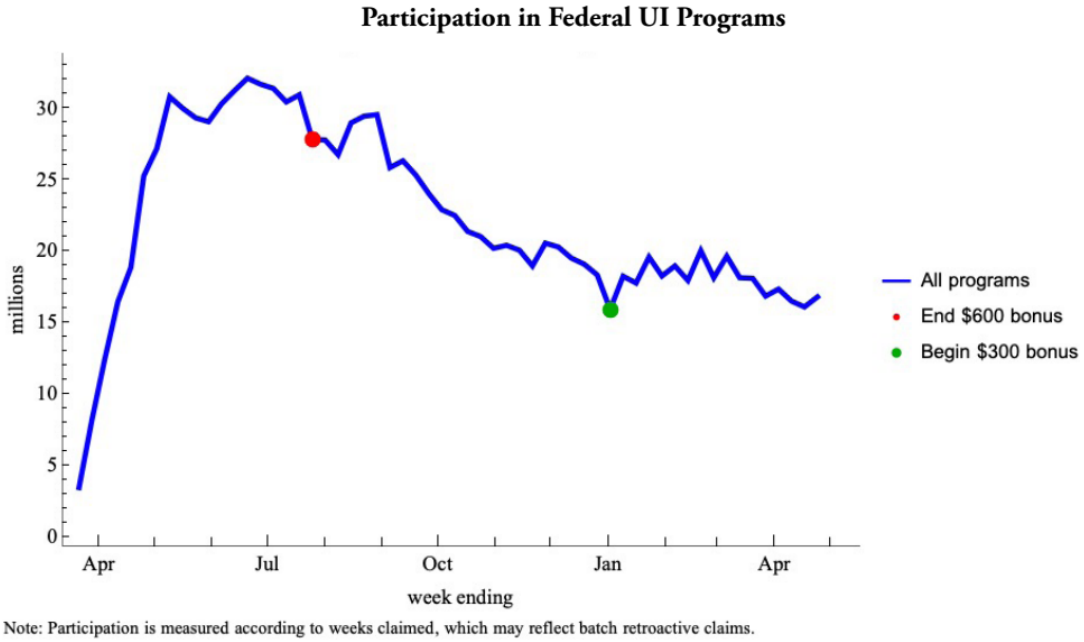
Lesson #4: Government Should Not Pay People More Not to Work

The COVID-era was the largest natural experiment in American history in what happens when the government pays people a substantial amount for not working.

Congress authorized $600 per week unemployment bonuses early in the pandemic, despite warnings that the consequences would be substantial, prolonged unemployment and associated economic underperformance.[26]

The previous largest federal unemployment bonus – enacted by President Obama and a Democratic Congress during the Great Recession – was just $25.

As expected, large federal bonuses that made unemployment pay more than work indeed resulted in elevated unemployment rates, which plunged rapidly when the original $600 bonus ended, before stalling when a $300 bonus took effect.[27] After all, economics is all about incentives.

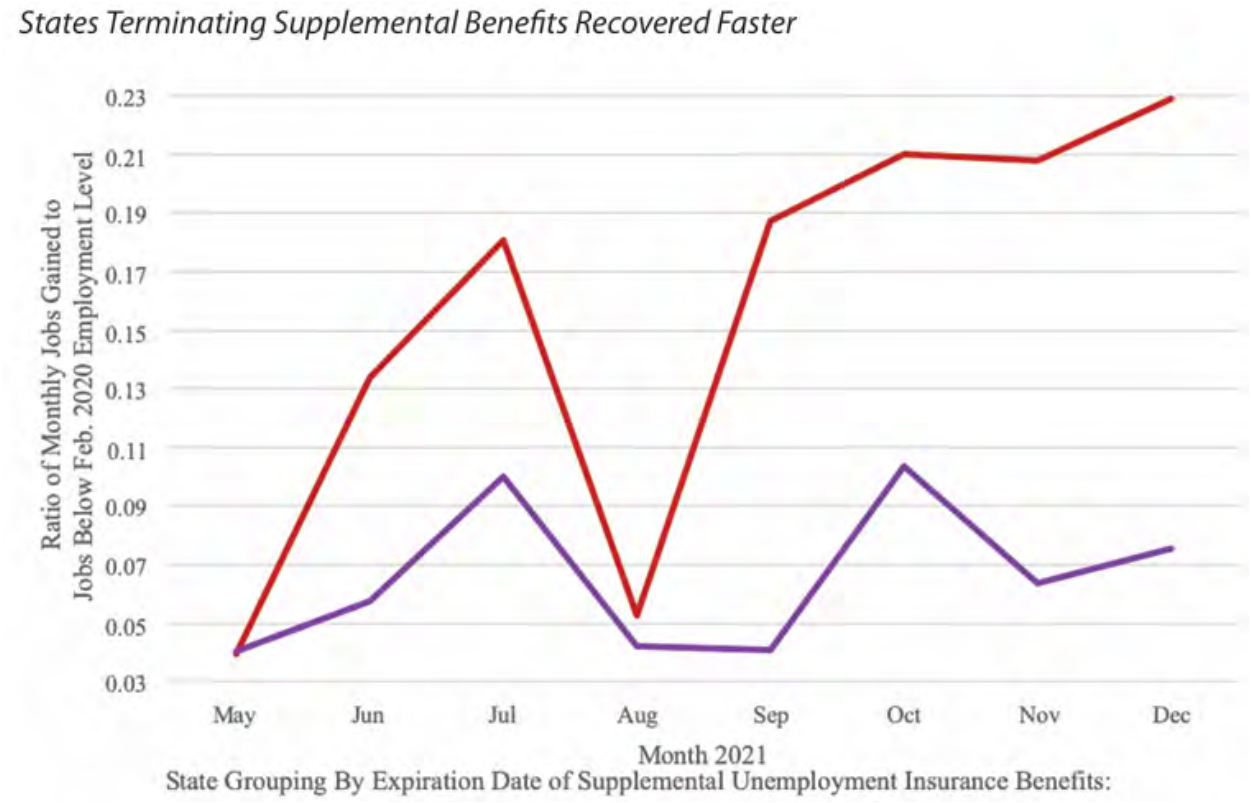


Source: Mulligan, C., Moore, S., & Antoni, E. J. (2021, June). Bonus Unemployment Benefits Are Causing Major Labor Shortage in America. Committee to Unleash Prosperity. https://committeetounleashprosperity.com/wp-content/uploads/2021/06/CTUP_BonusUnemploymentBenefitsLaborShortage.pdf

26 Moore, S., & Kerpen, P. (2020, March 31). The $2 trillion relief package makes unemployment pay more than work. The Hill. https://thehill.com/opinion/finance/490476-the-2-trillion-relief-package-makes-unemployment-pay-more-than-work/

27 Mulligan, C., Moore, S., & Antoni, E. J. (2021, June). Bonus Unemployment Benefits Are Causing Major Labor Shortage in America. Committee to Unleash Prosperity. https://committeetounleashprosperity.com/wp-content/uploads/2021/06/CTUP_BonusUnemploymentBenefitsLaborShortage.pdf

Some states – like Florida and Texas - ended bonus unemployment benefits far earlier than others – like New York and California. The states that cut off these extra benefits earlier had a much faster return-to-work effect. Their economies recovered much faster than those with high and prolonged benefits. Some high benefit states didn't fully recover all the lost employment for three years after the lockdowns and bonus benefits began.[28]



Source: Antoni, E.J. (2022, February). Paid Not To Work: How Supplemental Unemployment Insurance Benefits Decreased. Employment From 2020 To 2021. Texas Public Policy Foundation. https://www.texaspolicy.com/wp-content/uploads/2022/02/PaidNottoWork-02-22-Antoni.pdf

All of these payments for not working may have hurt the very people they were designed to benefit.

According to the Urban Institute: "The long-term unemployed tend to earn less once they find new jobs. They tend to be in poorer health and have children with worse academic performance than similar workers who

28 Antoni, E.J. (2022, February). Paid Not To Work: How Supplemental Unemployment Insurance Benefits Decreased Employment From 2020 To 2021. Texas Public Policy Foundation. https://www.texaspolicy.com/wp-content/uploads/2022/02/PaidNottoWork-02-22-Antoni.pdf

avoided unemployment. Communities with a higher share of long-term unemployed workers also tend to have higher rates of crime and violence."[29]

We need a safety net for those who lose their jobs. But it should never be the policy of the US government to lavishly subsidize unemployment and make non-work pay better than work.

29 Nichols, A., Mitchell, J., & Lindner, S. (2013, August 20). Consequences of Long-Term Unemployment. Urban Institute. https://www.urban.org/research/publication/consequences-long-term-unemployment

Lesson #5: Shutting Down Schools Was a Major Policy Mistake With Tragic Effects on Children, Especially the Poor

Healthy children do not have significant risk of serious illness or death from this virus, and that has been known with certainty since spring 2020. People under 20 years of age have a 99.997% chance of survival.[30]

Studies from early 2020 through today in Iceland[31], Norway, Sweden[32], Finland, Spain, the Netherlands[33], Ireland, Switzerland[34], France[35], Australia[36], Germany, Greece, South Korea[37], and the UK[38], almost all coronavirus transmission to children comes from adults, not the other way around.

Opened schools and childcare centers did not show significant dangers to children, adults or teachers, a profession with half its members younger than 41 and 82 percent under 55.[39] These facts were shown in spring

30 Centers for Disease Control and Prevention. (n.d.). COVID-19 Pandemic Planning Scenarios. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

31 Science Museum Group. (2020, April 27). Hunting down COVID-19. Retrieved from https://www.sciencemuseumgroup.org.uk/blog/hunting-down-covid-19/

32 Folkhälsomyndigheten. (2020). COVID-19 in school-aged children. Retrieved from https://www.folkhalsomyndigheten.se/contentassets/c1b78bffbfde4a7899eb0d8ffdb57b09/covid-19-school-aged-children.pdf

33 RIVM. (2020). Children and COVID-19. Retrieved from https://www.rivm.nl/en/coronavirus-covid-19/children-and-covid-19
Eurosurveillance. (2020). COVID-19 in children and the role of school settings in transmission - first review. Retrieved from https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.21.2000903

34 RTS. (2020). En Suisse, 104 enfants de moins de 10 ans ont été testés positifs au Covid-19. Retrieved from https://www.rts.ch/info/sciences-tech/medecine/11255942-en-suisse-104-enfants-de-moins-de-10-ans-ont-ete-testes-positifs-au-covid-19.html

35 BFMTV. (2020, May 12). Peu porteurs, peu transmetteurs: une étude confirme le rôle minime des enfants dans l'épidémie de Covid-19. https://www.bfmtv.com/sante/peu-porteurs-peu-transmetteurs-une-etude-confirme-le-role-minime-des-enfants-dans-l-epidemie-de-covid-19_AV-202005120233.html

36 Australian Health Protection Principal Committee. (2020, April 24). Coronavirus (COVID-19) statements. https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-coronavirus-covid-19-statements-on-24-april-2020#updated-advice-regarding-schools

37 Kerpen, P. (2020, July 22). New York Times-Hyped Korean Report Actually Shows Kids Are Not Spreading Coronavirus. https://thefederalist.com/2020/07/22/new-york-times-hyped-korean-report-actually-shows-kids-are-not-spreading-coronavirus/

38 Archives of Disease in Childhood. (2020). COVID-19: children and schools. https://adc.bmj.com/content/105/7/618
ScienceDaily. (2020, July 10). COVID-19 is not Influenza. https://www.sciencedaily.com/releases/2020/07/200710100934.htm
Education.org. (2021, January 25). One Year of School Disruption. https://education.org/facts-and-insights#f09a6e46-8c5f-4d01-8297-d2a3f6c8f873
American Academy of Pediatrics. (2021). COVID-19 Transmission in US Child Care Programs. https://publications.aap.org/pediatrics/article/147/1/e2020031971/33500/COVID-19-Transmission-in-US-Child-Care-Programs

39 National Center for Education Statistics. (n.d.). Number and percentage distribution of teachers in public and private elementary and secondary schools, by selected teacher characteristics: Selected years, 1987-88 through 2011-12. https://nces.ed.gov/surveys/sass/tables/sass1112_2013314_t1s_002.asp

2020 and verified in multiple studies, including from Brown University, Duke University, Norway, and many others.[40] Teachers who insisted they were at higher risk than other professions were either lying or simply did not know the facts.

These facts were plainly understood in the spring and summer of 2020, and were widely publicized by the authors of this report[41] and other leading academics.[42] Yet most schools remained closed for more than six months and some for almost two full school years.

By spring/summer 2020, almost all other industrialized nations had committed to opening schools for fall 2020. Yet teacher unions and some public health groups pressured authorities to extend school closures in the United States.[43] Shamefully, the American Academy of Pediatric reversed its open school advocacy just three days after appearing at a Trump White House pro-schools forum – in a literal joint statement with the teachers unions that advocated extending school closures until a massive new federal aid package was passed.[44]

The White House held another event on August 12, 2020 with assembled policy experts, teachers, parents, special needs families, and doctors calling for opening the schools.[45]

School closures were in fact extended, especially in Democratically-controlled jurisdictions, into 2021 and then even further as a matter of intentional Biden administration policy.[46]

40 The Atlantic. (2020, October 19). Schools Aren't Super-Spreaders. https://www.theatlantic.com/ideas/archive/2020/10/schools-arent-superspreaders/616669/
CIDRAP. (2021, January 19). Three studies highlight low COVID risk with in-person school. https://www.cidrap.umn.edu/news-perspective/2021/01/three-studies-highlight-low-covid-risk-person-school
Eurosurveillance. (2020). COVID-19 in children and the role of school settings in transmission - first review. https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.26.1.2002011
Biocomsc. (2020, October 2). Report 136: An analysis of school absences in England during the COVID-19 pandemic. https://biocomsc.upc.edu/en/shared/20201002_report_136.pdf

41 The Hill. (2020). Science says: Open the schools. https://thehill.com/opinion/education/500349-science-says-open-the-schools/

42 Kerpen, P. (2020, July). It's Not Safe to Keep Schools Closed. https://committeetounleashprosperity.com/wp-content/uploads/2020/10/CTUP_NotSafeToKeepSchoolsClosed_Study-1.pdf

43 EdWeek. (2020, December). How Teachers Unions Are Influencing Decisions on School Reopenings. https://www.edweek.org/teaching-learning/how-teachers-unions-are-influencing-decisions-on-school-reopenings/2020/12
EdWorkingPapers. (2020). The Impact of COVID-19 on Student Achievement and What It May Mean for Educators. https://www.edworkingpapers.com/ai20-304

44 American Academy of Pediatrics. (2020). Pediatricians, Educators and Superintendents Urge a Safe Return to School This Fall. https://www.aap.org/en/news-room/news-releases/aap/2020/pediatricians-educators-and-superintendents-urge-a-safe-return-to-school-this-fall/

45 C-SPAN. (2020, August 12). White House Event on Children Returning to School. https://www.c-span.org/video/?474738-1/white-house-event-children-returning-school#

46 Keene, H. (2023, September 6). Biden nixed goal of getting kids back to school post-COVID to avoid conflict with teachers' union boss: book. Fox News. https://www.foxnews.com/politics/biden-nixed-goal-kids-going-back-school-post-covid-avoid-conflict-randi-weingarten-book

From a nationwide analysis of insurance claims indicating visits for medical care, closing in-person schools during 2020, compared to the 2019 non-pandemic year, had the following impacts:[47]

- Mental health care visits for teenagers and college-aged children skyrocketed;
- Self-harm visits (e.g., extinguishing cigarettes on skin, slashing wrists) by teenagers to doctors doubled to tripled versus 2019;
- Manic-depressive and anxiety disorder visits by college-aged (19-22 years) to doctors skyrocketed;
- Overdoses and substance use disorders in teenagers increased by 40% to 120%.

These effects occurred even though overall medical claims decreased because medical care was shut down and public health leaders convinced the public that hospitals were dangerous environments for COVID.

The harms to children of closing in-person schooling are dramatic and irrefutable. These were already known after the first two or three months of spring 2020 closures and were entirely predictable. Online learning is a failure.

Serious harms were inflicted on children, including poor learning, school drop-out, social isolation, mental illness, drug abuse, suicidal ideation, all recognized in July 2020 by the CDC.[48] Most of these effects were far worse for lower income groups.[49] That included approximately 300,000 cases of child abuse, unreported in spring 2020 because schools are the number one agency where child abuse is noticed.[50]

The National Assessment of Educational Progress (NAEP) Report Card on America's school performance reported the largest score declines in math since the first assessments more than 30 years ago.[51] An analysis of these scores based on learning-mode found: "considerable declines in math and ELA pass rates for students in Grades 3–8 in Spring 2021, and these declines were larger in school districts with less in-person instruction. Pass rate declines were larger in districts serving a higher population of Black students."[52]

47 FAIR Health. (2021, March 18). FAIR Health Releases Study on Impact of COVID-19 on Pediatric Mental Health. https://www.fairhealth.org/article/fair-health-releases-study-on-impact-of-covid-19-on-pediatric-mental-health

48 Centers for Disease Control and Prevention. (2020). Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic. https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm

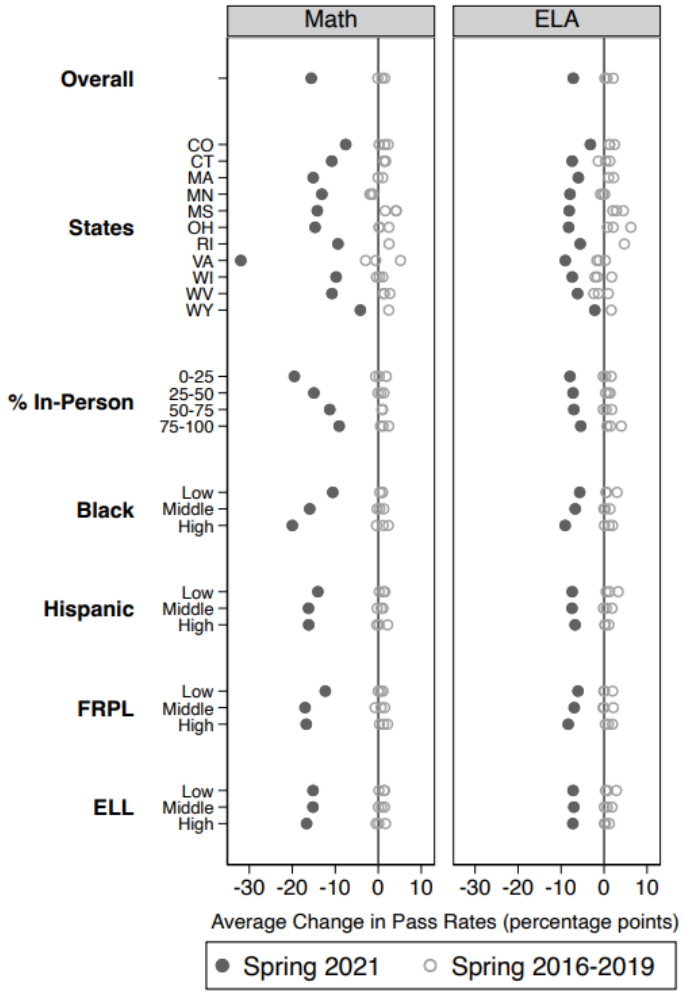
49 Centre for Economic Policy Research. (2020). Long-term effects of school closures. https://cepr.org/voxeu/columns/long-term-effects-school-closures

50 News-Medical.Net. (2020, November 12). 250,000 cases of child abuse or neglect may have gone unreported in US COVID pandemic. https://www.news-medical.net/news/20201112/250000-cases-of-child-abuse-or-neglect-may-have-gone-unreported-in-US-COVID-pandemic.aspx

51 The Nation's Report Card. (2023). https://www.nationsreportcard.gov/

52 Jack, R., Halloran, C., Okun, J. & Oster, E. (2022, April 26) Pandemic Schooling Mode and Student Test Scores: Evidence from U.S. School Districts. https://emilyoster.net/wp-content/uploads/MS_Updated_Revised.pdf

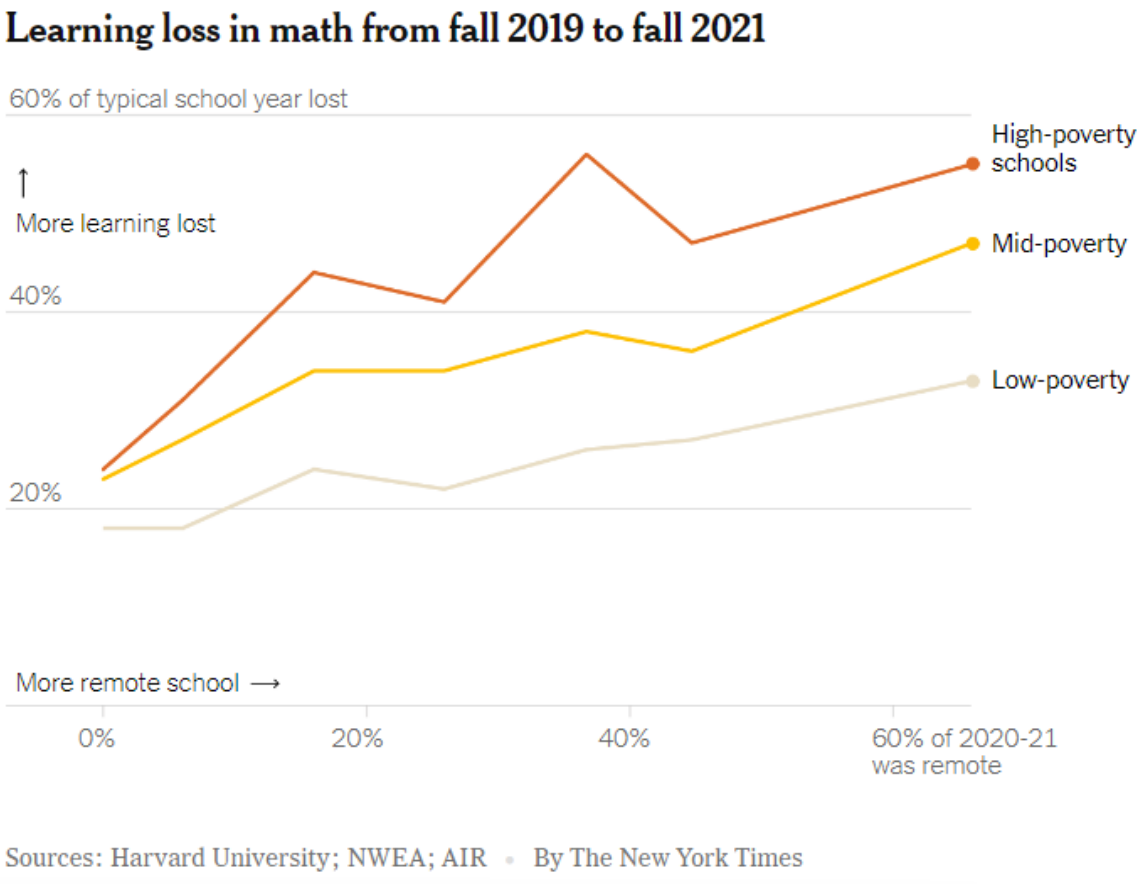
Average Change in Pass Rates on State Standardized Assessments in Spring 2021 vs. Spring 2016-2019



Source: Jack, R., Halloran, C., Okun, J. & Oster, E. (2022, April 26) Pandemic Schooling Mode and Student Test Scores: Evidence from U.S. School Districts. https://emilyoster.net/wp-content/uploads/MS_Updated_Revised.pdf

Learning loss was much more severe among poor and minority children, according to a study from Harvard's Center for Education Policy Research.[53]

53 Goldhaber, D., Kane, T., McEachin, A., Morton, E., Patterson, T., & Staiger, D. (2022). The Consequences of Remote and Hybrid Instruction During the Pandemic. Research Report. Cambridge, MA: Center for Education Policy Research, Harvard University. https://cepr.harvard.edu/files/cepr/files/5-4.pdf?m=1651690491



Source: Leonhardt, D. (2002, May 5). 'Not Good for Learning' New research is showing the high costs of long school closures in some communities. New York Times. https://www.nytimes.com/2022/05/05/briefing/school-closures-covid-learning-loss.html

One of the study's authors, Harvard professor of education Thomas Kane, told the New York Times: "This will probably be the largest increase in educational inequity in a generation."[54]

Another co-author, Stanford professor of education Sean Reardon, told PBS: "When you have a massive crisis, the worst effects end up being felt by the people with the least resources."[55]

The educational harms are also health harms because there is a well-established relationship between education and income as well as life-expectancy. For example, a 2020 study in the Journal of the American Medical

54 Leonhardt, D. (2002, May 5). 'Not Good for Learning' New research is showing the high costs of long school closures in some communities. New York Times. https://www.nytimes.com/2022/05/05/briefing/school-closures-covid-learning-loss.html

55 Vázquez Toness, B., & Lurye, S. (2022, October 28). COVID-19 pandemic massively set back learning, especially for high-poverty areas. PBS NewsHour. https://www.pbs.org/newshour/education/covid-19-pandemic-massively-set-back-learning-especially-for-high-poverty-areas

Association (JAMA) found that the loss of educational attainment the two months at the end of the 2019-20 school year is expected to reduce life expectancy by a staggering 13.8 million years of life.[56]

US public health recommendations and actions are not limited to the US, but have had a worldwide impact on school policies, and they selectively harmed children from low-income families and the poor. The sinful legacy of those who advocated for closing schools was recently highlighted in UNICEF's "The State of Global Learning Poverty: 2022 Update":[57]

- "… The increases (in learning poverty) have been especially large in South Asia and in Latin America and the Caribbean, the regions where schools have been closed the longest."
- "…new measurements of student learning is confirming that remote learning was largely ineffective and a poor substitute for in-person schooling … widespread school closures have disproportionally affected students from disadvantaged backgrounds …"
- "… recent analysis suggests that learning losses are concentrated among poor students, as documented in the Netherlands, Italy, United States, Mexico, Bangladesh, and Ghana."
- "Because universal foundational skills are essential to the flourishing of individuals and societies, this widespread learning poverty threatens to undermine the future of today's children and the economic prospects of their countries."

The original round of global school closures is estimated by the UN to result in $17 trillion in lost lifetime earnings for students, equal to about 14 percent of current world GDP.[58]

If that is not bad enough, school closures failed to achieve their narrow intended purpose of preventing pediatric SARS-CoV2 infections. In the CDC's December 2022 seroprevalence survey, 91.9% of children had infection-induced antibodies.[59] Because seroconversion does not happen in all cases, the true ever-infected percentage is likely close to 100%.[60]

Extended school closures severely harmed children with no offsetting benefit.

56 Christakis, D. A., Van Cleve, W., & Zimmerman, F. J. (2020). Estimation of US children's educational attainment and years of life lost associated with primary school closures during the coronavirus disease 2019 pandemic. JAMA Network Open, 3(11), e2028786. https://doi.org/10.1001/jamanetworkopen.2020.28786

57 UNICEF. (2022). State of Learning Poverty. https://www.unicef.org/media/122921/file/State%20of%20Learning%20Poverty%202022.pdf

58 COVID-19: Students face $17 trillion loss in lifetime earnings. (2021, December 8). UN News. https://news.un.org/en/story/2021/12/1107282

59 Centers for Disease Control and Prevention, "United States COVID-19 Pediatric Seroprevalence," updated January 27, 2023. https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence

60 D. Follmann, H. E. Janes, O. D. Buhule et al., "Antinucleocapsid antibodies after SARS-CoV-2 infection in the blinded phase of the randomized, placebo-controlled mRNA-1273 COVID-19 vaccine efficacy clinical trial," Annals of Internal Medicine, vol. 175, no. 9, pp. 1258–1265, 2022.https://www.acpjournals.org/doi/10.7326/M22-1300

Lesson #6: Masks Were of Little or No Value and Possibly Harmful

There was no high-quality evidence in support of community masking for respiratory viruses in spring 2020; in fact, the randomized clinical trials regarding masking for influenza found it to be ineffective for protecting the wearer and for preventing spread. Unfortunately, rather than commission cluster randomized controlled trials to produce high-quality evidence on masking with respect to SARS-CoV2, global and US public health authorities overstated the benefits of masking and persisted even as evidence to the contrary accumulated.

The CDC's own May 2020 systematic review found:

"Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza."[61]

This matched the July 2020 conclusion of University of Oxford's Centre for Evidence-Based Medicine's review of the literature: "Despite two decades of pandemic preparedness, there is considerable uncertainty as to the value of wearing masks."[62] Their subsequent fall 2020 review of 9 published trials found that: "Results of randomised trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."[63]

The landmark Respiratory Protection Effectiveness Clinical Trial (ResPECT) conducted in multiple sites over four years had just been published in 2019 and found that N95 respirators were ineffective for health care workers compared to placebo procedure masks.[64]

Nonetheless, the CDC and other public health authorities embraced unscientific, over-the-top claims of near perfect efficacy based on case studies (most infamously a case study of two hairstylists in Missouri) and endpoint-driven ecological studies.

The CDC dismissed a rigorous Danish randomized control trial on SARS2 and 10 additional viruses that found "the recommendation to wear a surgical mask when outside the home among others did not reduce, at conventional levels of statistical significance, the incidence of SARS-CoV-2 infection in mask wearers," as well

61 Xiao, J., Shiu, E., Gao, H., Wong, J. Y., Fong, M. W., Ryu, S…Cowling, B. J et. al. (2020). Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerging Infectious Diseases, 26(5), 967-975. https://doi.org/10.3201/eid2605.190994

62 Jefferson, T. and Heneghan, C. (2020, July 23). Masking lack of evidence with politics. Centre for Evidence-Based Medicine. https://www.cebm.net/covid-19/masking-lack-of-evidence-with-politics/

63 Jefferson T, et. al. (2020, November). Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database Syst Rev. doi: 10.1002/14651858.CD006207.pub5.

64 Radonovich, L. J., Simberkoff, M. S., Bessesen, M. T., et al. (2019). N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial. JAMA, 322(9), 824–833. https://doi.org/10.1001/jama.2019.11645

as all other viruses tested. The study used "high-quality surgical masks with a filtration rate of 98%."[65]

CDC called the Danish study with 4,862 participants "inconclusive" and "too small," while praising its own severely flawed case study of 67 self-selected close contacts of two hairdressers in Missouri as "showing that wearing a mask prevented the spread of infection."[66]

Some claimed support for masking from a Bangladesh trial, but it found a difference of only 20 fewer cases across 300 masked villages in two months, which may have been a result of observation bias and certainly not a result of mask mandates as masks were required (but widely ignored) in all villages in the trial, masked as well as unmasked.[67]

Masks became a symbol of political allegiance and highly divisive in a climate of fear. But ultimately the gold standard of evidence-based medicine, the Cochrane Review, reached the same conclusion about masking for COVID that previous research had shown for influenza:

> Wearing masks in the community probably makes little or no difference to the outcome of influenza-like illness (ILI)/COVID-19 like illness compared to not wearing masks (risk ratio (RR) 0.95, 95% confidence interval (CI) 0.84 to 1.09; 9 trials, 276,917 participants; moderate-certainty evidence. Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (RR 1.01, 95% CI 0.72 to 1.42; 6 trials, 13,919 participants; moderate-certainty evidence). Harms were rarely measured and poorly reported (very low-certainty evidence).[68]

It also confirmed the ResPECT finding that N95 masks were no more effective than ineffective surgical masks.

Mask mandates were likely imposed as a way to calm people's fears and help them re-engage in society. But they ended up doing the opposite – amplifying fears by creating the irrational belief that an unmasked face presented a threat, causing conflict and division among citizens, and giving high-risk people the mistaken impression that masks were protective, potentially resulting in some people risking exposure who otherwise may not have.

The CDC continues to recommend, contrary to evidence, masking for respiratory viruses, undermining its credibility.

65 Bundgaard, H. et. al. (2021). Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial. Ann Intern Med, 174(3), 335-343. https://doi.org/10.7326/M20-6817

66 Anderson, J. H. (2021, August 11). Do Masks Work? A review of the evidence. City Journal. https://www.city-journal.org/do-masks-work-a-review-of-the-evidence

67 Chikina, M., Pegden, W., & Recht, B. (2022). Re-analysis on the statistical sampling biases of a mask promotion trial in Bangladesh: a statistical replication. Trials, 23(1), 786. https://doi.org/10.1186/s13063-022-06704-z

68 Jefferson, T., Dooley, L., Ferroni, E., Al-Ansary, L. A., van Driel, M. L., Bawazeer, G. A., Jones, M. A., Hoffmann, T. C., Clark, J., Beller, E. M., Glasziou, P. P., & Conly, J. M. (2023). Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database of Systematic Reviews, 2023(1), CD006207. https://doi.org/10.1002/14651858.CD006207.pub6

Lesson #7: Government Should Not Suppress Dissent or Police the Boundaries of Science

A poisonous interplay to stop the free exchange of ideas, a combined effort between America's media, Big Tech, and the academic science and public health community, has severely harmed the public. University professors are granted a privileged position in society. They represent the experts in the eye of the public; the source of expertise in the media; the group from which the government selects health agency leaders; the controllers of research funding; and most importantly, they are entrusted as role models to teach children critical thinking.

During the pandemic, there was a symbiotic relationship, where both parties leveraged the other for the shared goal of suppression of "unaccepted" views. Scientists use the media and so-called fact checkers, along with their control of science funding and academic careers, to bully others. The media selects their favored scientists and gives them the imprimatur of "the experts" who then willingly disparage and dismiss opposing views.

Examples of censorship abound, and it took many forms. Legacy and print media, social media, and university campuses – in theory the center for the free exchange of ideas – overtly stopped the flow of information necessary to arise at the truths we need, particularly during a crisis. And when scientific journals published character smears in an attempt to intimidate and silence alternative views of the data, the public was seriously harmed.

Social media, particularly Twitter, YouTube, and Facebook, were actively suffocating voices that dissented from the accepted COVID narrative. These are private companies and therefore have the right to decide what content to allow on their platforms, but government policy should have been to encourage open public debate. Instead the government actively encouraged and perhaps demanded suppression of dissent, a potential First Amendment violation presently before the Supreme Court in Missouri v. Biden.[69]

Censorship was used as a key tool of the lockdown/mandate advocates at key policy inflection points. The active censorship of data on masks occurred in August 2020 on Twitter, blocking tweets from Scott Atlas when he was an advisor to the president. The active censorship of minuscule risk to children and the schools was done in September 2020 by YouTube pulling down a key Atlas interview on Uncommon Knowledge that cited the facts back in spring 2020.

Another vehicle for the suffocation of science was the most important source of research knowledge – the science journals and academia. Politically-motivated professors at elite universities and some of the world's most influential medical science journals abrogated their responsibility to the world and instead became opinionated vehicles for censorship and intimidation. Top medical journals suppressed data by omission in an effort to conjure up their chosen "consensus." As Bhattacharya and Hanke document in "SSRN and medRxiv Censor Counter-Narrative Science," the SSRN and medRxiv preprint servers, which are important platforms in the social sciences and medical fields respectively, actively censored research that questioned the efficacy of

69 A summary of the case is available from the New Civil Liberties Alliance, counsel for the plaintiffs. https://nclalegal.org/missouri-et-al-v-joseph-r-biden-jr-et-al/

lockdowns.[70] Major journals shockingly published opinion pieces in an attempt to intimidate and "cancel" the research and scientific interpretations of the evidence pointed out by Bhattacharya, Hanke, the acclaimed scientists authoring the Great Barrington Declaration, and other top experts.

In July 2020, the New England Journal of Medicine published an article on 'reopening primary schools during the pandemic'.[71] Amazingly, it did not even mention the evidence from one of the only major Western countries that kept schools open throughout the pandemic, Sweden. As Harvard's Martin Kulldorff put it, "That is like evaluating a new drug while ignoring data from the placebo control group."[72]

In February 2020, the influential journal Lancet published a remarkable letter signed by prominent virologists and other scientists. The authors began by lauding China for its "rapid, open, and transparent sharing of data" – even though the world knew that China delayed warning the world about the early COVID cases, forbade an open exploration of the Wuhan lab, and subsequently destroyed critical evidence that could have helped identify the origin of the virus.[73] The authors undermined the public's trust in science itself by abusing their platform as a tool of intimidation.

The authors of the Lancet letter wrote, "We stand together to strongly condemn conspiracy theories suggesting that COVID-19 does not have a natural origin. Scientists from multiple countries have published and analysed genomes of the causative agent, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and they overwhelmingly conclude that this coronavirus originated in wildlife." They then explicitly, and shockingly, called for "unity" – an unheard of plea from scientists interested in research-driven conclusions. It was an unbridled attempt to marginalize and pre-empt any scientist who might show contrary evidence about the origin of the virus – evidence that is now known was present even then, as shown by the trove of Fauci emails later exposed under the Freedom of Information Act.

Then in October 2020, Lancet published an extraordinarily misleading opinion piece in which a group of scientists and professors forcefully presented their assertions , onto the public as some sort of settled consensus, even though some of their arguments were contrary to scientific evidence about immunity.[74] As Kulldorff and Bhattacharya pointed out, the Lancet authors falsely stated "there is no evidence for lasting protective

70 Bhattacharya, J., & Hanke, S. H. (2023). SSRN and medRxiv Censor Counter-Narrative Science. Econ Journal Watch, 20(2), 450-459. https://econjwatch.org/File+download/1276/BhattacharyaHankeSept2023.pdf?mimetype=pdf

71 Levinson, M., Cevik, M., & Lipsitch, M. (2020, September 3). Reopening Primary Schools during the Pandemic. New England Journal of Medicine. https://doi.org/10.1056/NEJMms2024920

72 Kulldorff, M. (2021, June 4). Why I spoke out against lockdowns. Spiked Online. https://www.spiked-online.com/2021/06/04/why-i-spoke-out-against-lockdowns/

73 Calisher, C., et. al. (2020). Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19. Lancet. https://doi.org/10.1016/S0140-6736(20)30418-9

74 Alwan, N. A., et. al. (2020, October 15). Scientific consensus on the COVID-19 pandemic: we need to act now. The Lancet. https://doi.org/10.1016/S0140-6736(20)32153-X

immunity to SARS-CoV-2 following natural infection."[75] The Lancet piece tried to demonize the authors of the Great Barrington Declaration, wrongly claiming that they advocated letting the infection "spread freely until population immunity was achieved" – which would cause massive deaths.

Groupthink and censorship allowed policy errors to persist much longer than they would have in an environment of open and honest public debate.

75 Bhattacharya, J., Gupta, S., & Kulldorff, M. (2021, June 4). The Beauty of Vaccines and Natural Immunity. Smerconish. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity/

Lesson #8: The Real Hospital Story Was Underutilization

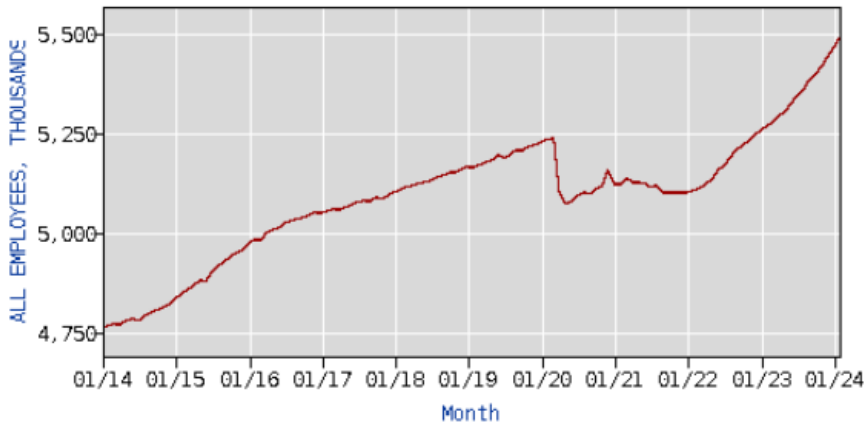
One of the most persistent myths of the pandemic was that hospitals were under unusually high load. In fact, the tragedy of the non-COVID death pandemic was likely driven by record low hospital utilization – with very few exceptions – throughout the entire pandemic period.

Hundreds of millions of dollars were spent on field hospitals, which were dismantled weeks later, most without serving a single patient.[76] Nurses – if they still had jobs after mass hospital layoffs (see the chart below)[77] – did choreographed dances in empty hospital hallways.[78]

Data extracted on: March 8, 2024 (3:44:24 PM)

Employment, Hours, and Earnings from the Current Employment Statistics survey (National)

Series Id: CES6562200001
Seasonally Adjusted
Series Title: All employees, thousands, hospitals, seasonally adjusted
Super Sector: Private education and health services
Industry: Hospitals
NAICS Code: 622
Data Type: ALL EMPLOYEES, THOUSANDS



Source: US Bureau of Labor Statistics. Series Id: CES6562200001 https://data.bls.gov/cgi-bin/srgate

76 NPR. (2020, May 7). U.S. Field Hospitals Stand Down, Most Without Treating Any COVID-19 Patients. https://www.npr.org/sections/health-shots/2020/05/07/851610771/u-s-field-hospitals-stand-down-most-without-treating-any-covid-19-patients

77 Bureau of Labor Statistics, Employment, Hours, and Earnings from the Current Employment Statistics survey (National), Series Id: CES6562200001 Data extracted on: February 13, 2023

78 Massachusetts Department of Public Health. (2022, January 31). COVID-10 Interactive Data Dashboard reports. https://www.mass.gov/info-details/covid-19-response-reporting

The collapse in hospital utilization was driven by political orders canceling medical procedures and stay-at-home orders causing people to cancel their own appointments. An equally if not more significant factor was the environment of fear that kept people out of hospitals – including the deadly false belief that the underutilized hospitals were too busy for people suffering from heart attacks and strokes.

Notably, emergency visits collapsed nationally, even in areas where COVID was not spreading. A study published in JAMA concluded this was a result of public health messaging:

> "A possible explanation for these temporal associations is that the public responded more to national-level risk messaging about COVID-19 than to changes in the local situation with regard to reported cases. For example, individuals may have avoided seeking emergency care because of a fear of being exposed to COVID-19 in the ED, concerns about the possibility of extended wait times, or a sense of civic responsibility to avoid using health care services that others may have needed."[79]

A study of emergency department utilization in the HCA health care system found volume dropped 44 percent with an associated rise in all-cause mortality.[80] The study's author explained:

> "We see a direct inverse correlation. As the volume went down, we saw out-of-hospital cardiac arrests going up, and as near as we can tell, that was not due to COVID. Without adding too many details to violate privacy, we saw several people who were suffering from conditions that were essentially benign and easy to treat in the early stage but who waited much, much longer than they would have in any other time frame, and then suffered pretty drastic complications, disability and even death; some things that, really, no one should die from."[81]

Dr. Scott Atlas summarized the foregone care:

> "In Spring of 2020 alone, there were 650,000 chemotherapy patients in America alone, half of which never got treatment. They were told it was too dangerous to go to medical facilities; 85 percent of living organ transplants in the U.S. didn't get done. 50 percent of Americans suffering a stroke or heart attack refrained from calling an ambulance out of fear."[82]

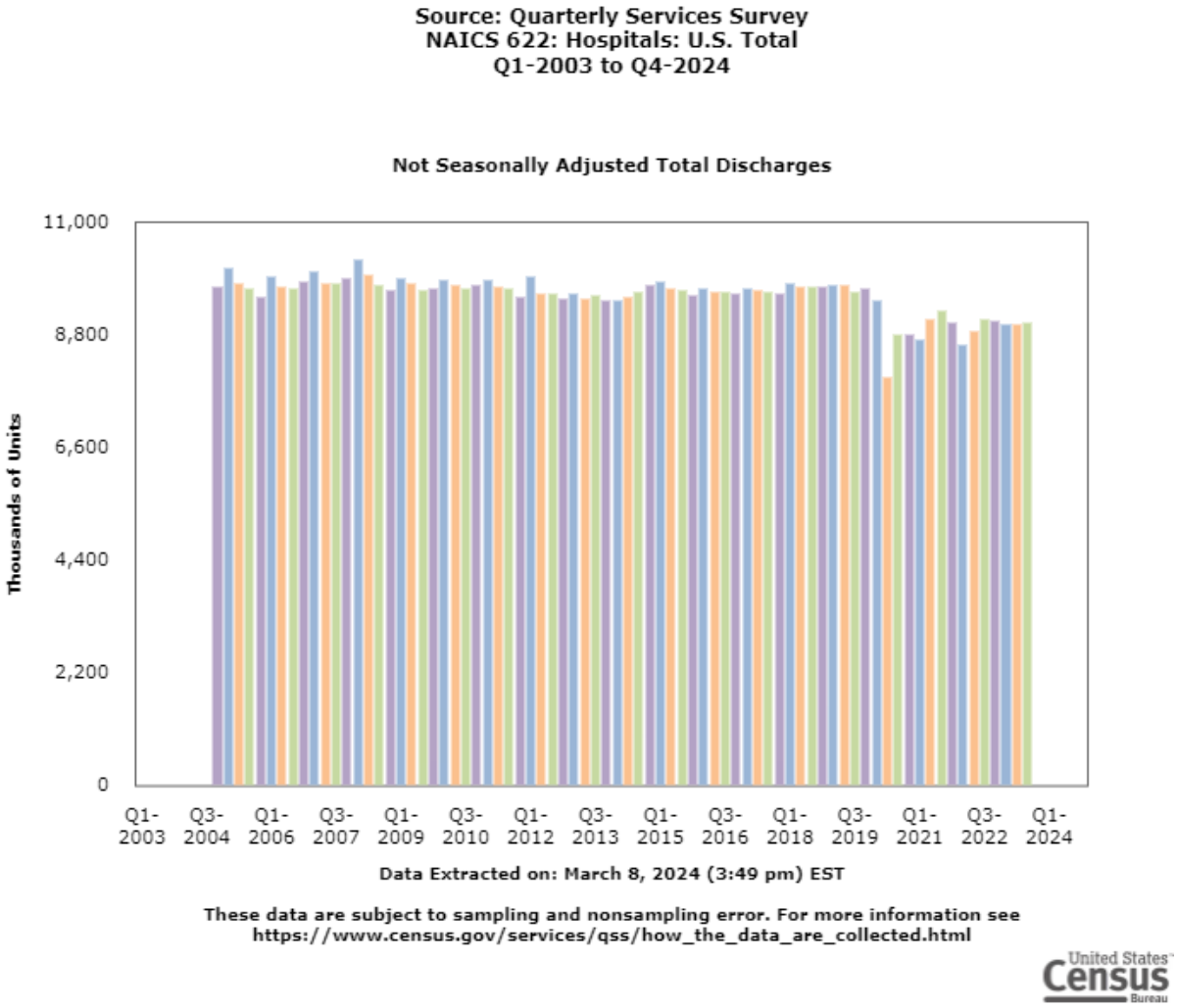
79 Jeffery MM, D'Onofrio G, Paek H, et al. Trends in Emergency Department Visits and Hospital Admissions in Health Care Systems in 5 States in the First Months of the COVID-19 Pandemic in the US. JAMA Intern Med. 2020;180(10):1328–1333. doi:10.1001/jamainternmed.2020.3288 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768777

80 Gutovitz S, Pangia J, Finer A, Rymer K, Johnson D. Emergency department utilization and patient outcomes during the COVID-19 pandemic in America. J Emerg Med. 2021;60(6):798-806. doi:10.1016/j.jemermed.2021.01.002

81 My Horry News, "Horry County and S.C. saw a spike in non-COVID deaths in 2020. But why?," June 14, 2021. https://www.myhorrynews.com/coronavirus/horry-county-and-south-carolina-saw-a-spike-in-non-covid-death-in-2020/article_4cb9811e-c4a3-11eb-8fb7-a73ec28b723e.html

82 Remarks at Committee to Unleash Prosperity Economic Summit, October 21, 2022. https://www.c-span.org/video/?523748-2/trump-administration-officials-covid-19-pandemic-economy

These charts show monthly utilization collapsed sharply at the advent of the pandemic and failed to reach 2019 levels for inpatients or emergency visits in any month during the pandemic:[83]

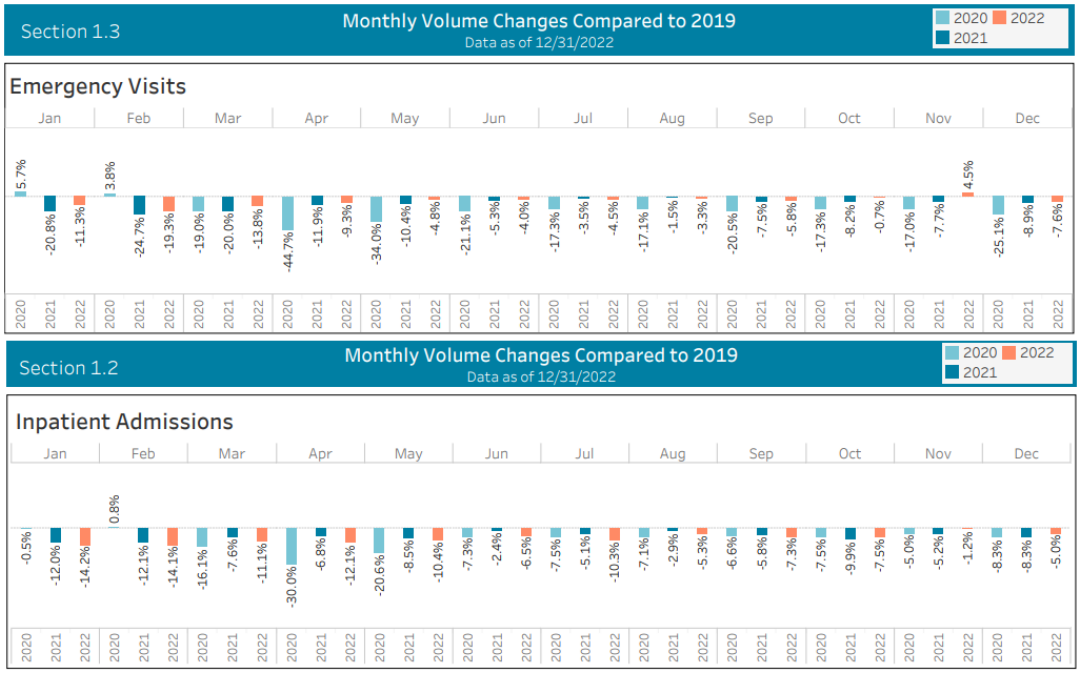


Source: Strata Decision, NationalPatientandProcedureVolumeTracker™ Monthly Update 12/31/2022, https://info.stratadecision.com/hubfs/Website/NPPVT/NPPVT%202023%20January_Final_w_Appendix.pdf

This data comes from a private market analyst, Strata Decision, because the official hospital utilization data series from HHS never collected retrospective data, and so cannot be easily compared to pre-pandemic utilization levels. Census survey data, however, shows total discharges plunging to a record low level when the pandemic began:[84]

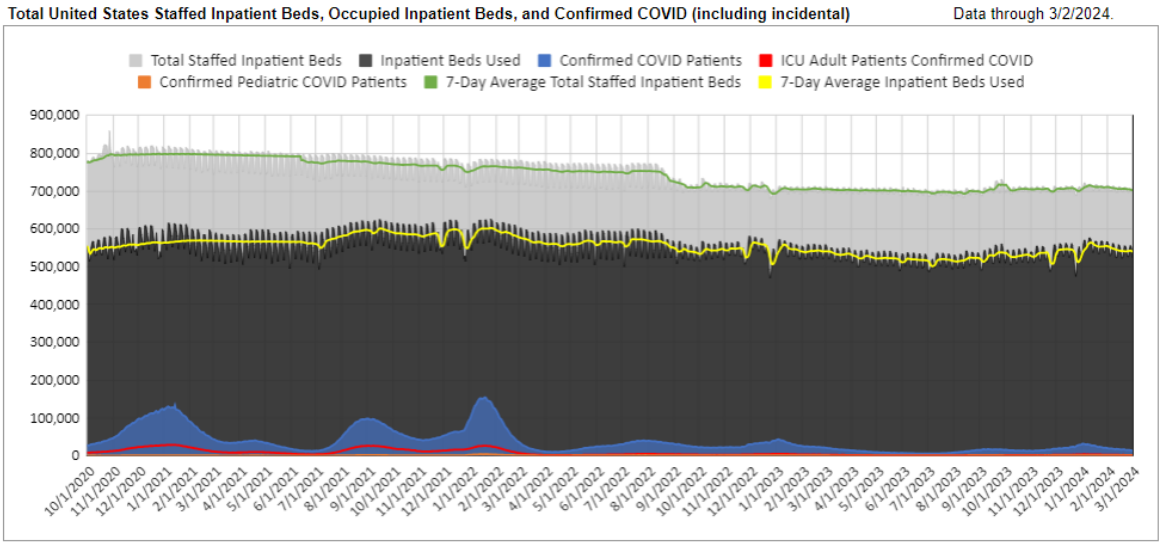
83 Strata Decision, NationalPatientandProcedureVolumeTracker™ Monthly Update 12/31/2022, https://info.stratadecision.com/hubfs/Website/NPPVT/NPPVT%202023%20January_Final_w_Appendix.pdf

84 US Census Bureau, Quarterly Services Survey, 622: Hospitals: U.S. Total — Not Seasonally Adjusted Total Discharges



Source: US Census Bureau. Quarterly Services Survey. https://www.census.gov/econ/

The HHS data shows that COVID waves rarely moved topline inpatient utilization, there were substantial numbers of unused staffed beds throughout the period, and the total number of staffed beds steadily declined – the opposite of what might have been expected given headlines about high utilization and record transfers of tax dollars to hospital systems.



Source: Author's calculation using HHS Protect data. https://docs.google.com/spreadsheets/d/15YbHKtjdHgS8kpZ7JUwluYLcVATvP95ypoGqUBdgcUo/edit?usp=sharing

This is not a composition effect; state charts all follow the same pattern. The COVID utilization numbers from HHS are overstated because the agency has refused to differentiate causal from incidental COVID, even as the latter category has increased to around 70 percent in Massachusetts[85] and a reported 90 percent at Los Angeles County's largest safety-net hospital.[86]

Congress should consider requiring retrospective hospital reporting of midnight census by service line going back five or ten years to better understand normal utilization levels and what happened during the pandemic.

85 Massachusetts Department of Public Health COVID-10 Interactive Data Dashboard reports, for instance: "On January 31, 202, there were 211 patients primarily hospitalized for COVID-19 related illness and 744 total patients hospitalized with COVID-19." https://www.mass.gov/info-details/covid-19-response-reporting

86 Los Angeles Times. (2022, July 18). Coronavirus cases are soaring in L.A. County, but this wave is different. https://www.latimes.com/california/story/2022-07-18/l-a-county-faces-coronavirus-paradox-soaring-cases-but-hospitals-less-taxed

Lesson #9: Protect the Most Vulnerable

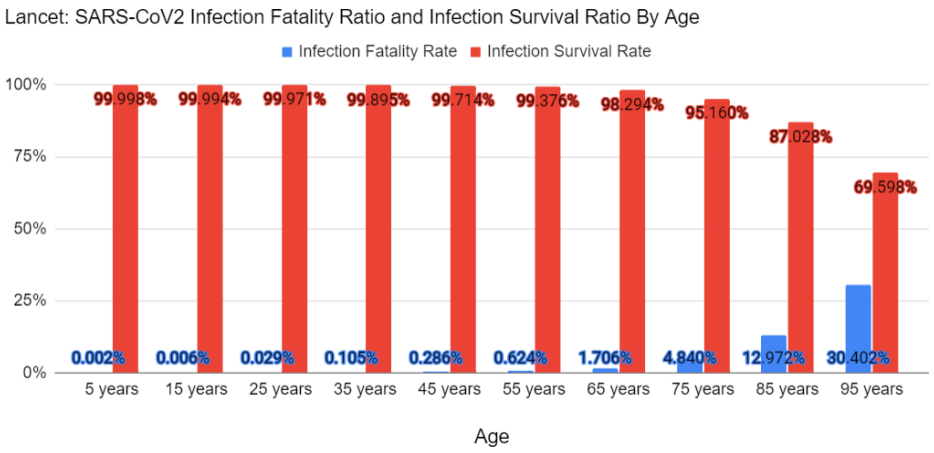
One of the most striking features of the earliest COVID morbidity and mortality data was a profound differential in risk between the old and the young.

As Martin Kulldorf explained in April 2020, based on data published in February and March:

> "Among COVID-19 exposed individuals, people in their 70s have roughly twice the mortality of those in their 60s, 10 times the mortality of those in their 50s, 40 times that of those in their 40s, 100 times that of those in their 30s, 300 times that of those in their 20s, and a mortality that is more than 3000 times higher than for children. Since COVID-19 operates in a highly age specific manner, mandated counter measures must also be age specific. If not, lives will be unnecessarily lost."[87]

It was also mathematically demonstrated that a virus with this feature would be deadlier society-wide than with targeted mitigation strategies in a model posted on March 16, 2020, by Maria Chikina of the University of Pittsburgh and Wes Pegden of Carnegie Mellon University.[88]

A global analysis of infection fatality rates by the Lancet found the survival rate was above 99% for every age under 60, even before it attenuated with the Omicron variants.[89]



Source: The Lancet. (2022). Variation in the COVID-19 infection–fatality ratio by age, time, and geography during the pre-vaccine era: a systematic analysis. The Lancet, 397(10269), 163-175. https://doi.org/10.1016/S0140-6736(21)02867-1

87 Kulldorff, M. (2020, April 10). COVID-19 Counter Measures Should be Age Specific. LinkedIn. https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/

88 Chikina, M., & Pegden, W. (2020, March 16). Fighting COVID-19: the heterogeneous transmission thesis. https://www.math.cmu.edu/~wes/covid.html

89 The Lancet. (2022). Variation in the COVID-19 infection–fatality ratio by age, time, and geography during the pre-vaccine era: a systematic analysis. The Lancet, 397(10269), 163-175. https://doi.org/10.1016/S0140-6736(21)02867-1

Not surprisingly, first-wave COVID deaths were concentrated not just among the elderly but specifically in nursing homes. As of April 12, 2020, it was reported that nursing home residents comprised 57 percent of all COVID-19 deaths in Spain, 53 percent in Italy, and 45 percent in France.[90]

Through June 2020, more than half of all US COVID deaths were among nursing home residents. This fact was partly underappreciated because neither HHS nor CDC tracked these data. However, the Committee to Unleash Prosperity compiled it regularly from state sources and presented it to Congress. Remarkably, several states pursued the precise opposite of a protect the vulnerable strategy – an expose the vulnerable strategy – of requiring still-infectious patients to be returned to nursing homes once they were clinically stable.[91]

In New Jersey, whistleblowers in the state health department alleged that the governor's administration intentionally diverted testing supplies needed at nursing homes to public drive-up testing sites.[92]

When specific populations are known to have a high risk for death or serious illness, a strategic use of resources to heighten their protection and awareness should be employed. Specific steps might include: prioritized testing to nursing homes and senior centers; high-frequency testing of all nursing home staff and visitors; extra infection control standards in nursing homes, in alliance with hospitals; frequent monitoring and alert outreach to high-risk seniors in communities and nursing homes when infections are high.

Targeted measures were specifically proposed by Scott Atlas within the White House task force. Still, his proposals were mischaracterized as doing nothing by other task force members and denigrated in favor of ineffective lockdown measures.[93]

The Great Barrington Declaration was a simple statement of the importance of focusing protection on the at-risk population.[94] When the declaration was issued, public health authorities in the United States neither embraced it nor refuted it – instead they suppressed it and smeared its signatories.

90 Comas-Herrera, A., & Zalakain, J. (2020, April 12). Mortality associated with COVID-19 outbreaks in care homes: early international evidence. International Long Term Care Policy Network. https://ltccovid.org/wp-content/uploads/2020/04/Mortality-associated-with-COVID-12-April-3.pd

91 Kerpen, P. (2020, June 11). COVID-19: The Nursing Home Disease. Testimony to the House Select Committee on Coronavirus. https://committeetounleashprosperity.com/wp-content/uploads/2020/10/465227534-Kerpen-Testimony-6-11.pdf

92 Members of the NJ Pandemic Response Team. (n.d.). Letter to the Bipartisan Review and Recovery Committee to Investigate COVID-Related Crises. https://s3.documentcloud.org/documents/6934674/Letter-From-N-J-Health-Department-Employees.pdf

93 Atlas, S. (2020, October 15). [Email response to Deborah Birx]. Twitter. https://twitter.com/ScottAtlas_IT/status/1753117473606668419/

94 Great Barrington Declaration. (n.d.). https://gbdeclaration.org/

Indeed, NIH Director Francis Collins directed a smear campaign, writing in an email that was later made public: "This proposal from the three fringe epidemiologists . . . seems to be getting a lot of attention – and even a co-signature from Nobel Prize winner Mike Leavitt [sic] at Stanford. There needs to be a quick and devastating published take down of its premises."[95]

The most persistent criticism of shielding the vulnerable has been that it is impossible to segment society and; therefore, no one can be protected without protecting everyone. However there is empirical evidence that it is possible to achieve differential protection.[96] Moreover, to the extent that mitigation measures can succeed for anyone, educating the vulnerable on their risks allows them to make their own decisions and take voluntary measures based on their values without the societal disruptions associated with mandates.

A future virus may not have the same profound age differential risk as COVID. Identifying the most vulnerable groups and focusing resources on their protection will always be critical to any sensible crisis response.

95 Wall Street Journal. (2021, December 21). How Fauci and Collins Shut Down Covid Debate. https://www.wsj.com/articles/fauci-collins-emails-great-barrington-declaration-covid-pandemic-lockdown-11640129116?st=7f3jxc8xeafz64u&reflink=desktopwebshare_permalink

96 Axfors, C., et. al. (2023). Differential COVID-19 infection rates in children, adults, and elderly: Systematic review and meta-analysis of 38 pre-vaccination national seroprevalence studies. J Glob Health, 13(06004). https://doi.org/10.7189/jogh.13.06004

Lesson #10: Warp Speed: Deregulate But Don't Mandate

Project Warp Speed was a remarkable achievement in reducing time of drug development. It developed multiple highly effective monoclonal antibody treatments. It also facilitated the development of vaccines in record time. Most critics asserted that it would take two to four years to deploy a vaccine – by which time the pandemic would be over. But while the speed of innovation was a remarkable deregulatory success story, there were multiple failures, including the focus on new treatments to the exclusion of conducting trials of repurposed existing drugs, politicized distribution of treatments, and most significantly, an all-out "vaccinate everyone" pressure campaign that papered over real evidence of potential harms and undermined informed consent. This culminated in Biden's shameful mandates that sought to exclude people from the military, government service, and even private sector employment based on their vaccination status.

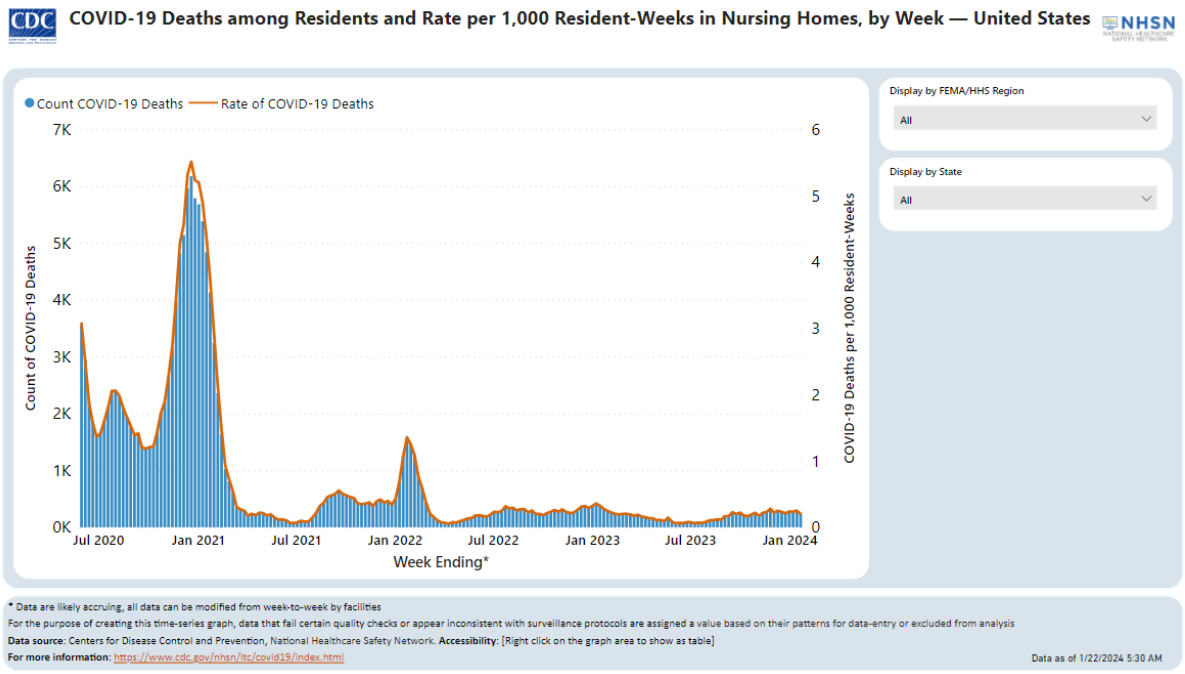
Government monopoly purchasing and distribution of monoclonal antibodies created chronic shortages and politicized distribution decisions, most catastrophically the announcement at the peak of the Delta wave that Regeneron would be rationed in the South, where it was needed, due to concerns for "equitable distribution, both geographically and temporally."[97] By the time the expected winter COVID wave arrived in the North, Regeneron distribution was stopped completely because it was ineffective against Omicron, even though there was still substantial Delta circulation and testing could have been used to identify likely Delta cases. The stockpiled Regeneron that was denied to people in the South who needed it went unused.

Four companies with authorized monoclonals were effective during Delta. Had these remedies been purchased and distributed through normal commercial channels, there would have been no shortages, no politicized distribution decisions, and likely substantially fewer deaths.

The vaccines were also a deregulatory triumph. The original vaccine was well-matched to then-circulating variants, and there was a sharp drop-off in hospitalizations and deaths, especially among the nursing home population.[98]

97 Public Health Emergency. (2021, September 16). FAQs on Monoclonal Antibodies. [Archived page]. https://web.archive.org/web/20210916155644/https://www.phe.gov/emergency/events/COVID19/Investigation-MCM/Pages/FAQs-mAB.aspx

98 Centers for Disease Control and Prevention. (n.d.). COVID-19 Long-term Care Facility Module. https://www.cdc.gov/nhsn/covid19/ltc-report-overview.html#anchor_1594393305



Source: Centers for Disease Control and Prevention. (n.d.). COVID-19 Long-term Care Facility Module. https://www.cdc.gov/nhsn/covid19/ltc-report-overview.html#anchor_1594393305

Because viruses mutate rapidly, the Warp Speed deregulatory approach that enabled rapid development was critical to making a vaccine available quickly enough to be beneficial. An estimate by Casey Mulligan found that if normal regulatory timelines had been imposed, "additional deaths and more delays in returning to work and school, pushing back access to vaccines by even six months would have cost more than $1 trillion in the U.S. alone."[99]

But moving at Warp Speed should prompt public officials to be meticulous in communicating the experimental nature of the vaccine, the known and unknown potential risks, and the relative risks of COVID itself. The opposite approach was taken, which falsely communicated universal benefit and actively suppressed critical information.

The Biden administration went all-in on a "vaccinate everyone" push that included even low-risk younger populations for whom the risk/benefit equation was questionable. Suppression of dissent also undermined informed consent by downplaying vaccine side effects, especially myocarditis for which the CDC blocked the release of an alert to shape public opinion.[100]

99 Mulligan, C. B. (2023, October 6). We Need More 'Warp Speed' Operations. Wall Street Journal. https://www.wsj.com/articles/we-need-more-operation-warp-speed-covid-cancer-diabetes-bureaucracy-fda-ace77028

100 Stieber, Z. (2024, January 25). Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis. Epoch Times. https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675?utm_medium=social&utm_source=twitter&utm_campaign=digitalsub

The public was not adequately informed about the chosen clinical end-points of the early clinical trials, and about what was not assessed. Those were not "lives saved" or "serious illness prevented"; instead, less important end-points were chosen. In addition, the public was not informed that infection prevention was not studied.

While the development of monoclonal antibody treatments was a success, the focus on developing new drugs was to the exclusion of conducting high-quality trials of already FDA-approved drugs safely used for other infections in billions of doses worldwide. Implausibly, Fauci's National Institute of Allergy and Infectious Diseases (NIAID) claimed it could not find enough volunteers for such trials. That should have been a top priority, given that those drugs were so safe that in some countries they are often purchased over-the-counter without prescription.

Royalty payments likely biased regulators in favor of new drugs. Over $325 million in royalties were received by NIH employees, including Anthony Fauci and Francis Collins, from private drug companies in the 2009-2019 period.[101] Those agreements should have been disclosed to the public up front.

As Omicron variants displaced earlier strains in late 2021 and early 2022, there was far less benefit to the vaccine because the virus itself was much less virulent, and the vaccine no longer had any appreciable effect on transmission – Omicron spread through nearly the entire population with generally mild disease, ending the pandemic. A vaccine not deployed until after that point would have had negligible benefits, underscoring the essential value of speed to market in a pandemic.

Yet the Biden administration nonetheless pressed forward with its efforts to effect or even mandate universal vaccination. The White House even directed child-vaccine and booster approvals instead of allowing the FDA to conduct appropriate trials. This resulted in the resignation of the FDA's top two vaccine officials.[102]

Aside from inadequate understanding of safety and potential serious adverse effects, the most catastrophic vaccine error was the Biden administration policy mandating vaccination throughout the private economy, a policy which was only stopped by a 6 to 3 decision of the Supreme Court in NFIB v. OSHA.[103] If the Court had allowed the OSHA rule to take effect, the vaccine would have been mandated as a condition of employment for every private company in the country with 50 or more employees.

The successful rapid development of vaccines and therapeutics in a pandemic should focus on removing regulatory barriers, conducting high-quality trials, effectively communicating known risks and benefits, and allowing commercial channels to handle distribution. Moreover, the safety of new drugs must be prioritized and assessed in a detailed and thorough manner. This is especially critical in new technologies like the mRNA vaccines. Mandates and intentional undermining of informed consent should be rejected, allowing individuals to make their own decisions.

101 Open The Books. (2023, August 11). NIH Secret Third-Party Royalty Database Uncovered. https://www.openthebooks.com/nih-secret-third-party-royalty-database-uncovered/

102 Endpoints News. (2021, August 31). In a major blow to vaccine efforts, senior FDA leaders stepping down. https://endpts.com/breaking-in-a-major-blow-to-vaccine-efforts-senior-fda-leaders-stepping-down-report/

103 National Federation of Independent Business v. Department of Labor, Occupational Safety and Health Administration, 595 U.S. ___ (2022), https://www.supremecourt.gov/opinions/21pdf/21a244_hgci.pdf

Conclusion: Limit Government Emergency Powers and Earn Back Public Trust

From the very start of COVID, politicians assigned unprecedented powers to public health agencies – many of which imposed strict limits on Americans' basic civil liberties. There was very little oversight or limitation on the powers conferred to these agencies.

Granting public health agencies these extraordinary powers was a major error. It, in effect, granted these agencies a license to deceive the public. Contrary to popular belief, Bjornskov and Voigt found that "the more advantages emergency constitutions confer to the executive, the higher the number of people killed as a consequence of a natural disaster, controlling for its severity."[104]

Lockdowns, school closures, and mandates were tragically flawed strategies but they were pushed with remarkable fervor by public health authorities at all levels. Consequently, these authorities have discredited themselves to a large segment of the American public. To the extent that means future catastrophic policy errors may provoke a robust public backlash, which may be a good thing. But even better would be to reform these institutions to be worthy of trust.

Towards that end, we recommend that Congress and the states define by law "public health emergency" with strict limitations on powers conferred to the executives and time limits (e.g., two weeks), that requires legislation to extend. Crises are when checks and balances and well-functioning institutions are most needed – not when they should be discarded and decision-making outsourced to alleged experts like Francis Collins, who casually confessed to a completely incorrect decision calculus years later.

Congress and the states should establish term limits (e.g., six years) for all senior health agency positions, including top- and mid-level posts, after first replacing the heads of CDC, NIH, and FDA. For instance, Anthony Fauci worked as a bureaucrat for 38 years. Such longevity accrues power and seems to inhibit dissenting voices, while setting up unhealthy relationships with outside parties, including the media.

There is a serious structural problem when the principal face of pandemic response policy – Anthony Fauci – is the head of the largest federal grantmaking entity on which nearly all medical experts are dependent for their research funding. This structural problem created an environment in which it was very difficult for most experts to break with the dominant narratives on lockdowns, masks, or overwhelmed hospitals regardless of their own research findings, experiences, or judgment. Worse, those who did break with the party line were subject to intimidation and abuse, as well as censorship at the request and insistence of government actors.

104 Bjørnskov, C., & Voigt, S. (2021). Emergencies: on the misuse of government powers. Public Choice, 190(1–2), 1–32. https://doi.org/10.1007/s11127-021-00918-6

While NIH became the principal advocate of lockdown policies, it also conspicuously failed to do its job – running high-quality trials of repurposed drugs and non-pharmaceutical interventions. As a result, clinicians were largely flying blind, and policy decisions were made based on very limited high-quality evidence.

When NIH and NIAID control the grants on which the majority of scientists make a living, it is inappropriate for the heads of those agencies to be key policy advisers to the president as well as public communicators establishing an alleged scientific consensus. NIH funding itself should be decentralized or block-granted to the states. A total of 19 U.S. medical centers receive over $500 million yearly from the NIH.[105] Indeed, NIH is the dominant funder of all scientific research, to the tune of $48 billion per year.[106]

The heads of NIH and its subagency NIAID should be people with little or no publicly facing role, who will allocate grant money on the merits of applications and commit to a research agenda that quickly identifies and rigorously applies randomized control trials to both repurposed drugs and non-pharmaceutical interventions in an emergency.

It requires full transparency of all FDA, CDC, and NIH discussions and immediate posting to public forums. Statements from all advisors in those meetings, such as the startling October 26, 2021, recommendation of Eric Rubin, M.D., FDA advisor for children's COVID vaccines, that "we're never going to learn about how safe this vaccine is [in children] unless we start giving it. That's just the way it goes,"[107] must be widely visible to the public.

Restate definitively that the CDC and other health agencies are strictly advisory and do not have the power to set laws or mandates. Limiting health agency power is a way to begin holding elected officials accountable to the citizens, rather than allowing the pretense of hiding behind those agencies.

Immediately halt all binding agreements or pledges to the World Health Organization. The U.S. is the largest nation funding WHO activities, but the WHO record is abysmal on the issues covered in this report.

Until key institutions openly acknowledge that lockdowns, school closures, and mask and vaccine mandates were catastrophic errors that will not be repeated in the future, the American people will – and should – withhold their trust.

105 Nietzel, M. (2024, February 10) Top 20 Universities For NIH Funding; Johns Hopkins Ranks First Again. Forbes. https://www.forbes.com/sites/michaeltnietzel/2024/02/10/top-20-universities-for-nih-funding-johns-hopkins-ranks-first-again/

106 NIH (2024). Budget. https://www.nih.gov/about-nih/what-we-do/budget

107 Makary, M. (2022, June 23). CDC recommends COVID-19 vaccines for babies, kids under 5. Here are 6 things parents need to know. Fox News. https://www.foxnews.com/opinion/cdc-recommends-covid-19-vaccines-babies-kids-under-5-6-things-parents-need-know



COMMITTEE TO UNLEASH PROSPERITY

Mask case

Derek Zisk <dzisk81@gmail.com>

Wed 3/20/2024 7:35 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

To Whom It May Concern:

Good Evening, I am writing to express my dissatisfaction with this case and the fact that masks in school is once again a talking point. It has been proven over and over again that masking children in schools causes more harm than good, there is no proof that surgical or cloth masks stop transmission of pathogens, numerous studies have shown bacteria growth on masks that are worn on school children's mouthes all day, schools are not sterile environments & school age children frequently touch their faces & masks which thus makes them more vulnerable to illnesses, this is in addition to the developmental and psychological harm caused by wearing masks in school settings. Furthermore, no one has addressed the irreparable harm forced masking has on our most vulnerable children, foster children, children who have special needs (developmental and/or physical limitations). It is often most difficult for children with special needs to be forced masked all day.

Masking should always be a personal choice, like it is right now. We see people out and about today that wear masks in public. That's good, that's great for them to make that choice for themselves. The choice for children to be masked for any reason should be made by the student and parents not by the state or district. In America, no one should be forced to wear something on their face especially if the worn article is causing more harm/damage to the individual. What happened to personal autonomy?

I believe the court needs to go back and review the findings from the Southwell vs McKee case, I think the evidence was laid out very clearly that masks and forced masking causes irreparable harm and damage to children and their wellbeing.

I oppose any and all legislation that would allow forced masking on school children and I ask you as our representative officials to do the same.

Thank you,
Derek Zisk

Urgent

Kimberly Ramos <kimmiramos33@yahoo.com>

Wed 3/20/2024 7:41 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender

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Report Suspicious

Hello Zachary,

I am righting to you as a very concerned mother, long time Rhode Island resident and military veteran. I just viewed a very disturbing post online to which I hope is not true. The post stated that masking children in school is up for ruling. This is something that I am completely appalled by, the forced masking of students?! Why would this even be considered at this time or at all. To take away freedom of choice? I am against this and would like you to represent the freedom to choose anywhere,school, work etc. The only people that should decide this should be each person for themselves. Thank you for reading, and please have the courage to stand up in honor to choose freedom.

Sincerely,
Kimberly Ramos

Oppose mask mandates

Elizabeth moylan <Elizabeth_valeika@hotmail.com>

Wed 3/20/2024 8:02 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>
Cc:consent4ri@hotmail.com <consent4ri@hotmail.com>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

Dear Sir,

As a parent and tax paying homeowner of the state I vehemently oppose any mask mandates in schools. If masks are mandatory in public schools our family will pull our two children from the Woonsocket school district and we will homeschool. We also chose to homeschool our children during the Covid mask mandates.

Regards,
Elizabeth Moylan
Woonsocket
Sent from my iPhone

** Stop School Masking **

JAB <jab123079@aol.com>

Wed 3/20/2024 10:19 PM

To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>;admin@healthchoiceri.com <admin@healthchoiceri.com>

2 attachments (678 KB)

Screenshot_20240320_194148_Email.jpg; FB_IMG_1710985906625.jpg;

This Message Is From an External Sender

This message came from outside your organization.

Report Suspicious

Dear Zack & Delusional DOH bureaucrats,

I have 2 questions:
1) WTF is wrong w/ you?
2) How do we cut funding and power to your overfunded, useless Leftist agenda driven department?

My child will not be arbitrarily wearing a mask in any foreseeable future. The ScamDEMic stole our freedom, our money & trust in Government. For the children their chance of a normal childhood and school experiance was stolen. Screw you and the "new normal" bullshit.

While sick Individuals like youselves may feel arbitrary restrictions and useless tyrannical mandates help save lives.
The rest of us know the truth. They did little to "slow the curve" or "stop the spread". Unnecessarily masking children did irreparable harm! Approving fact! More harm than the virus in most cases for most individuals especially children.
Forcing "the jab" into so many arms and the millions of childen who did not need it should be treated as a crime against humanity and people like you are the criminals.

I urge you to use what little sense you have and repeal this bill.

Joseph Broccoli & Family
Rhode Island Voters

Sent from my T-Mobile 5G Device

no more mask mandates....ever

Carol Daukas <caroldaukas@gmail.com>
Wed 3/20/2024 10:23 PM
To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

This Message Is From an External Sender
This message came from outside your organization.

Report Suspicious

To whom it may concern at RIDOH,

I spoke the other day at the Mask hearing, and am following through with an email opposing's RIDOH's push for a regulation allowing them the right to enforce masking, even though masking children has been scientifically proven to neither do the purported job of stopping the spread of flu like illnesses, and worse that it causes "irreparable harm."

Mask mandates have hurt children in every arena: their physical health, their social connections, their learning/education, their mental / emotional health. The damage has been done and we do not know how far into the future this damage will follow them and adversely effect them.

You saw and heard first hand at the hearing.
You need to let this desire to be able to inflict this gratuitous abuse on RI children in the future drop. Drop it now.

Carol Daukas

Good morning,

My name is Jason Romblad, I am an unaffiliated voter from Woonsocket. I am here today to vehemently oppose the school masking proposal that the RI DOH is proposing today. I want to point out that school masking started during covid era lockdowns using executive orders and supposed emergency powers. There were no studies used as reference when issuing these mandates and there were no studies conducted in this state regarding the effects on the children being forced to inhale their own carbon dioxide for hours at a time. The uncleanliness of these masks, over time, are detrimental to the health of the human body, inhibiting the flow of fresh air and oxygen. Nearly all masks worn, will not stop a virus and states exactly that on the packaging. To issue these authoritative mandates, with no followup studies, is negligent and quite frankly, should be criminal.

To this day, not one person under the age of 18 has died from covid, in RI. This is direct information from the RI DOH covid portal. To force masks on healthy children who have no risk of dying from a virus, is inhumane.

The same people, who issued mask mandates in Rhode Island, including this agency, allowed masks to be removed in restaurants, while sitting and consuming food and beverages. Do you expect all of us commonsensical people in this state, to believe that nonsense? Do you expect us to believe, that we are safe from catching a virus while we are sitting but we are not safe while standing? How absurd and insulting. I am still shocked today, that the general public fell for this hoax and that the RI legislature allowed the dictators/governors to rule for so long under supposed emergency powers.

These same people, including this agency, eventually allowed masks to be removed at retail locations, if plexiglass was installed at the cash registers, ignoring the fact that a virus will spread easily around such plexiglass. The lack of science when issuing these mandates, is astounding.

We are here today to discuss school masking, but let's make it clear, this was just one tool used to propulgate the greatest medical hoax in world history. Covid. Big Pharma spends hundreds of millions, if not billions, to push their products and that is exactly what these rules and mandates were, a ruse to instill

fear in the general public, in order to convince them to take an experimental shot.

This agency, the RI DOH, often referred to using the guidance of the CDC, FDA and NIH. They called for a 6 foot social distancing rule, which closed many schools, setting many children back in their studies. Just recently Anthony Fauci testified that this rule was "likely not based on scientific data". In laymens terms, they lied. With such an
agregious admission how are we to believe any of their recommendations. This agency, the RI DOH, followed along blindly, with the recommendations of these agencies that are heavily intertwined with big pharma. Many top officials at the FDA, CDC & NIH have previously worked for the same pharmaceutical companies who are producing the covid shots being pushed, and vice versa. They also collect royalties from these same pharmaceutical companies. Moderna announced last year,that they alone, paid the NIH, $400 million in royalties, probably to the same people that approved their clot shots.

Covid has more than a 99% survival rate and there are over the counter medications that work against it. For that reason alone, the Emergency Use Authorization, for the covid shots, was both unnecessary and illegal. These shots are not safe and effective and have many adverse reactions, including death. This information was provided in the Pfizer clinical trials, which they tried to get sealed for 75 years.

This RI DOH sent letters to our medical professionalss, threatening that they would lose their medical licenses if they spoke out against these lies. This state goverment also forced many to take these shots and terminated employment to those who did not comply. This is in direct violation of the Nuremburg Codes and people should be held liable.

You should all be ashamed that this agency, resorted to fear, intimidation and control tactics.

So in closing, I again state, that I vehemently oppose the school masking regulation being proposed. Thank you.

Good morning. My name is Richard Southwell and I am the lead plaintiff in the Southwell v. McKee lawsuit.

Before providing my feedback on the proposed school mask regulation, I thought it would be useful to walk through a timeline of key events.

March 16, 2020
15 days to flatten the curve. RI school children were sent home to learn remotely and did not return to school for the remainder of the school year.

September, 2020 - 5 months after 15 days to flatten the curve
After a summer of contentious debate, the decision is made to reopen schools for in-person learning with strict Covid protocols, including mandatory masking for all children throughout the school day.

Summer, 2021 - 16 months after 15 days to flatten the curve
Concerned parents began engaging with school committees to adopt “mask optional” policies for the upcoming school year. There was a growing recognition of the physical and psychological harm that Covid protocols generally and mask requirements specifically were causing among school children. There was also growing skepticism about the efficacy of masking children while they are in school. The skeptics note that despite being nearly a year and a half into the pandemic, there has been little to no scientific research on the benefits or harms that masking school children may cause. There is no historical research that supports the use of masks to reduce the spread of airborne illness. Despite the lack of evidence, public health officials continued to insist that “masks work”.

September, 2021 -
The Centers for Disease Control (CDC) releases a study with the title:

Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021

This will come to be known as “The Pima AZ Study”

The stunning conclusion reached in the Pima AZ Study was that school districts WITHOUT mask mandates were nearly 3X as likely to have an outbreak of Covid. This soundbyte was aggressively pushed by public health officials and major media outlets as THE scientific proof that “masks work”.

October, 2021 -
The Pima Study was entered into evidence by the Rhode Island Department of Health as part of their defense in the Southwell v. McKee lawsuit.

November, 2021 -
The CDC awards Rhode Island an $81.7 million grant for the construction of a new public health laboratory.

December, 2021 -
An article titled **The CDC's Flawed Case for Wearing Masks in School** was published in The Atlantic magazine. Based on discussions with several research scientists, the author raised legitimate questions about the data set and underlying methodology in the Pima study.

The science was being questioned

The CDC, which published the Pima AZ study in its Morbidity and Mortality Weekly Report (MMWR) responded to the article's author by stating *"MMWR is committed to quickly correcting errors when they are identified. We reviewed the specific items that you describe below and found no errors."*

American author, Upton Sinclair was right when he said "It is difficult to get a man to understand something when his salary depends on him not understanding it."

February 1, 2022 - nearly 2 years after 15 days to flatten the curve
The General Assembly held committee hearings on extending the Governor's emergency powers. Concerned parents testified en masse to oppose the measure based on the implications that it could have on continued school masking. Dr. James McDonald submitted written testimony to the committees and cited the findings of The Pima Study as justification for continued school masking.

March, 2022
Rhode Island's school mask mandate ends.

September 30, 2022
One year after the Pima AZ study was published, researchers Chandra and Hoeg released a study titled **Lack of correlation between school mask mandates and paediatric COVID-19 cases in a large cohort**. It was published in the Journal of Infection.

Objectives: To expand upon an observational study published by the Centers for Disease Control (CDC) showing an association between school mask mandates and lower pediatric COVID-19 cases. We examine whether this association persists in a larger, nationally representative dataset over a longer period.

Conclusions: The association between school mask mandates and cases did not persist in the extended sample. Observational studies of interventions are prone to multiple biases and provide insufficient evidence for recommending mask mandates.

The study was a direct challenge to “the science” that RIDOH had been relying on to support its school masking policies. What did they do? Did they look into it? No. They did not. Why? Could it have something to do with what was scheduled to happen on December 9, 2022?

December 9, 2022
Rhode Island Department of Health breaks ground on its new, $81.7 million CDC funded health lab.



To paraphrase Upton Sinclair, “It is difficult to get the public health bureaucracy to understand something when its funding depends on them not understanding it.”

The Rhode Island Department of Health has failed to provide credible scientific evidence to support masking school children as an effective intervention for stopping the spread of airborne disease. The best science that they have been able to muster thus far is the now highly suspect Pima AZ study.

Yet, here we are discussing a proposed regulation that would allow them to “require face masks for students in school to prevent the spread of an infectious disease”.

A few thoughts on the current DRAFT of the regulation:

**** The rationale described in section 4.3.A needs to be significantly more detailed than a statement that “Masks Work”. At a minimum, it should address in detail, the items listed in 4.3.B.9, which reads

Scientific evidence of the effectiveness, disadvantages and side-effects of masks on the pathogen including an assessment of the quality and availability of such evidence.

4.3.A should be expanded to require a more detailed statement and rationale should a school mask mandate be implemented.

**** Section 4.3.B provides a list of factors to be considered in deciding whether to require students to wear masks at school.

Items 6, 7 and 8 are an indirect reference to vaccines. The availability of a vaccine and/or the rate at which people choose to take that vaccine should have no bearing on the decision to mask school children. These items should be removed from the final regulation.

Item 10 indicates that parents or guardians MAY be included as stakeholders who provide input into the decision to mask students. This language should be changed to “Parents and guardians MUST be included as stakeholders from whom input will be sought.”

Item 13 is part of the “layered approach to stopping the spread” argument that we heard during Covid. Masking either provides a significant and measurable benefit on its own or it doesn’t. This item should be removed from the final regulation.

**** Section 4.3.C provides significant latitude to RIDOH in the selection, weighting and interpretation of scientific evidence used to make a decision on whether or not to mask K-12 students. It reads in part *“this balancing of evidence requires the exercise of judgment based on the facts and circumstances that exist at any given time as well as the experience and expertise of those engaged in the decision making process.”*

This much discretion requires significant transparency and accountability. RIDOH must disclose publicly all of the individuals who reviewed the scientific evidence, their credentials and what specific evidence they relied upon to reach their conclusions. This basic information should be included in the statement described in 4.3.A.

In closing, I will note one more time that RIDOH should not implement this regulation until it can provide credible scientific evidence that masking school children is an effective method for preventing the spread of airborne disease.