Charles J Cote MD

Comments regarding

Dentists, Dental Hygienists, and Dental Assistants (216-RICR-40-05-2)

General Overview

By way of introduction I am a board-certified pediatrician and pediatric anesthesiologist Prof. emeritus Department of anesthesia at the Massachusetts General Hospital Boston, and Harvard Medical School. I have been the primary author of every iteration of the sedation guidelines of the American Academy of Pediatrics and co-author of the guideline from the American Academy of Pediatric Dentistry. In the early 1980s several children died in dental offices in California. The American Academy of Pediatrics leadership asked the Section on Anesthesiology to help them write guidelines for sedation/anesthesia in nonstandard locations and the first guideline was published in 1985. During the intervening years I was informed through the Freedom of Information Act that I could acquire all adverse drug reports from the Food and Drug Administration. I obtained 700+ reports plus information from the United States Pharmacopeia as well as a survey I sent to all members of the Sections on Emergency Medicine, Pediatric Intensive Care, and Pediatric Anesthesiology. Two anesthesiologists, one emergency medicine physician, and one pediatric critical care specialist examined all these cases independently and then we debated the causes that led to the adverse outcomes. We narrowed it down to 95 cases upon which we could all agree on causation; **60 had death or neurologic injury and 29 were related to dental care.** [1 2] 80% of these events presented as desaturation (the patient turning blue for lack of oxygen) meaning that the children should have been rescued had the practitioners involved had the necessary skills. Interestingly, **a three-fold higher rate of cardiac arrest was associated with non-hospital events along with a ~93% mortality rate when something went seriously wrong in the dental office!** We could not determine specialty of the dentists except that there were at least 11 described as oral surgeons. This dental population was on average also older by a factor of 2 and healthier than the hospital-based population, but the dental population had a dismal outcome because there were inadequate skilled personnel available to rescue them. Had we known that the **dental specialty** would be so highly represented, **accounting for half of these deaths**, we certainly would have invited a pediatric dentist or an oral surgeon to assist us in evaluating these terrible events. Unfortunately, such preventable deaths continue to happen in the dental setting.[3,4]

This leads us to the current bill being considered and my grave concerns about how it is written and **inaccurate characterization of the sedation guideline of the American Academy of Pediatrics** (I was the primary author of this document so I clearly know its content and intent, please see my specific comments below). Most importantly this proposed legislation would codify a dangerous practice whereby an oral surgeon or dentist may direct the sedation/anesthesia of the pediatric patient while at the same time performing the dental procedure.[5,6] In other words doing two procedures at the same time and billing for both. The American Academy of Pediatrics guideline as well as the American Academy of Pediatric Dentistry guideline specifically state that children who are deeply sedated require an independent observer whose only responsibility is to continuously observe the patient. ***"This individual must, at a minimum, be trained in PALS and capable of assisting with any emergency event."*** This proposed legislation codifies that a Dental Anesthesia Assistant National Certification Examination (DAANCE) certified maxillofacial surgery assistant may fulfill this role (section 2.3). I would take great umbrage that such an individual could be of much help in a true life-threatening emergency since their only training consists of 36 hours of Internet courses (https://www.aaoms.org/continuing-education/certification-program-daance). Their course of study includes the following:

Dental Anesthesia Assistant National Certification Examination (DAANCE)

The self-study materials and the final exam cover 5 major areas:

1. Basic sciences
2. Evaluation and preparation of patients with systemic diseases
3. Anesthetic drugs and techniques
4. Anesthesia equipment and monitoring
5. Office anesthesia emergencies

To be eligible to participate in DAANCE, an assistant must be:

1. Employed for at least six months by either an AAOMS fellow/member, or by a dental professional who holds a valid anesthesia permit
2. CPR or BLS certified*

Note: there are no educational requirements regarding even high school certificates (Section 2.8.2) thus it appears that the majority of their training consists of on the job training (OJT) under the direction of an oral surgeon. These individuals may be either basic life support or CPR certified. ACLS training does not generally apply to pediatric patients; pediatric advanced life support (PALS) is more appropriate for pediatric patients. As you all know when push comes to shove someone who is not medically trained is unlikely to be able to perform the tasks needed to successfully rescue the patient in partnership with the oral surgeon when a true life-threatening event occurs. These individuals have no real-life experience which would provide them with the medical knowledge to assist the oral surgeon with a life-threatening event such as the child who has stopped breathing due to drug effects, developed spasm of the voice box muscles (laryngospasm), a seizure from local anesthetic overdose, sudden allergic drug reaction (anaphylaxis), or other life-threatening events which, although rare, still occur even in the best of hands. Obviously whenever a life-threatening emergency occurs having two brains, four eyes, and two pairs of hands that are skilled in dealing with emergencies will greatly improve the likelihood of solving and correcting the adverse event. In the case of the dental patient that means rescuing the patient without neurologic injury. A DAANCE certified individual does not fulfill the requirements of the American Academy of Pediatrics or the American Academy of Pediatric Dentistry. **It is astonishing and totally incongruous that a dental hygienist is required to have three years of training experience encompassing 4500 hours clinical experience, but the independent DAANCE observer expected to assist with a medical emergency is only required have 36 hours of Internet training (2.3 section A.39)!**

Specific Comments:

In **section 2.3 A, number 30**: the definition of minimal sedation is incorrect and not consistent with the definition of the American Academy of pediatrics. The AAP document defines *"**minimal sedation (old terminology "anxiolysis") is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation.**"* There is no recommended dosage in the AAP document and nitrous oxide is clearly not part of minimal sedation. In fact there is a specific section devoted to nitrous oxide analgesia which states: *"If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations greater than 50%, the likelihood for moderate or deep sedation increases.*[107,198,491,493,494] *In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response."*

Section 2.3 A 30 c and d apply to moderate and deep sedation not minimal sedation as with minimal sedation the patient is interactive.

Section 2.11.3 D regarding qualifications for individual anesthesia permit, simply states that they must have 60 hours of a training course in the management of 20 adult cases but the number of pediatric cases in this case defined as less than 13 years of age is not described.

Section 2.11.9 C.1.b Moderate sedation allows the second member of the team to be basic life support certified. The American Academy of Pediatrics in the American Academy of Pediatric Dentistry guideline states that this independent observer must be pediatric advanced life support certified (PALS) not basically support certified (BLS). Since any sedated child may easily progress from a state of moderate to deep sedation, with the concurrent risks described above BLS certification is inadequate.

Section 2.11.9 D allows the use of a DAANCE-certified assistant who is PALS certified (note that this contradicts the DAANCE document which states that they may be either BLS or CPR certified without description of what CPR course they are expected to have passed). Such an individual would not have any real-life experiences and is likely incapable of assisting with a true life-threatening event.

Section 2.11.9.D 5 only requires one person to be PALS certified rather than two individuals required by the American Academy of Pediatrics in the American Academy of Pediatric Dentistry guideline.

Section 2.11.9 D 2 j does not mandate that an adequately trained individual must continuously observe the patient during the recovery period, prior to achieving discharge criteria.

Section 2.11.9 D 5 c states that an individual experienced in recovery must be in attendance in the recovery facility but does not say what the level of experience is, nor does it state that this person must be there continuously.

Section 2.11.9 F c does not mandate end-tidal carbon dioxide monitoring for deep sedation or general anesthesia, rather it states that "auscultation a breath sounds or monitoring ~~internal~~ end tidal (expired) carbon dioxide". The AAP/AAPD clearly states that all patients who are deeply sedated or under general anesthesia require continuous expired carbon dioxide monitoring and for children who are moderately sedated, the use of expired carbon dioxide monitoring is encouraged after the child becomes sedated. **It is not an "either/or" situation and as you know if there is no expired carbon dioxide this indicated a blocked airway, a child who is not breathing, or a child who has sever low blood pressure.**

Section 2.11.9 F 2 I think the wording of this section could be improved to be consistent with that of the Academy of pediatrics i.e. age and size appropriate equipment should be available.

Section 2.13.1 C&D do not require a means for administering positive pressure ventilation (as in section 2.13.1.E.1 a). In fact, **all age and size appropriate airway adjuncts for rescue should be present regardless of the level of sedation because of the potential for inadvertent drug overdose, patient sensitivity, or anaphylaxis. Likewise, equipment necessary to start intravenous access should also be required for all levels of sedation not just deep sedation or general anesthesia (section 2.13.1.E.1.d)**

Section 2.13.2 A 3 b 3 Clinical guidelines for general anesthesia. Regarding pulse oximetry and expired carbon dioxide measurements, it states that these values should be recorded **"If taken".** Clearly someone who is under general anesthesia must have continuous pulse oximetry and capnography and these data must be recorded on the anesthesia/sedation time-based record. I do not understand what they mean by "if taken"

Section 2.13.2.A 4 a regarding recovery and discharge. It states that "oxygen and suction equipment must be immediately available in the discharge area and or operatory". Oxygen and suction must be present in both locations; **this is not an either/or situation**.

Section 2.13.1.A 4 d regarding discharge criteria. The American Academy of Pediatrics and the American Academy of Pediatric Dentistry guideline state that the patient should be returned to their pre-sedation state of consciousness which is much more specific than just having "stable oxygenation, ventilation and circulation".

Section 2.13.2 E 2 c Equipment requirements "noted in AAP guideline" is vague and non-specific (See table 2 in AAP Guideline)

Section 2.13.2.E 3 a. Moderate sedation. This is the first time that PALS certification is required for one of the assistants, but it again does not specify that the dentist must also be PALS certified so that two people hold such certification as required by AAP/AAPD guideline. **There is no section describing the requirements for deep sedation or general anesthesia.** The only time the individual responsible for monitoring the patient may assist with interruptible tasks is with moderate sedation but this is not permitted with a state of deep sedation or general anesthesia (Section 2.13.2.E 3a). Whereby their only responsibility is to monitor the patient.

The skills for administering deep sedation or general anesthesia are very specific in the AAP document:

"The individual providing sedation must be skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required. At least one practitioner skilled in obtaining vascular access in children immediately available."

Summary:

The AAP/AAPD Guideline is very specific: If the intended level of sedation is minimal the practitioner must have the skills to rescue from a state of moderate sedation. If the intended level of sedation is moderate the practitioner must have the skills to rescue from a state of dep sedation. If the intended level of sedation is deep, then the practitioner must have the skills to rescue from a state of general anesthesia. **An independent observer whose only responsibility is to continuously monitor the patient is required.** ***"This individual must, at a minimum, be trained in PALS and <u>capable of assisting with any emergency event.</u>"***

The single provider model, i.e., the oral surgeon performing the procedure and directing the anesthesia/sedation at the same time is fraught with danger since when something goes wrong with this practice model there is no other skilled medical or dental professional present to assist in patient rescue. Caleb's law in California was proposed because of the death of a 5-year-old in an oral surgeon's office. His aunt sent me the office records and it was clear that this particular individual was not skilled in patient rescue. When Caleb's oxygen levels dropped, and he stopped breathing, he panicked. No reversal agents were administered, no oral devices to clear the obstructed airway had been attempted, he could not perform basic bag/mask ventilation, or intubation (he knocked out multiple teeth) and he even attempted a surgical airway but from the side of the neck (instead of the middle of the neck), so he did not know even basic anatomy. Caleb was pulseless when 911 arrived. Had an extra skilled anesthesia trained person been present (A medical anesthesiologist, a dental anesthesiologist, a certified registered nurse anesthetist, a second oral surgeon), Caleb would have easily been rescued and I would not be talking about it this morning. This is an extreme example of why a skilled independent anesthesia provider must be present, particularly in a non-hospital venue where the only way to obtain skilled help is to call 911. This is exactly why one practitioner cannot perform two services at the same time. **I would ask each of you if you ever would board a commercial airline flight where there was a pilot but no copilot, instead the co-pilot's role was fulfilled by flight attendant who can inform the pilot that something is wrong but is not able to assist in the emergency? Like the Geico add that *states "that is the worst cavity I have ever seen but we just report it, we can't fix it"*. That is what this legislation is asking you to codify into law and to support this very dangerous practice.** There is no where else in medicine where this practice is allowed except in the ER with brief emergent procedures but with the help of experienced ER nurses as the second pair of skilled hands and independent observer and not a DAANCE trained person who could be a high school drop-out whose only education was provided by an internet course. Would you allow your child, your grandchild, or yourself to be placed at such risk where the DAANCE trained individual is the person expected to assist the oral surgeon with a life-threatening event when they have never touched a real live patient and have never even observed such an event let alone know immediately what to do to provide assistance without panic? **Think carefully about this!**

Respectfully submitted

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1. Cote CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. *Pediatrics.* Apr 2000;105(4 Pt 1):805-814.
2. Coté CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. *Pediatrics.* Apr 2000;105(4 Pt 1):805-814.
3. Lee HH, Milgrom P, Starks H, Burke W. Trends in death associated with pediatric dental sedation and general anesthesia. *Paediatr Anaesth.* Aug 2013;23(8):741-746.
4. Agarwal R, Kaplan A, Brown R, Cote CJ. Concerns Regarding the Single Operator Model of Sedation in Young Children. *Pediatrics.* Apr 2018;141(4).
5. Coté CJ, Wilson S. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatr Dent.* 2016;38(4):13-39.
6. Coté CJ, Wilson S, American Academy Of P, American Academy Of Pediatric D. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics.* Jul 2016;138(1).

Table 2. Comparison of Moderate and Deep Sedation Equipment and Personnel Requirements in AAP Guideline.

	Moderate Sedation	Deep Sedation
Personnel	An observer who will monitor the patient but who may also assist with interruptible tasks; should be trained in PALS	**An independent observer whose only responsibility is to continuously monitor the patient; trained in PALS**
Responsible practitioner	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction including the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation. Recommended that at least one practitioner should be skilled in obtaining vascular access in children; trained in PALS.	**Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required. At least one practitioner skilled in obtaining vascular access in children immediately available.**
Monitoring	Pulse oximetry	Pulse oximetry
	ECG recommended	ECG required
	Heart rate	Heart rate
	Blood pressure	Blood pressure
	Respiration	Respiration
	Capnography recommended	Capnography required
Other equipment	Suction equipment Adequate oxygen source/supply	Suction equipment Adequate oxygen source/supply Defibrillator required
Documentation	Name, route, site, time of administration, and dosage of all drugs administered. Continuous oxygen saturation, heart rate, and ventilation (capnography recommended). Parameters recorded every 10 minutes.	Name, route, site, time of administration, and dosage of all drugs administered. Continuous oxygen saturation, heart rate, and ventilation (capnography required). Parameters recorded at least every 5 minutes
Emergency check lists	Recommended	Recommended
Rescue cart - properly stocked with rescue drugs and age and size appropriate equipment (see Appendix C and D)	Required	Required
Dedicated recovery area with rescue cart properly stocked with rescue drugs and age and size appropriate equipment (see Appendix C and D) and dedicated recovery personnel. Adequate oxygen supply.	Recommended. Initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased.	Recommended. Initial recording of vital signs may be needed at least 5 minute intervals until the child begins to awaken, then recording intervals may be increased to 10-15 minutes.
Discharge criteria	See Appendix A	See Appendix A

Charles J Coté MD

Guideline for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Developed and Endorsed by

American Academy of Pediatric Dentistry and American Academy of Pediatrics

Latest Revision*

2016

Abstract

The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical/dental supervision, careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications, appropriate fasting for elective procedures and a balance between the depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure, a focused airway examination for large (kissing) tonsils or anatomic airway abnormalities that might increase thepotential for airway obstruction, a clear understanding of the medication's pharmacokinetic and pharmacodynamic effects and drug interactions, appropriate training and skills in airway management to allow rescue of the patient, age- and size-appropriate equipment for airway management and venous access, appropriate medications and reversal agents, sufficient numbers of staff to both carry out the procedure and monitor the patient, appropriate physiologic monitoring during and after the procedure, a properly equipped and staffed recovery area, recovery to the presedation level of consciousness before discharge from medical/dental supervision, and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children.

Introduction

The number of diagnostic and minor surgical procedures performed on pediatric patients outside of the traditional operating room setting has increased in the past several decades. As a consequence of this change and the increased awareness of the importance of providing analgesia and anxiolysis, the need for sedation for procedures in physicians' offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, other inpatient hospital settings, and ambulatory surgery centers also has increased markedly.[1-52] In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) have published a series of guidelines for the monitoring and management of pediatric patients during and after sedation for a procedure.[53-58] The purpose of this updated report is to unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities, particularly regarding continuous expired carbon dioxide measurement; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes. This document uses the same language to define sedation categories and expected physiologic responses as The Joint Commission, the American Society of Anesthesiologists (ASA), and the AAPD.[56,57,59-61]

This revised statement reflects the current understanding of appropriate monitoring needs of pediatric patients both during and after sedation for a procedure.[3,4,11,18,20,21,23,24,33,39,41,44,47,51,62-73] The monitoring and care outlined may be exceeded at any time on the basis of the judgment of the responsible practitioner. Although intended to encourage high-quality patient care, adherence to the recommendations in this document cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate these safety

ABBREVIATIONS

AAP: American Academy of Pediatrics. **AAPD:** American Academy of Pediatric Dentistry. **ASA:** American Society of Anesthesiologists. **BIS:** Bispectral index. **CPAP:** Continuous positive airway pressure. **ECG:** Electrocardiography. **EEG:** Electroencephalogram/electroencephalography. **EMS:** Emergency medical services. **LMA:** Laryngeal mask airway. **MRI:** Magnetic resonance imaging. **OSA:** Obstructive sleep apnea. **PALS:** Pediatric advanced life support.

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** This guideline was originally adopted in 2006 and reaffirmed in 2011.*

principles have been widely implemented and shown to reduce morbidity.[11,23,24,27, 30–33,35,39,41,44,47,51,74–84] These practice recommendations are proffered with the awareness that, regardless of the intended level of sedation or route of drug administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression, laryngospasm, impaired airway patency, apnea, loss of the patient's protective airway reflexes, and cardiovascular instability.[38,43,45,47,48,59,62,63,85–112]

Procedural sedation of pediatric patients has serious associated risks.[2,5,38,43,45,47,48,62,63,71,83,85,88–105, 107–138] These adverse responses during and after sedation for a diagnostic or therapeutic procedure may be minimized, but not completely eliminated, by a careful preprocedure review of the patient's underlying medical conditions and consideration of how the sedation process might affect or be affected by these conditions: for example, children with developmental disabilities have been shown to have a threefold increased incidence of desaturation compared with children without developmental disabilities.[74,78,103] Appropriate drug selection for the intended procedure, a clear understanding of the sedating medication's pharmacokinetics and pharmacodynamics and drug interactions, as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are critical.[42, 48,62,63,92,97,99,125–127, 132,133,139–158] Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for the accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.[44,63, 64,67,68,74,90,96,110,159–174] The work of the Pediatric Sedation Research Consortium has improved the sedation knowledge base, demon-strating the marked safety of sedation by highly motivated and skilled practitioners from a variety of specialties practicing the above modalities and skills that focus on a culture of sedation safety.[45,83,95,128–138] However, these groundbreaking studies also show a low but persistent rate of potential sedation-induced life-threatening events, such as apnea, airway obstruction, laryngospasm, pulmonary aspiration, desaturation, and others, even when the sedation is provided under the direction of a motivated team of specialists.[129] These studies have helped define the skills needed to rescue children experiencing adverse sedation events.

The sedation of children is different from the sedation of adults. Sedation in children is often administered to relieve pain and anxiety as well as to modify behavior (e.g., immobility) so as to allow the safe completion of a procedure. A child's ability to control his or her own behavior to cooperate for a procedure depends both on his or her chronologic age and cognitive/ emotional development. Many brief procedures, such as suture of a minor laceration, may be accomplished with distraction and guided imagery techniques, along with the use of topical/local anesthetics and minimal sedation, if needed.[175–181] However, longer procedures that require immobility involving children younger than 6 years or those with developmental delay often require an increased depth of sedation to gain control of their behavior.[86,87,103] Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.[129] Children in this age group are particularly vulnerable to the sedating medication's effects on respiratory drive, airway patency, and protective airway reflexes.[62,63] Other modalities, such as careful preparation, parental presence, hypnosis, distraction, topical local anesthetics, electronic devices with age-appropriate games or videos, guided imagery, and the techniques advised by child life specialists, may reduce the need for or the needed depth of pharmacologic sedation.[29,46,49,182–211]

Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation,[85,88,212,213] making the concept of rescue essential to safe sedation. Practitioners of sedation must have the skills to rescue the patient from a deeper level than that intended for the procedure. For example, if the intended level of sedation is "minimal," practitioners must be able to rescue from "moderate sedation"; if the intended level of sedation is "moderate," practitioners must have the skills to rescue from "deep sedation"; if the intended level of sedation is "deep," practitioners must have the skills to rescue from a state of "general anesthesia." The ability to rescue means that practitioners must be able to recognize the various levels of sedation and have the skills and age- and size-appropriate equipment necessary to provide appropriate cardiopulmonary support if needed.

These guidelines are intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office). Sedation and anesthesia in a nonhospital environment (e.g., private physician's or dental office, freestanding imaging facility) historically have been associated with an increased incidence of "failure to rescue" from adverse events, because these settings may lack immediately available backup. Immediate activation of emergency medical services (EMS) may be required in such settings, but the practitioner is responsible for life-support measures while awaiting EMS arrival.[63,214] Rescue techniques require specific training and skills.[63,74,215,216] The maintenance of the skills needed to rescue a child with apnea, laryngospasm, and/or airway obstruction include the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation, insert an oral airway, a nasopharyngeal airway, or a laryngeal mask airway (LMA), and, rarely, perform tracheal intubation. These skills are likely best maintained with frequent simulation and team training for the management of rare events.[128,130,217–220] Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs. 1, 2, and 3).[215,216,221–223]

Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications. A number of reviews and handbooks for sedating pediatric patients are available.[30,39,65,75,171,172,201,224–233] There are specific situations that are beyond the scope of this document. Specifically, guidelines for the delivery of general anesthesia and monitored anesthesia care (sedation or analgesia), outside or within the operating room by anesthesiologists or other practitioners functioning within a department of anesthesiology, are addressed by policies developed by the ASA and by individual departments of anesthesiology.[234] In addition, guidelines for the sedation of patients undergoing mechanical ventilation in a critical care environment or for providing analgesia for patients postoperatively, patients with chronic painful conditions, and patients in hospice care are beyond the scope of this document.

Goals of Sedation

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are as follows: (1) to guard the patient's safety and welfare; (2) to minimize physical discomfort and pain; (3) to control anxiety, minimize psychological trauma, and maximize the potential for amnesia; (4) to modify behavior and/or movement so as to allow the safe completion of the procedure; and (5) to return the patient to a state in which discharge from medical/dental supervision is safe, as determined by recognized criteria (Supplemental Appendix 1).

These goals can best be achieved by selecting the lowest dose of drug with the highest therapeutic index for the procedure. It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching

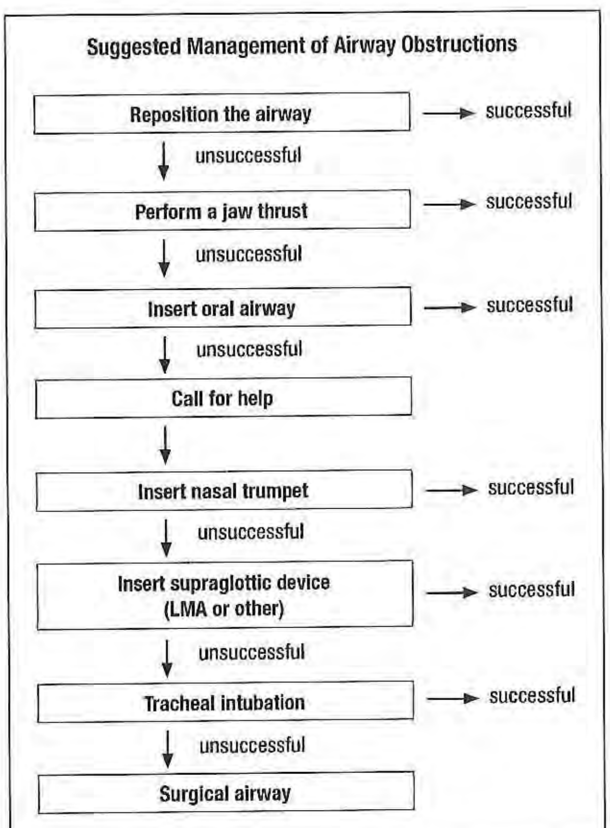

Figure 1. Suggested management of airway obstruction.

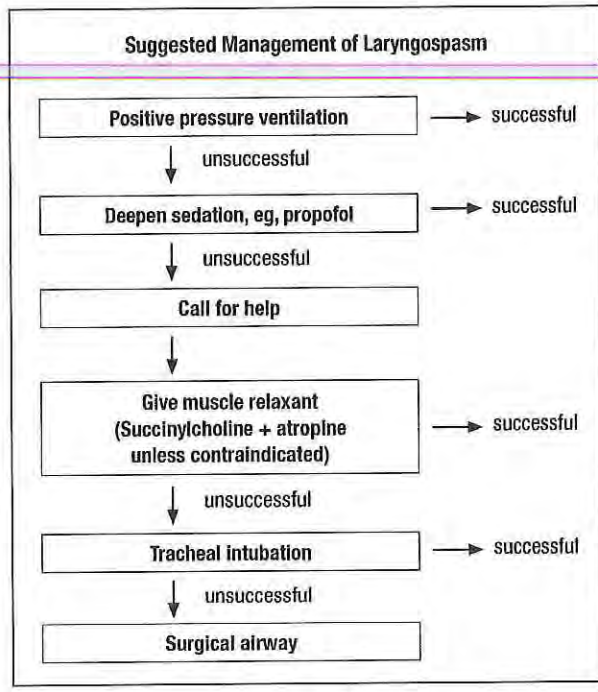

Figure 2. Suggested management of laryngospasm.

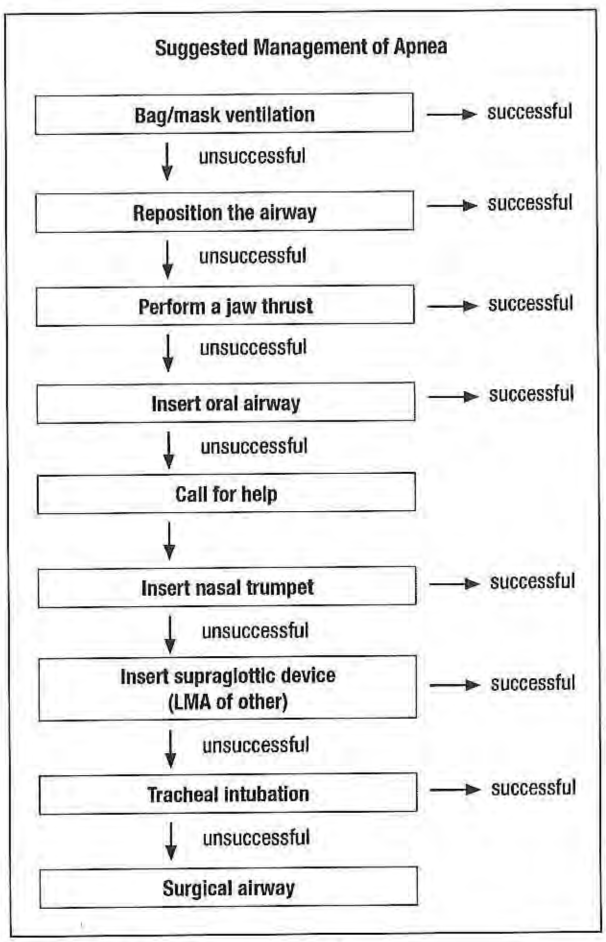

Figure 3. Suggested management of apnea.

drug selection to the type and goals of the procedure are essential for safe practice. For example, analgesic medications, such as opioids or ketamine, are indicated for painful procedures. For nonpainful procedures, such as computed tomography or MRI, sedatives/hypnotics are preferred. When both sedation and analgesia are desirable (e.g., fracture reduction), either single agents with analgesic/sedative properties or combination regimens are commonly used. Anxiolysis and amnesia are additional goals that should be considered in the selection of agents for particular patients. However, the potential for an adverse outcome may be increased when 2 or more sedating medications are administered.[62,127,136,173,235] Recently, there has been renewed interest in noninvasive routes of medication administration, including intranasal and inhaled routes (e.g., nitrous oxide; see below).[236]

Knowledge of each drug's time of onset, peak response, and duration of action is important (e.g., the peak EEG effect of intravenous midazolam occurs at ~ 4.8 minutes, compared with that of diazepam at ~ 1.6 minutes[237–239]). Titration of drug to effect is an important concept; one must know whether the previous dose has taken full effect before administering additional drugs.[237] Drugs that have a long duration of action (e.g., intramuscular pentobarbital, phenothiazines) have fallen out of favor because of unpredictable responses and prolonged recovery. The use of these drugs requires a longer period of observation even after the child achieves currently used recovery and discharge criteria.[62,238–241] This concept is particularly important for infants and toddlers transported in car safety seats; re-sedation after discharge attributable to residual prolonged drug effects may lead to airway obstruction.[62,63,242] In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a "black box warning" regarding fatal respiratory depression in children younger than 2 years.[243] Although the liquid formulation of chloral hydrate is no longer commercially available, some hospital pharmacies now are compounding their own formulations. Low-dose chloral hydrate (10–25 mg/kg), in combination with other sedating medications, is used commonly in pediatric dental practice.

General Guidelines

Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Supplemental Appendix 2). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or moderate to severe tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.[68,244–249] Practitioners are encouraged to consult with appropriate subspecialists and/ or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

Responsible person

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. It is preferable to have 2 adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by 1 of the adults.[250]

Facilities

The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. The most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, laryngospasm, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from the inadequate recognition and treatment of respiratory compromise.[42,48,92,97,99,125,132,139–155] Other rare complications also may include seizures, vomiting, and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

Back-up emergency services

A protocol for immediate access to back-up emergency services shall be clearly outlined. For nonhospital facilities, a protocol for the immediate activation of the EMS system for life-threatening complications must be established and maintained.[44] It should be understood that the availability of EMS does not replace the practitioner's responsibility to provide initial rescue for life-threatening complications.

On-site monitoring, rescue drugs, and equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain the necessary age-and size-appropriate equipment (oral and nasal airways, bag-valve-mask device, LMAs or other supraglottic devices, laryngoscope blades, tracheal tubes, face masks, blood pressure cuffs, intravenous catheters, etc) to resuscitate a nonbreathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical/dental facility or to another area within the facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Supplemental Appendices 3 and 4 for suggested drugs and emergency life support equipment to consider before the need for rescue occurs). Monitoring devices, such as electrocardiography (ECG) machines, pulse oximeters with size-appropriate probes, end-tidal carbon dioxide monitors, and defibrillators with size-appropriate patches/ paddles, must have a safety and function check on a regular basis as required by local or state regulation. The use of emergency checklists is recommended, and these should be immediately available at all sedation locations; they can be obtained from *http://www.pedsanesthesia.org/*.

Documentation

Documentation prior to sedation shall include, but not be limited to, the following recommendations:

1. Informed consent: The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.[251,252]
2. Instructions and information provided to the responsible person: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation.[163,253–255] Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Transportation in a car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine because deaths after procedural sedation have been reported.[62,63,238,242,256,257] Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (e.g., only 1 adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem, an underlying medical condition such as significant obstructive sleep apnea (OSA), or a former preterm infant younger than 60 weeks' postconceptional age. A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

Table 1. APPROPRIATE INTAKE OF FOOD AND LIQUIDS BEFORE ELECTIVE SEDATION

Ingested material	Minimum fasting period (h)
Clear liquids: water, fruit juices without pulp, carbonated beverages, clear tea, black coffee	2
Human milk	4
Infant formula	6
Nonhuman milk: because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period	6
Light meal: a light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.	6

Source: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. An updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. Available at: "https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx". For emergent sedation, the practitioner must balance the depth of sedation versus the risk of possible aspiration; see also Mace et al.[272] and Green et al.[273]

Dietary precautions

Agents used for sedation have the potential to impair protective airway reflexes, particularly during deep sedation. Although a rare occurrence, pulmonary aspiration may occur if the child regurgitates and cannot protect his or her airway.[95,127,258] Therefore, the practitioner should evaluate preceding food and fluid intake before administering sedation. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulations.[259,260] However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from ~1 in 825 to ~1 in 30 037.[95,127,129,173,244,261] Therefore, standard practice for fasting before elective sedation generally follows the same guidelines as for elective general anesthesia; this requirement is particularly important for solids, because aspiration of clear gastric contents causes less pulmonary injury than aspiration of particulate gastric contents.[262,263]

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is ~ 1 in 373 compared with ~ 1 in 4544 for elective anesthetics.[262] Because there are few published studies with adequate statistical power to provide guidance to the practitioner regarding the safety or risk of pulmonary aspiration of gastric contents during procedural sedation,[95,127,129,173,244,259-261,264-268] it is unknown whether the risk of aspiration is reduced when airway manipulation is not performed/ anticipated (e.g., moderate sedation). However, if a deeply sedated child requires intervention for airway obstruction, apnea, or laryngospasm, there is concern that these rescue maneuvers could increase the risk of pulmonary aspiration of gastric contents. For children requiring urgent/emergent sedation who do not meet elective fasting guidelines, the risks of sedation and possible aspiration are as-yet unknown and must be balanced against the benefits of performing the procedure promptly. For example, a prudent practitioner would be unlikely to administer deep sedation to a child with a minor condition who just ate a large meal; conversely, it is not justifiable to withhold sedation/analgesia from the child in significant pain from a displaced fracture who had a small snack a few hours earlier. Several emergency department studies have reported a low to zero incidence of pulmonary aspiration despite variable fasting periods[260,264,268]; however, each of these reports have, for the most part, clearly balanced the urgency of the procedure with the need for and depth of sedation.[268,269] Although emergency medicine studies and practice guidelines generally support a less restrictive approach to fasting for brief urgent/ emergent procedures, such as care of wounds, joint dislocation, chest tube placement, etc, in healthy children, further research in many thousands of patients would be desirable to better define the relationships between various fasting intervals and sedation complications.[262–270]

Before elective sedation

Children undergoing sedation for elective procedures generally should follow the same fasting guidelines as those for general anesthesia (Table 1).[271] It is permissible for routine necessary medications (e.g., antiseizure medications) to be taken with a sip of clear liquid or water on the day of the procedure.

For the emergency patient

The practitioner must always balance the possible risks of sedating nonfasted patients with the benefits of and necessity for completing the procedure. In particular, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity (BMI ≥95% for age and sex), pregnancy, or bowel motility dysfunction, require careful evaluation before the administration of sedatives. When proper fasting has not been ensured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. In this circumstance, additional techniques for achieving analgesia and patient cooperation, such as distraction, guided imagery, video games, topical and local anesthetics, hematoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered.[29,49,182–201,274,275] The use of agents with less risk of depressing protective airway reflexes, such as ketamine, or moderate sedation, which would also maintain protective reflexes, may be preferred.[276] Some emergency patients requiring deep sedation (e.g., a trauma patient who just ate a full meal or a child with a bowel obstruction) may need to be intubated to protect their airway before they can be sedated.

Use of immobilization devices (protective stabilization)

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction.[277–281] The child's head position and respiratory excursions should be checked frequently to ensure airway patency. If an immobilization device is used, a hand or foot should be kept exposed, and the child should never be left unattended. If sedating medications are administered in conjunction with an immobilization device, monitoring must be used at a level consistent with the level of sedation achieved.

Documentation at the time of sedation

1. Health evaluation: Before sedation, a health evaluation shall be performed by an appropriately licensed practitioner and reviewed by the sedation team at the time of treatment for possible interval changes.[282] The purpose of this evaluation is not only to document baseline status but also to determine whether the patient has specific risk factors that may warrant additional consultation before sedation. This evaluation also facilitates the identification of patients who will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

An important concern for the practitioner is the widespread use of medications that may interfere with drug absorption or metabolism and therefore enhance or shorten the effect time of sedating medications. Herbal medicines (e.g., St. John's wort, ginkgo, ginger, ginseng, garlic) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations (midazolam, cyclosporine, tacrolimus).[283–292] Kava may increase the effects of sedatives by potentiating γ-aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity.[293–295] Valerian may itself produce sedation that apparently is mediated through the modulation of γ-aminobutyric acid neurotransmission and receptor function.[291,296–299] Drugs such as erythromycin, cimetidine, and others may also inhibit the cytochrome P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.[300–304] Medications used to treat HIV infection, some anticonvulsants, immunosuppressive drugs, and some psychotropic medications (often used to treat children with autism spectrum disorder) may also produce clinically important drug-drug interactions.[305–314] Therefore, a careful drug history is a vital part of the safe sedation of children. The practitioner should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.[315–319] The U.S. Food and Drug Administration issued a warning in February 2013 regarding the use of codeine for postoperative pain management in children undergoing tonsillectomy, particularly those with OSA. The safety issue is that some children have duplicated cytochromes that allow greater than expected conversion of the prodrug codeine to morphine, thus resulting in potential overdose; codeine should be avoided for postprocedure analgesia.[320–324]

The health evaluation should include the following:

- Age and weight (in kg) and gestational age at birth (preterm infants may have associated sequelae such as apnea of prematurity); and
- Health history, including (1) food and medication allergies and previous allergic or adverse drug reactions; (2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs; (3) relevant diseases, physical abnormalities (including genetic syndromes), neurologic impairments that might increase the potential for airway obstruction, obesity, a history of snoring or OSA,[325–328] or cervical spine instability in Down syndrome, Marfan syndrome, skeletal dysplasia, and other conditions; (4) pregnancy status (as many as 1% of menarchal females presenting for general anesthesia at children's hospitals are pregnant)[329–331] because of concerns for the potential adverse effects of most sedating and

anesthetic drugs on the fetus[329,332–338]; (5) history of prematurity (may be associated with subglottic stenosis or propensity to apnea after sedation); (6) history of any seizure disorder; (7) summary of previous relevant hospitalizations; (8) history of sedation or general anesthesia and any complications or unexpected responses; and (9) relevant family history, particularly related to anesthesia (e.g., muscular dystrophy, malignant hyperthermia, pseudocholinesterase deficiency).

The review of systems should focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications. A specific query regarding signs and symptoms of sleep-disordered breathing and OSA may be helpful. Children with severe OSA who have experienced repeated episodes of desaturation will likely have altered mu receptors and be analgesic at opioid levels one-third to one-half those of a child without OSA[325–328,339,340]; lower titrated doses of opioids should be used in this population. Such a detailed history will help to determine which patients may benefit from a higher level of care by an appropriately skilled health care provider, such as an anesthesiologist. The health evaluation should also include:

- Vital signs, including heart rate, blood pressure, respiratory rate, room air oxygen saturation, and temperature (for some children who are very upset or noncooperative, this may not be possible and a note should be written to document this circumstance);
- Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy [e.g., mandibular hypoplasia], high Mallampati score [i.e., ability to visualize only the hard palate or tip of the uvula]) to determine whether there is an increased risk of airway obstruction[74,341–344];
- Physical status evaluation (ASA classification [see Appendix 2]); and
- Name, address, and telephone number of the child's home or parent's, or caregiver's cell phone; additional information such as the patient's personal care provider or medical home is also encouraged.

For hospitalized patients, the current hospital record may suffice for adequate documentation of presedation health; however, a note shall be written documenting that the chart was reviewed, positive findings were noted, and a management plan was formulated. If the clinical or emergency condition of the patient precludes acquiring complete information before sedation, this health evaluation should be obtained as soon as feasible.

2. Prescriptions. When prescriptions are used for sedation, a copy of the prescription or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions that were given to the responsible person. Prescription medications intended to accomplish procedural sedation must not be administered without the safety net of direct supervision by trained medical/dental personnel. The administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats because deaths as a result of this practice have been reported.[63,257]

Documentation during treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/ kilogram, and patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and laterality and site of the procedure.[59] During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administration, special attention must be paid to the calculation of dosage (i.e., mg/kg); for obese patients, most drug doses should likely be adjusted lower to ideal body weight rather than actual weight.[345] When a programmable pump is used for the infusion of sedating medications, the dose/kilogram per minute or hour and the child's weight in kilograms should be double-checked and confirmed by a separate individual. The patient's chart shall contain documentation at the time of treatment that the patient's level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, expired carbon dioxide values, and oxygen saturation were monitored. Standard vital signs should be further documented at appropriate intervals during recovery until the patient attains predetermined discharge criteria (Appendix 1). A variety of sedation scoring systems are available that may aid this process.[212,238 346–348] Adverse events and their treatment shall be documented.

Documentation after treatment

A dedicated and properly equipped recovery area is recommended (see Appendices 3 and 4). The time and condition of the child at discharge from the treatment area or facility shall be documented, which should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria (see Appendix 1). Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation[62,104,256,349,350] and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (e.g., a step-down observation area) before discharge from medical/dental supervision may be indicated.[239] Several scales to evaluate recovery have been devised and validated.[212, 346–348, 351, 352] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238]

Continuous quality improvement

The essence of medical error reduction is a careful examination of index events and root-cause analysis of how the event could be avoided in the future.[353-359] Therefore, each facility should maintain records that track all adverse events and significant interventions, such as desaturation; apnea; laryngospasm; need for airway interventions, including the need for placement of supraglottic devices such as an oral airway, nasal trumpet, or LMA; positive-pressure ventilation; prolonged sedation; unanticipated use of reversal agents; unplanned or prolonged hospital admission; sedation failures; inability to complete the procedure; and unsatisfactory sedation, analgesia, or anxiolysis.[360] Such events can then be examined for the assessment of risk reduction and improvement in patient/family satisfaction.

Preparation for sedation procedures

Part of the safety net of sedation is using a systematic approach so as to not overlook having an important drug, piece of equipment, or monitor immediately available at the time of a developing emergency. To avoid this problem, it is helpful to use an acronym that allows the same setup and checklist for every procedure. A commonly used acronym useful in planning and preparation for a procedure is SOAPME, which represents the following:

- **S** = Size-appropriate suction catheters and a functioning suction apparatus (e.g., Yankauer-type suction).
- **O** = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery.
- **A** = size-appropriate Airway equipment (e.g., bag-valve-mask or equivalent device [functioning]), nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask.
- **P** = Pharmacy: all the basic drugs needed to support life during an emergency, including antagonists as indicated.
- **M** = Monitors: functioning pulse oximeter with size-appropriate oximeter probes,[361,362] end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (e.g., noninvasive blood pressure, ECG, stethoscope).
- **E** = special Equipment or drugs for a particular case (e.g., defibrillator).

Specific guidelines for intended level of sedation

Minimal sedation

Minimal sedation (old terminology, "anxiolysis") is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation. Some children will become moderately sedated despite the intended level of minimal sedation; should this occur, then the guidelines for moderate sedation apply.[85,363]

Moderate sedation

Moderate sedation (old terminology, "conscious sedation" or "sedation/analgesia") is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation; drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Because the patient who receives moderate sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to what is necessary for deep sedation.[85]

Personnel

The practitioner. The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring described in these guidelines, and to manage complications of these techniques (i.e., to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation should the child progress to a level of deep sedation. Training in, and maintenance of, advanced pediatric airway skills is required (e.g., pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged.[79,80,128,130,217-220,364]

Support personnel. The use of moderate sedation shall include the provision of a person, in addition to the practitioner, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required. This individual may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment.[60] This individual should be trained in and capable of providing advanced airway skills (e.g., PALS). The support person shall have specific assignments in the event of an emergency and current knowledge of the emergency cart inventory. The practitioner and all ancillary personnel should participate in periodic reviews, simulation of rare emergencies, and practice drills of the facility's emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.[133,365-367] It is recommended that at least 1 practitioner be skilled in obtaining vascular access in children.

Monitoring and documentation

Baseline. Before the administration of sedative medications, a baseline determination of vital signs shall be documented. For some children who are very upset or uncooperative, this may not be possible, and a note should be written to document this circumstance.

During the procedure. The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the qualified health care provider administering the medication to confirm the dose verbally before administration. There shall be continuous monitoring of oxygen saturation and heart rate; when bidirectional verbal communication between the provider and patient is appropriate and possible (i.e., patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (e.g., Bluetooth™ technology)[368-371] or precordial stethoscope is strongly recommended. If bi-directional verbal communication is not appropriate or not possible, monitoring of ventilation by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope is required. Heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide values should be recorded, at minimum, every 10 minutes in a time-based record. Note that the exact value of expired carbon dioxide is less important than simple assessment of continuous respiratory gas exchange. In some situations in which there is excessive patient agitation or lack of cooperation or during certain procedures such as bronchoscopy, dentistry, or repair of facial lacerations capnography may not be feasible, and this situation should be documented. For uncooperative children, it is often helpful to defer the initiation of capnography until the child becomes sedated. Similarly, the stimulation of blood pressure cuff inflation may cause arousal or agitation; in such cases, blood pressure monitoring may be counterproductive and may be documented at less frequent intervals (e.g., 10-15 minutes, assuming the patient remains stable, well oxygenated, and well perfused). Immobilization devices (protective stabilization) should be checked to prevent airway obstruction or chest restriction. If a restraint device is used, a hand or foot should

Table 2. COMPARISON OF MODERATE AND DEEP SEDATION EQUIPMENT AND PERSONNEL REQUIREMENTS

	Moderate sedation	Deep sedation
Personnel	An observer who will monitor the patient but who may also assist with interruptible tasks; should be trained in PALS	An independent observer whose only responsibility is to continuously monitor the patient; trained in PALS
Responsible practitioner	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation; recommended that at least 1 practitioner should be skilled in obtaining vascular access in children; trained in PALS	Skilled to rescue a child with apnea, laryngspasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required; at least 1 practitioner skilled in obtaining vascular access in children immediately available
Monitoring	Pulse oximetry ECG recommended Heart rate Blood pressure Respiration Capnography recommended	Pulse oximetry ECG required Heart rate Blood pressure Respiration Capnography required
Other equipment	Suction equipment, adequate oxygen source/supply	Suction equipment, adequate oxygen source/supply, defibrillator required
Documentation	Name, route, site, time of administration, and dosage of all drugs administered Continuous oxygen saturation, heart rate, and ventilation (capnography recommended); parameters recorded every 10 minutes	Name, route, site, time of administration, and dosage of all drugs administered; continuous oxygen saturation, heart rate, and ventilation (capnography required); parameters recorded at least every 5 minutes
Emergency checklists	Recommended	Recommended
Rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4)	Required	Required
Dedicated recovery area with rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4) and dedicated recovery personnel; adequate oxygen supply	Recommended; initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased	Recommended; initial recording of vital signs may be needed for at least 5-minute intervals until the child begins to awaken, then recording intervals may be increased to 10–15 minutes
Discharge criteria	See Appendix 1	See Appendix 1

be kept exposed. The child's head position should be continuously assessed to ensure airway patency.

After the procedure. The child who has received moderate sedation must be observed in a suitably equipped recovery area, which must have a functioning suction apparatus as well as the capacity to deliver >90% oxygen and positive-pressure ventilation (bag-valve mask) with an adequate oxygen capacity as well as age- and size-appropriate rescue equipment and devices. The patient's vital signs should be recorded at specific intervals (e.g., every 10–15 minutes). If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met (see Appendix 1). Because sedation medications with a long half-life may delay the patient's complete return to baseline or pose the risk of re-sedation, some patients might benefit from a longer period of less intense observation (e.g., a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical/dental supervision (see section entitled "Documentation Before Sedation" above).[62,256,349,350] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238] Patients who have received reversal agents, such as flumazenil or naloxone, will require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, resulting in re-sedation.

Deep sedation/General anesthesia

"Deep sedation" ("deep sedation/ analgesia") is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (e.g., purposefully pushing away the noxious stimuli). Reflex withdrawal from a painful stimulus is not considered a purposeful response and is more consistent with a state of general anesthesia. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may pass from a state of deep sedation to the state of general anesthesia. In some situations, such as during MRI, one is not usually able to assess responses to stimulation, because this would defeat the purpose of sedation, and one should assume that such patients are deeply sedated.

"General anesthesia" is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Table 3. COMMONLY USED LOCAL ANESTHETIC AGENTS FOR NERVE BLOCK OR INFILTRATION: DOSES, DURATION, AND CALCULATIONS

Local anesthetic	Maximum dose with Epinephrine [a] (mg/kg)		Maximum dose without Epinephrine (mg/kg)		Duration of action [b] (min)
	Medical	Dental	Medical	Dental	
Esters					
Procaine	10.0	6	7	6	60-90
Chloroprocaine	20.0	12	15	12	30-60
Tetracaine	1.5	1	1	1	180-600
Amides					
Lidocaine	7.0	4.4	4	4.4	90-200
Mepivacaine	7.0	4.4	5	4.4	120-240
Bupivacaine	3.0	1.3	2.5	1.3	180-600
Levobupivacaine [c]	3.0	2	2	2	180-600
Ropivacaine	3.0	2	2	2	180-600
Articaine [d]	—	7	—	7	60-230

Maximum recommended doses and durations of action are shown. Note that lower doses should be used in very vascular areas.

[a] These are maximum doses of local anesthetics combined with epinephrine; lower doses are recommended when used without epinephrine. Doses of amides should be decreased by 30% in infants younger than 6 mo. When lidocaine is being administered intravascularly (e.g., during intravenous regional anesthesia), the dose should be decreased to 3 to 5 mg/kg; long-acting local anesthetic agents should not be used for intravenous regional anesthesia.

[b] Duration of action is dependent on concentration, total dose, and site of administration; use of epinephrine; and the patient's age.

[c] Levobupivacaine is not available in the United States.

[d] Use in pediatric patients under 4 years of age is not recommended.

Table 4. LOCAL ANESTHETIC CONVERSION CHART

Concentration (%)	mg/mL
4.0	40
3.0	30
2.5	25
2.0	20
1.0	10
0.5	5
0.25	2.5
0.125	1.25

Table 5. TREATMENT OF LOCAL ANESTHETIC TOXICITY

1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
2. Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers, ß-blockers, or additional local anesthetic. Reduce epinephrine dosages. Prolonged effort may be required.
3. Seizure management: benzodiazepines preferred (e.g., intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
4. Administer 1.5 mL/kg 20% lipid emulsion over ~1 minute to trap unbound amide local anesthetics. Repeat bolus once or twice for persistent cardiovascular collapse.
5. Initiate 20% lipid infusion (0.25 mL/kg per minute) until circulation is restored; double the infusion rate if blood pressure remains low. Continue infusion for at least 10 minutes after attaining circulatory stability. Recommended upper limit of ~10 mL/kg.
6. A fluid bolus of 10–20 mL/kg balanced salt solution and an infusion of phenylephrine (0.1 μg/kg per minute to start) may be needed to correct peripheral vasodilation.

Source: https://www.asra.com/advisory-guidelines/article/3/checklist-for-treatment-of-local-anesthetic-systemic-toxicity.

Personnel

During deep sedation, there must be 1 person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS and capable of assisting with any emergency event. At least 1 individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and or airway obstruction. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation.

Equipment

In addition to the equipment needed for moderate sedation, an ECG monitor and a defibrillator for use in pediatric patients should be readily available.

Vascular access

Patients receiving deep sedation should have an intravenous line placed at the start of the procedure or have a person skilled in establishing vascular access in pediatric patients immediately available.

Monitoring

A competent individual shall observe the patient continuously. Monitoring shall include all parameters described for moderate sedation. Vital signs, including heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide, must bedocumented at least every 5 minutes in a time-based record. Capnography should be used for almost all deeply sedated children because of the increased risk of airway/ventilation compromise. Capnography may not be feasible if the patient is agitated or uncooperative during the initial phases of sedation or during certain procedures, such as bronchoscopy or repair of facial lacerations, and this circumstance should be documented. For uncooperative children, the capnography monitor may be placed once the child becomes sedated. Note that if supplemental oxygen is administered, the capnograph may underestimate the true expired carbon dioxide value; of more importance than the numeric reading of exhaled carbon dioxide is the assurance of continuous respiratory gas exchange (i.e., continuous waveform). Capnography is particularly useful for patients who are difficult to observe (e.g., during MRI or in a darkened room).[64,67,72,90,96,110,159–162,164–166,167–170,372–375]

The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the nurse administering the medication to confirm the dose verbally before administration. The inspired concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented.

Postsedation care

The facility and procedures followed for postsedation care shall conform to those described under"moderate sedation." The initial recording of vital signs should be documented at least every 5 minutes. Once the child begins to awaken, the recording intervals may be increased to 10 to 15 minutes. Table 2 summarizes the equipment, personnel, and monitoring requirements for moderate and deep sedation.

Special considerations

Neonates and former preterm infants

Neonates and former preterm infants require specific management, because immaturity of hepatic and renal function may alter the ability to metabolize and excrete sedating medications,[376] resulting in prolonged sedation and the need for extended post-sedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea,[377] but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.[378]

Other concerns regarding the effects of anesthetic drugs and sedating medications on the developing brain are beyond the scope of this document. At this point, the research in this area is preliminary and inconclusive at best, but it would seem prudent to avoid unnecessary exposure to sedation if the procedure is unlikely to change medical/dental management (e.g., a sedated MRI purely for screening purposes in preterm infants).[379–382]

Local anesthetic agents

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular weight-based attention should be paid to cumulative dosage in all children.[118,120,125,383–386] To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (e.g., mg/kg) should be calculated before administration. There may be enhanced sedative effects when the highest recommended doses of local anesthetic drugs are used in combination with other sedatives or opioids (see Tables 3 and 4 for limits and conversion tables of commonly used local anesthetics).[118,125,387–400] In general, when administering local anesthetic drugs, the practitioner should aspirate frequently to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.[401] If high doses or injection of amide local anesthetics (bupivacaine and ropivacaine) into vascular tissues is anticipated, then the immediate availability of a 20% lipid emulsion for the treatment of local anesthetic toxicity is recommended (Tables 3 and 5).[402–409] Topical local anesthetics are commonly used and encouraged, but the practitioner should avoid applying excessive doses to mucosal surfaces where systemic uptake and possible toxicity (seizures, methemoglobinemia) could result and to remain within the manufacturer'srecommendations regarding allowable surface area application.[410–415]

Pulse oximetry

Newer pulse oximeters are less susceptible to motion artifacts and may be more useful than older oximeters that do not contain updated software.[416–420] Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. The oximeter probe must be properly positioned; clip-on devices are easy to displace, which may produce artifactual data (under-or overestimation of oxygen saturation).[361,362]

Capnography

Expired carbon dioxide monitoring is valuable to diagnose the simple presence or absence of respirations, airway obstruction, or respiratory depression, particularly in patients sedated in less-accessible locations, such as in MRI machines or darkened rooms.[64,66,67,72,90,96,110,159–162,164–170,372–375,421–427] In patients receiving supplemental oxygen, capnography facilitates the recognition of apnea or airway obstruction several minutes before the situa-tion would be detected just by pulse oximetry. In this situation, desaturation would be delayed due to increased oxygen reserves; capnography would enable earlier intervention.[161] One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation (7% to 1%).[174] The use of expired carbon dioxide monitoring devices is now required for almost all deeply sedated children (with rare exceptions), particularly in situations in which other means of assessing the adequacy of ventilation are limited. Several manufacturers have produced nasal cannulae that allow simultaneous delivery of oxygen and measurement of expired carbon dioxide values.[421,422,427] Although these devices can have a high degree of false-positive alarms, they are also very accurate for the detection of complete airway obstruction or apnea.[164,168,169] Taping the sampling line under the nares under an oxygen face mask or nasal hood will provide similar information. The exact measured value is less important than the simple answer to the question: Is the child exchanging air with each breath?

Processed EEG (Bispectral Index)

Although not new to the anesthesia community, the processed EEG (bispectral index [BIS]) monitor is slowly finding its way into the sedation literature.[428] Several studies have attempted to use BIS monitoring as a means of noninvasively assessing the depth of sedation. This technology was designed to examine EEG signals and, through a variety of algorithms, correlate a number with depth of unconsciousness: that is, the lower the number, the deeper the sedation. Unfortunately, these algorithms are based on adult patients and have not been validated in children of varying ages and varying brain development. Although the readings correspond quite well with the depth of propofol sedation, the numbers may paradoxically go up rather than down with sevoflurane and ketamine because of central excitation despite a state of general anesthesia or deep sedation.[429, 430]

Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent with stage 2 sleep.[431] Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales.[347,363,432–435] It appears that there is some correlation with BIS values in moderate sedation, but there is not a reliable ability to distinguish between deep sedation and moderate sedation or deep sedation from general anesthesia.[432] Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol[363]; in general, it is still considered a research tool and not recommended for routine use.

Adjuncts to airway management and resuscitation

The vast majority of sedation complications can be managed with simple maneuvers, such as supplemental oxygen, opening the airway, suctioning, placement of an oral or nasopharyngeal airway, and bag-mask-valve ventilation. Rarely, tracheal intubation is required for more prolonged ventilatory support.

In addition to standard tracheal intubation techniques, a number of supraglottic devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the LMA, the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.[436,437]

The largest clinical experience in pediatrics is with the LMA, which is available in multiple sizes, including those for late preterm and term neonates. The use of the LMA is now an essential addition to advanced airway training courses, and familiarity with insertion techniques can be life-saving.[438–442] The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities.[443, 444] Practitioners are encouraged to gain experience with these techniques as they become incorporated into PALS courses.

Another valuable emergency technique is intraosseous needle placement for vascular access. Intraosseous needles are available in several sizes; insertion can be life-saving when rapid intravenous access is difficult. A relatively new intraosseous device (EZ-IO Vidacare, now part of Teleflex, Research Triangle Park, NC) is similar to a hand-held battery-powered drill. It allows rapid placement with minimal chance of misplacement; it also has a low-profile intravenous adapter.[445–450] Familiarity with the use of these emergency techniques can be gained by keeping current with resuscitation courses, such as PALS and advanced pediatric life support.

Patient simulators

High-fidelity patient simulators are now available that allow physicians, dentists, and other health care providers to practice managing a variety of programmed adverse events, such as apnea, bronchospasm, and laryngospasm.[133,220,450–452], The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events.[128, 131,451,453–455] One study that simulated the quality of cardiopulmonary resuscitation compared standard management of ventricular fibrillation versus rescue with the EZ-IO for the rapid establishment of intravenous access and placement of an LMA for establishing a patent airway in adults; the use of these devices resulted in more rapid establishment of vascular access and securing of the airway.[456]

Monitoring during MRI

The powerful magnetic field and the generation of radiofrequency emissions necessitate the use of special equipment to provide continuous patient monitoring throughout the MRI scanning procedure.[457–459] MRI-compatible pulse oximeters and capnographs capable of continuous function during scanning should be used in any sedated or restrained pediatric patient. Thermal injuries can result if appropriate precautions are not taken; the practitioner is cautioned to avoid coiling of all wires (oximeter, ECG) and to place the oximeter probe as far from the magnetic coil as possible to diminish the possibility of injury. ECG monitoring during MRI has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.[460–463] If sedation is achieved by using an infusion pump, then either an MRI-compatible pump is required or the pump must be situated outside of the room with long infusion tubing so as to maintain infusion accuracy. All equipment must be MRI compatible, including laryngoscope blades and handles, oxygen tanks, and any ancillary equipment. All individuals, including parents, must be screened for ferromagnetic materials, phones, pagers, pens, credit cards, watches, surgical implants, pacemakers, etc, before entry into the MRI suite.

Nitrous oxide

Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100% and never less than 25% oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide >50% to oxygen that covers the mouth and nose must be used in conjunction with a calibrated and functional oxygen analyzer. All nitrous oxide-to-oxygen inhalation devices should be calibrated in accordance with appropriate state and local requirements. Consideration should be given to the National Institute of Occupational Safety and Health Standards for the scavenging of waste gases.[464] Newly constructed or reconstructed treatment facilities, especially those with piped-in nitrous oxide and oxygen, must have appropriate state or local inspections to certify proper function of inhalation sedation/analgesia systems before any delivery of patient care.

Nitrous oxide in oxygen, with varying concentrations, has been successfully used for many years to provide analgesia for a variety of painful procedures in children.[14,36, 49,98,465–493] The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of ≤50% with the balance as oxygen, without any other sedative, opioid, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient in ASA class I or II. The patient is able to maintain verbal communication throughout the procedure. It should be noted that although local anesthetics have sedative properties, for purposes of this guideline they are not considered sedatives in this circumstance. If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations >50%, the likelihood for moderate or deep sedation increases.[107,197,492,494,495] In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.[496]

References

1. Milnes AR. Intravenous procedural sedation: an alternative to general anesthesia in the treatment of early childhood caries. J Can Dent Assoc 2003;69:298–302.
2. Law AK, Ng DK, Chan KK. Use of intramuscular ketamine for endoscopy sedation in children. Pediatr Int 2003;45(2):180–5.
3. Flood RG, Krauss B. Procedural sedation and analgesia for children in the emergency department. Emerg Med Clin North Am 2003;21(1):121–39.

4. Jaggar SI, Haxby E. Sedation, anaesthesia and monitoring for bronchoscopy. Paediatr Respir Rev 2002;3(4):321–7.
5. de Blic J, Marchac V, Scheinmann P. Complications of flexible bronchoscopy in children: prospective study of 1,328 procedures. Eur Respir J 2002;20(5):1271–6.
6. Mason KP, Michna E, DiNardo JA, et al. Evolution of a protocol for ketamine-induced sedation as an alternative to general anesthesia for interventional radiologic procedures in pediatric patients. Radiology 2002;225(2):457–65.
7. Houpt M. Project USAP 2000—use of sedative agents by pediatric dentists: a15-year follow-up survey. Pediatr Dent 2002;24(4):289–94.
8. Vinson DR, Bradbury DR. Etomidate for procedural sedation in emergency medicine. Ann Emerg Med 2002; 39(6):592–8.
9. Everitt IJ, Barnett P. Comparison of two benzodiazepines used for sedation of children undergoing suturing of a laceration in an emergency department. Pediatr Emerg Care 2002;18(2):72–4.
10. Karian VE, Burrows PE, Zurakowski D, Connor L, Poznauskis L, Mason KP. The development of a pediatric radiology sedation program. Pediatr Radiol 2002;32(5):348–53.
11. Kaplan RF, Yang CI. Sedation and analgesia in pediatric patients for procedures outside the operating room. Anesthesiol Clin North America 2002;20(1):181–94, vii.
12. Wheeler DS, Jensen RA, Poss WB. A randomized, blinded comparison of chloral hydrate and midazolam sedation in children undergoing echocardiography. Clin Pediatr (Phila) 2001;40(7):381–7.
13. Hain RD, Campbell C. Invasive procedures carried out in conscious children: contrast between North American and European paediatric oncology centres. Arch Dis Child 2001;85(1):12–5.
14. Kennedy RM, Luhmann JD. Pharmacological management of pain and anxiety during emergency procedures in children. Paediatr Drugs 2001;3(5):337–54.
15. Kanagasundaram SA, Lane LJ, Cavalletto BP, Keneally JP, Cooper MG. Efficacy and safety of nitrous oxide in alleviating pain and anxiety during painful procedures. Arch Dis Child 2001;84(6):492–5.
16. Younge PA, Kendall JM. Sedation for children requiring wound repair: a randomised controlled double blind comparison of oral midazolam and oral ketamine. Emerg Med J 2001;18(1):30–3.
17. Ljungman G, Gordh T, Sörensen S, Kreuger A. Lumbar puncture in pediatric oncology: conscious sedation vs. general anesthesia. Med Pediatr Oncol 2001;36(3):372–9.
18. Poe SS, Nolan MT, Dang D, et al. Ensuring safety of patients receiving sedation for procedures: evaluation of clinical practice guidelines. Jt Comm J Qual Improv 2001; 27(1):28–41.
19. D'Agostino J, Terndrup TE. Chloral hydrate versus midazolam for sedation of children for neuroimaging: a randomized clinical trial. Pediatr Emerg Care 2000;16(1): 1–4.
20. Green SM, Kuppermann N, Rothrock SG, Hummel CB, Ho M. Predictors of adverse events with intramuscular ketamine sedation in children. Ann Emerg Med 2000;35 (1):35–42.
21. Hopkins KL, Davis PC, Sanders CL, Churchill LH. Sedation for pediatric imaging studies. Neuroimaging Clin N Am 1999;9(1):1–10.
22. Bauman LA, Kish I, Baumann RC, Politis GD. Pediatric sedation with analgesia. Am J Emerg Med 1999;17(1): 1–3.
23. Bhatt-Mehta V, Rosen DA. Sedation in children: current concepts. Pharmacotherapy 1998;18(4):790–807.
24. Morton NS, Oomen GJ. Development of a selection and monitoring protocol for safe sedation of children. Paediatr Anaesth 1998;8(1):65–8.
25. Murphy MS. Sedation for invasive procedures in paediatrics. Arch Dis Child 1997;77(4):281–4.
26. Webb MD, Moore PA. Sedation for pediatric dental patients. Dent Clin North Am 2002;46(4):803–14, xi.
27. Malviya S, Voepel-Lewis T, Tait AR, Merkel S. Sedation/ analgesia for diagnostic and therapeutic procedures in children. J Perianesth Nurs 2000;15(6):415–22.
28. Zempsky WT, Schechter NL. Office based pain managemen: the 15-minute consultation. Pediatr Clin North Am 2000;47(3):601–15
29. Kennedy RM, Luhmann JD. The "ouchless emergency department": getting closer: advances in decreasing distress during painful procedures in the emergency department. Pediatr Clin North Am 1999;46(6):1215–47, vii–viii.
30. Rodriguez E, Jordan R. Contemporary trends in pediatric sedation and analgesia. Emerg Med Clin North Am 2002;20(1):199–222.
31. Ruess L, O'Connor SC, Mikita CP, Creamer KM. Sedation for pediatric diagnostic imaging: use of pediatric and nursing resources as an alternative to a radiology department sedation team. Pediatr Radiol 2002;32(7):505–10.
32. Weiss S. Sedation of pediatric patients for nuclear medicine procedures. Semin Nucl Med 1993;23(3):190–8.
33. Wilson S. Pharmacologic behavior management for pediatric dental treatment. Pediatr Clin North Am 2000;47 (5):1159–75.
34. McCarty EC, Mencio GA, Green NE. Anesthesia and analgesia for the ambulatory management of fractures in children. J Am Acad Orthop Surg 1999;7(2):81–91.
35. Egelhoff JC, Ball WS Jr, Koch BL, Parks TD. Safety and efficacy of sedation in children using a structured sedation program. AJR Am J Roentgenol 1997;168(5):1259–62.
36. Heinrich M, Menzel C, Hoffmann F, Berger M, Schweinitz DV. Selfadministered procedural analgesia using nitrous oxide/oxygen (50:50) in the pediatric surgery emergency room: effectiveness and limitations. Eur J Pediatr Surg 2015;25(3):250-6.

37. Hoyle JD Jr, Callahan JM, Badawy M, et al; Traumatic Brain Injury Study Group for the Pediatric Emergency Care Applied Research Network (PECARN). Pharmacological sedation for cranial computed tomography in children after minor blunt head trauma. Pediatr Emerg Care 2014;30(1):1–7.
38. Chiaretti A, Benini F, Pierri F, et al. Safety and efficacy of propofol administered by paediatricians during procedural sedation in children. Acta Paediatr 2014;103(2): 182–7.
39. Pacheco GS, Ferayorni A. Pediatric procedural sedation and analgesia. Emerg Med Clin North Am 2013;31(3): 831–52.
40. Griffiths MA, Kamat PP, McCracken CE, Simon HK. Is procedural sedation with propofol acceptable for complex imaging? A comparison of short vs. prolonged sedations in children. Pediatr Radiol 2013;43(10):1273–8.
41. Doctor K, Roback MG, Teach SJ. An update on pediatric hospitalbased sedation. Curr Opin Pediatr 2013;25(3): 310–6.
42. Alletag MJ, Auerbach MA, Baum CR. Ketamine, propofol, and ketofol use for pediatric sedation. Pediatr Emerg Care 2012;28(12):1391–5; quiz: 1396–8.
43. Jain R, Petrillo-Albarano T, Parks WJ, Linzer JF Sr, Stockwell JA. Efficacy and safety of deep sedation by non-anesthesiologists for cardiac MRI in children. Pediatr Radiol 2013;43(5):605–11.
44. Nelson T, Nelson G. The role of sedation in contemporary pediatric dentistry. Dent Clin North Am 2013;57(1): 145–61.
45. Monroe KK, Beach M, Reindel R, et al. Analysis of procedural sedation provided by pediatricians. Pediatr Int 2013;55(1):17–23.
46. Alexander M. Managing patient stress in pediatric radiology. Radiol Technol 2012;83(6):549–60.
47. Macias CG, Chumpitazi CE. Sedation and anesthesia for CT: emerging issues for providing high-quality care. Pediatr Radiol 2011;41(suppl 2):517–22.
48. Andolfatto G, Willman E. A prospective case series of pediatric procedural sedation and analgesia in the emergency department using single-syringe ketamine-propofol combination (ketofol). Acad Emerg Med 2010;17(2): 194–201.
49. Brown SC, Hart G, Chastain DP, Schneeweiss S, McGrath PA. Reducing distress for children during invasive procedures: randomized clinical trial of effectiveness of the PediSedate. Paediatr Anaesth. 2009;19(8):725–31.
50. Yamamoto LG. Initiating a hospital-wide pediatric sedation service provided by emergency physicians. Clin Pediatr (Phila) 2008;47(1):37–48.
51. Doyle L, Colletti JE. Pediatric procedural sedation and analgesia. Pediatr Clin North Am 2006;53(2):279–92.
52. Todd DW. Pediatric sedation and anesthesia for the oral surgeon. Oral Maxillofac Surg Clin North Am 2013;25 (3):467–78, vi–vii.
53. Committee on Drugs, Section on Anesthesiology, American Academy of Pediatrics. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatrics 1985;76(2):317–21.
54. American Academy of Pediatric Dentistry. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. ASDC J Dent Child 1986;53(1):21–2.
55. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. Pediatrics 1992;89(6 pt 1): 1110–5.
56. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: addendum. Pediatrics 2002;110(4): 836–8.
57. American Academy of Pediatrics, American Academy of Pediatric Dentistry. Guidelines on the elective use of minimal, moderate, and deep sedation and general anesthesia for pediatric dental patients. 2011. Available at: http://www.aapd.org/media/policies_ guidelines/g_ sedation.pdf. Accessed May 27, 2016.
58. Coté CJ, Wilson S; American Academy of Pediatrics; American Academy of Pediatric Dentistry; Work Group on Sedation. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. Pediatrics 2006; 118(6):2587–602.
59. The Joint Commission. Comprehensive Accreditation Manual for Hospitals (CAMH): the official handbook. Oakbrook Terrace, IL: The Joint Commission; 2014.
60. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002;96(4):1004–17.
61. Committee of Origin: Ad Hoc on Non-Anesthesiologist Privileging. Statement on granting privileges for deep sedation to non-anesthesiologist sedation practitioners. 2010. Available at: "http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/advisory-on-granting-privileges-for-deep-sedation-to-non-anesthesiologist.pdf". Accessed May 27, 2016.
62. Coté CJ, Karl HW, Notterman DA, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: analysis of medications used for sedation. Pediatrics 2000;106 (4):633–44.
63. Coté CJ, Notterman DA, Karl HW, Weinberg JA, Mc Closkey C. Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. Pediatrics 2000;105(4 pt 1):805–14.
64. Kim G, Green SM, Denmark TK, Krauss B. Ventilatory response during dissociative sedation in children-a pilot study. Acad Emerg Med 2003;10(2):140–5.

65. Coté CJ. Sedation for the pediatric patient: a review. Pediatr Clin North Am 1994;41(1):31–58.
66. Mason KP, Burrows PE, Dorsey MM, Zurakowski D, Krauss B. Accuracy of capnography with a 30 foot nasal cannula for monitoring respiratory rate and end-tidal CO2 in children. J Clin Monit Comput 2000;16(4): 259–62.
67. McQuillen KK, Steele DW. Capnography during sedation/ analgesia in the pediatric emergency department. Pediatr Emerg Care 2000;16(6):401–4.
68. Malviya S, Voepel-Lewis T, Tait AR. Adverse events and risk factors associated with the sedation of children by non-anesthesiologists. Anesth Analg 1997;85(6):1207–13.
69. Coté CJ, Rolf N, Liu LM, et al. A single-blind study of combined pulse oximetry and capnography in children. Anesthesiology. 1991;74(6):980–7.
70. Guideline SIGN; Scottish Intercollegiate Guidelines Network. SIGN Guideline 58: safe sedation of children undergoing diagnostic and therapeutic procedures. Paediatr Anaesth 2008;18(1):11–2.
71. Peña BM, Krauss B. Adverse events of procedural sedation and analgesia in a pediatric emergency department. Ann Emerg Med 1999;34(4 pt 1):483–91.
72. Smally AJ, Nowicki TA. Sedation in the emergency department. Curr Opin Anaesthesiol 2007;20(4):379–83.
73. Ratnapalan S, Schneeweiss S. Guidelines to practice: the process of planning and implementing a pediatric sedation program. Pediatr Emerg Care 2007;23(4):262–6.
74. Hoffman GM, Nowakowski R, Troshynski TJ, Berens RJ, Weisman SJ. Risk reduction in pediatric procedural sedation by application of an American Academy of Pediatrics/ American Society of Anesthesiologists process model. Pediatrics 2002;109(2):236–43.
75. Krauss B. Management of acute pain and anxiety in children undergoing procedures in the emergency department. Pediatr Emerg Care 2001;17(2):115–122; quiz: 123–5.
76. Slovis TL. Sedation and anesthesia issues in pediatric imaging. Pediatr Radiol 2011;41(suppl 2):514–6.
77. Babl FE, Krieser D, Belousoff J, Theophilos T. Evaluation of a paediatric procedural sedation training and credentialing programme: sustainability of change. Emerg Med J 2010;27(8):57781.
78. Meredith JR, O'Keefe KP, Galwankar S. Pediatric procedural sedation and analgesia. J Emerg Trauma Shock 2008; 1(2):88–96.
79. Priestley S, Babl FE, Krieser D, et al. Evaluation of the impact of a paediatric procedural sedation credentialing programme on quality of care. Emerg Med Australas 2006;18(5–6):498–504.
80. Babl F, Priestley S, Krieser D, et al. Development and implementation of an education and credentialing programme to provide safe paediatric procedural sedation in emergency departments. Emerg Med Australas 2006;18 (5-6):489–97.
81. Cravero JP, Blike GT. Pediatric sedation. Curr Opin Anaesthesiol 2004;17(3):247–51.
82. Shavit I, Keidan I, Augarten A. The practice of pediatric procedural sedation and analgesia in the emergency department. Eur J Emerg Med 2006;13(5):270–5.
83. Langhan ML, Mallory M, Hertzog J, Lowrie L, Cravero J; Pediatric Sedation Research Consortium. Physiologic monitoring practices during pediatric procedural sedation: a report from the Pediatric Sedation Research Consortium. Arch Pediatr Adolesc Med 2012;166(11):990–8.
84. Primosch RE. Lidocaine toxicity in children—prevention and intervention. Todays FDA 1992;4:4C–5C.
85. Dial S, Silver P, Bock K, Sagy M. Pediatric sedation for procedures titrated to a desired degree of immobility results in unpredictable depth of sedation. Pediatr Emerg Care 2001;17(6):414–20.
86. Maxwell LG, Yaster M. The myth of conscious sedation. Arch Pediatr Adolesc Med 1996;150(7):665–7.
87. Coté CJ. "Conscious sedation": time for this oxymoron to go away! J Pediatr 2001;139(1):15–7; discussion: 18–9.
88. Motas D, McDermott NB, VanSickle T, Friesen RH. Depth of consciousness and deep sedation attained in children as administered by nonanaesthesiologists in a children's hospital. Paediatr Anaesth 2004;14(3):256–60.
89. Cudny ME, Wang NE, Bardas SL, Nguyen CN. Adverse events associated with procedural sedation in pediatric patients in the emergency department. Hosp Pharm 2013; 48(2):134–42.
90. Mora Capín A, Míguez Navarro C, López López R, Marañón Pardillo R. Usefulness of capnography for monitoring sedoanalgesia: infl uence of oxygen on the parameters monitored [in Spanish]. An Pediatr (Barc) 2014;80(1): 41–6.
91. Frieling T, Heise J, Kreysel C, Kuhlen R, Schepke M. Sedation-associated complications in endoscopy—prospective multicentre survey of 191142 patients. Z Gastroenterol 2013;51(6):568–72.
92. Khutia SK, Mandal MC, Das S, Basu SR. Intravenous infusion of ketaminepropofol can be an alternative to intravenous infusion of fentanylpropofol for deep sedation and analgesia in paediatric patients undergoing emergency short surgical procedures. Indian J Anaesth 2012; 56(2):145–50.
93. Kannikeswaran N, Chen X, Sethuraman U. Utility of endtidal carbon dioxide monitoring in detection of hypoxia during sedation for brain magnetic resonance imaging in children with developmental disabilities. Paediatr Anaesth 2011;21(12):1241–6.
94. McGrane O, Hopkins G, Nielson A, Kang C. Procedural sedation with propofol: a retrospective review of the experiences of an emergency medicine residency program 2005 to 2010. Am J Emerg Med 2012;30(5):706–11.