# Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures

Charles J. Coté, MD, FAAP, Stephen Wilson, DMD, MA, PhD, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

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 the potential 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 appropriately trained 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

# abstract



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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.\* 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 principles have been widely implemented and shown to reduce morbidity.† 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.‡

Procedural sedation of pediatric patients has serious associated risks.§ 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.# 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.\*\* The work of the

Pediatric Sedation Research Consortium has improved the sedation knowledge base, demonstrating 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 (eg, 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 vounger 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

<sup>\*</sup> Refs 3, 4, 11, 18, 20, 21, 23, 24, 33, 39, 41, 44, 47, 51, and 62–73

 $<sup>^{\</sup>dagger}$  Refs 11, 23, 24, 27, 30–33, 35, 39, 41, 44, 47, 51, and 74–84

<sup>\*</sup> Refs 38, 43, 45, 47, 48, 59, 62, 63, and 85–112

<sup>§</sup> Refs 2, 5, 38, 43, 45, 47, 48, 62, 63, 71, 83, 85, 88–105, and 107–138

<sup>#</sup> Refs 42, 48, 62, 63, 92, 97, 99, 125-127, 132, 133, and 139-158

<sup>\*\*</sup> Refs 44, 63, 64, 67, 68, 74, 90, 96, 110, and 159–174

respiratory drive, airway patency, and protective airway reflexes. <sup>62,63</sup> 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. <sup>29,46,49,182-211</sup>

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 (eg, 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.†† 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

#### Suggested Management of Airway Obstructions

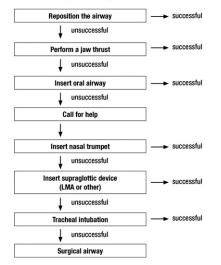


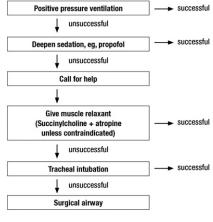
FIGURE 1 Suggested management of airway obstruction.

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

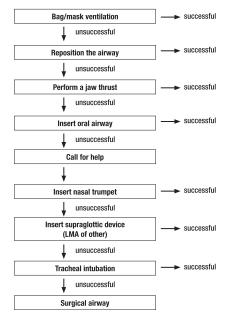
#### Suggested Management of Laryngospasm



**FIGURE 2** Suggested management of laryngospasm.

<sup>††</sup> Refs 30, 39, 65, 75, 171, 172, 201, 224–233

#### **Suggested Management of Apnea**



**FIGURE 3**Suggested management of apnea.

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 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 magnetic resonance imaging (MRI), sedatives/ hypnotics are preferred. When both sedation and analgesia are desirable (eg, 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 (eg, nitrous oxide; see below). 236

Knowledge of each drug's time of onset, peak response, and duration of action is important (eg, the peak electroencephalogram (EEG) effect of intravenous midazolam occurs at ~4.8 minutes, compared with that of diazepam at  $\sim$ 1.6 minutes<sup>237–239</sup>). 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 (eg, 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.<sup>62,63,242</sup> 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.<sup>250</sup>

#### **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.‡‡ Other rare complications also may include

<sup>\*\*</sup> Refs 42, 48, 92, 97, 99, 125, 132, and 139-155

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 lifethreatening complications must be established and maintained. <sup>44</sup> It should be understood that the availability of EMS does not replace the practitioner's responsibility to provide initial rescue for lifethreatening 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 ageand 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 sizeappropriate 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. <sup>251,252</sup>
- 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.<sup>62,63,238,242,256,257</sup> Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (eg, 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.

## **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. <sup>262</sup> 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, §§ it is unknown whether the risk of aspiration is

<sup>\$\$</sup> Refs 95, 127, 129, 173, 244, 259–261, and 264–268

reduced when airway manipulation is not performed/anticipated (eg, 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<sup>260,264,268</sup>: however, each of these reports has, 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).<sup>271</sup> It is permissible for routine necessary medications (eg, antiseizure medications) to be taken

**TABLE 1** Appropriate Intake of Food and Liquids Before Elective Sedation

| Ingested Material  | Minimum<br>Fasting<br>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<sup>278</sup> and Green et al <sup>278</sup>

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. Some emergency patients requiring deep sedation (eg, 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 (eg, 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.<sup>293–295</sup> Valerian may itself produce sedation that apparently is mediated through the modulation of  $\gamma$ -aminobutyric acid neurotransmission and receptor function.<sup>291,296-299</sup> 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 US 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<sup>329,332-338</sup>; (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 (eg, 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<sup>325-328,339,340</sup>; 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 [eg, mandibular hypoplasia], high Mallampati score [ie, 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. <sup>63,257</sup>

## **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. <sup>59</sup> 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 (ie, mg/kg); for obese patients, most drug doses should likely be adjusted lower to ideal body weight rather than actual weight.<sup>345</sup> 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<sup>62,104,256,349,350</sup> and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (eg, a step-down observation area) before discharge from medical/dental supervision may be indicated.<sup>239</sup> 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.<sup>238</sup>

#### **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 (eg, Yankauer-type suction)
- O = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery
- A = size-appropriate Airway equipment (eg, 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, <sup>361,362</sup> end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, ECG, stethoscope)
- **E** = special Equipment or drugs for a particular case (eg, 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.<sup>85,363</sup>

#### **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 (ie, 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 (eg, pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged. <sup>79,80,128,130,217–220,364</sup>

#### 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.<sup>60</sup> This individual should be trained in and capable of providing advanced airway skills (eg, 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 (ie, patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (eg, Bluetooth technology)<sup>368–371</sup> or precordial stethoscope is strongly recommended. If bidirectional 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 (eg, 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 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 (bagvalve mask) with an adequate oxygen capacity as well as age- and sizeappropriate rescue equipment and devices. The patient's vital signs should be recorded at specific intervals (eg, 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 resedation, some patients might benefit from a longer period of less intense observation (eg, 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.<sup>238</sup> 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 (eg, 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 druginduced 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.

#### Personnel

During deep sedation and/or general anesthesia of a pediatric patient in a dental facility, there must be at least 2 individuals present with the patient throughout the procedure. These 2 individuals must have appropriate training and up-to-date certification in patient rescue, as

delineated below, including drug administration and PALS or Advanced Pediatric Life Support (APLS). One of these 2 must be an independent observer who is independent of performing or assisting with the dental procedure. This individual's sole responsibility is to administer drugs and constantly observe the patient's vital signs, depth of sedation, airway patency, and adequacy of ventilation. The independent observer must, at a minimum, be trained in PALS (or APLS) and capable of managing any airway, ventilatory, or cardiovascular emergency event resulting from the deep sedation and/or general anesthesia. The independent observer must be trained and skilled to establish intravenous access and draw up and administer rescue medications. The independent observer must have the training and skills to rescue a nonbreathing child; a child with airway obstruction; or a child with hypotension, anaphylaxis, or cardiorespiratory arrest, including the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, or laryngeal mask airway), and perform successful bagvalve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation. The independent observer in the dental facility, as permitted by state regulation, must be 1 of the following: a physician anesthesiologist, a certified registered nurse anesthetist, a second oral surgeon, or a dentist anesthesiologist. The second individual, who is the practitioner in the dental facility performing the procedure, must be trained in PALS (or APLS) and capable of providing skilled assistance to the independent observer with the rescue of a child experiencing any of the adverse events described above.

During deep sedation and/or general anesthesia of a pediatric patient in a hospital or surgicenter setting, at least 2 individuals must be present with the patient throughout the procedure with skills in patient rescue and up-to-date PALS (or APLS) certification, as delineated above. One of these individuals may either administer drugs or direct their administration by the skilled independent observer. The skills of the individual directing or administering sedation and/or anesthesia medications must include those described in the previous paragraph. Providers who may fulfill the role of the skilled independent observer in a hospital or surgicenter, as permitted by state regulation, must be a physician with sedation training and advanced airway skills, such as, but not limited to, a physician anesthesiologist, an oral surgeon, a dentist anesthesiologist, or other medical specialists with the requisite licensure, training, and competencies; a certified registered nurse anesthetist or certified anesthesiology assistant; or a nurse with advanced emergency management skills, such as several years of experience in the emergency department, pediatric recovery room, or intensive care setting (ie, nurses who are experienced with assisting the individual administering or directing sedation with patient rescue during life-threatening emergencies).

# 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 be documented 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 (ie, continuous waveform). Capnography is particularly useful for patients who are difficult to observe (eg, during MRI or in a darkened room).##

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

<sup>\*\*\*</sup> Refs 64, 67, 72, 90, 96, 110, 159–162, 164–170, and 372–375

TABLE 2 Comparison of Moderate and Deep Sedation Equipment and Personnel Requirements

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

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,<sup>376</sup> resulting in prolonged sedation and the need for extended postsedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea,<sup>377</sup> but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.<sup>378</sup>

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 (eg, 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 weightbased 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 (eg, 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

TABLE 3 Commonly Used Local Anesthetic Agents for Nerve Block or Infiltration: Doses, Duration, and Calculations

| Local Anesthetic             | Maximum Dose With<br>Epinephrine, <sup>a</sup> mg/kg |        | Maximum Dose Without<br>Epinephrine, mg/kg |        | Duration of Action, <sup>b</sup> 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 <sup>c</sup> | 3.0  | 2      | 2  | 2      | 180-600                              |
| Ropivacaine                  | 3.0  | 2      | 2  | 2      | 180-600                              |
| Articaine <sup>d</sup>       | _  | 7      | _  | 7      | 60-230                               |

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

(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's recommendations 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

TABLE 4 Local Anesthetic Conversion Chart

| Concentration,<br>% | mg/<br>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      |

oximeters that do not contain updated software. A16-420 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).

#### 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.\*\*\* In patients receiving supplemental oxygen, capnography facilitates the recognition of apnea or airway obstruction several minutes before the situation 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%).<sup>174</sup> 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

<sup>&</sup>lt;sup>a</sup> 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 (eg, 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.

<sup>&</sup>lt;sup>c</sup> Levobupivacaine is not available in the United States.

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

<sup>\*\*\*</sup> Refs 64, 66, 67, 72, 90, 96, 110, 159–162, 164–170, 372–375, and 421–427

- 1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
- Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers, β-blockers, or additional local anesthetic. Reduce epinephrine dosages. Prolonged effort may be required.
- Seizure management: benzodiazepines preferred (eg, intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
- 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  $\mu$ g/kg per minute to start) may be needed to correct peripheral vasodilation.

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

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<sup>363</sup>; 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 lifesaving 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-tooxygen 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  $\leq 50\%$  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. In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.

#### **LEAD AUTHORS**

Charles J. Coté, MD, FAAP Stephen Wilson, DMD, MA, PhD

#### **AMERICAN ACADEMY OF PEDIATRICS**

# AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

#### STAFF

Jennifer Riefe, MEd Raymond J. Koteras, MHA

## **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: larvngeal mask airway

MRI: magnetic resonance imaging

OSA: obstructive sleep apnea PALS: pediatric advanced life

support

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