

# Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures

## Developed and Endorsed by

American Academy of Pediatrics and the American Academy of Pediatric Dentistry

## Adopted

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### 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 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 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 tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction, a clear understanding of the pharmacokinetic and pharmacodynamic effects of the medications used for sedation as well as an appreciation for 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 people 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 pre-sedation level of consciousness before discharge from medical supervision, and appropriate discharge instructions.

### Introduction

Invasive diagnostic and minor surgical procedures on pediatric patients outside the traditional operating room setting have increased in the last decade. 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 physician offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, and ambulatory surgery centers also has markedly increased.<sup>1-37</sup> In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and 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.<sup>38-42</sup> The purpose of this updated statement is to unify

the guidelines for sedation used by medical and dental practitioners, add clarifications regarding monitoring modalities, provide new information from medical and dental literature, and suggest methods for further improvement in safety and outcomes. With the revision of this document, the Joint Commission on Accreditation of Healthcare Organizations, the American Society of Anesthesiologists (ASA), the AAP, and the AAPD will use similar language to define sedation categories and the expected physiologic responses.<sup>41-44</sup>

This revised statement reflects the current understanding of appropriate monitoring needs both during and after sedation for a procedure.<sup>4,5,12,19,21,22,26,45-53</sup> The monitoring and care out-lined in this guideline may be exceeded at any time, based on the judgment of the responsible practitioner. Although intended to encourage high-quality patient care, adherence to this guideline cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate the principles in this document have been widely implemented and shown to reduce morbidity.<sup>29,32-34,37,54,55</sup> This guideline is proffered with the awareness that, regardless of the intended level of sedation or route of administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression and the loss of the patient's protective reflexes.<sup>43,57-60</sup>

Sedation of pediatric patients has serious associated risks, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment.<sup>2,6,22,45,46,54,60-69</sup> 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.<sup>54</sup> Appropriate drug selection for the intended procedure as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are essential. Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.<sup>46,51,54</sup>

The sedation of children is different from the sedation of adults. Sedation in children often is administered to control behavior 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 and developmental age. Often, children younger than 6 years and those with developmental delay require deep levels of sedation to gain control of their behavior.<sup>57</sup> Therefore, the need for deep sedation should be anticipated. Children in this age group are particularly vulnerable to the sedating medication's effects on respiratory drive, patency of the airway, and protective reflexes.<sup>46</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.<sup>56,59,70</sup> For older and cooperative children, other modalities, such as parental presence, hypnosis, distraction, topical local anesthetics, and guided imagery, may reduce the need for or the needed depth of pharmacologic sedation.<sup>31,71-81</sup>

The concept of rescue is 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 necessary to provide appropriate cardiopulmonary support if needed. Sedation and anesthesia in a nonhospital environment (private physician or dental office or freestanding imaging facility) may be associated with an increased incidence of "failure to rescue" the patient should an adverse event occur, because the only backup in this venue may be to activate emergency medical services (EMS).<sup>46,82</sup> Rescue therapies require specific training and skills.<sup>46,54,83,84</sup> Maintenance of the skills needed to perform successful bag-valve-mask ventilation is essential to successfully rescue a child who has become apneic or developed airway obstruction. Familiarity with emergency airway management procedure algorithms is essential.<sup>83-87</sup> 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.<sup>32,48,55,88-93</sup> This guideline is intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office).

There are other guidelines for specific situations and personnel 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.<sup>94</sup> Also, 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 hospice care are beyond the scope of this document.

### Definitions of Terms for This Report

- "Pediatric patients": all patients through 21 years of age, as defined by the AAP.
- "Must" or "shall": an imperative need or duty that is essential, indispensable, or mandatory.
- "Should": the recommended need and/or duty.
- "May" or "could": freedom or liberty to follow a suggested or reasonable alternative.
- "Medical supervision" or "medical personnel": a current, licensed practitioner in medicine, surgery, or dentistry trained in the administration of medications used for procedural sedation and the management of complications associated with these medications.
- "Are encouraged": a suggested or reasonable action to be taken.
- "ASA Physical Status Classification": guidelines for classifying the baseline health status according to the ASA (see Appendix B).
- "Minimal sedation" (old terminology "anxiolysis"): 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.
- "Moderate sedation" (old terminology "conscious sedation" or "sedation/analgesia"): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (eg, "open your eyes" either alone or accompanied by light tactile stimulation—a light tap on the shoulder or face, not a sternal rub). For older patients, this level of sedation implies an interactive state; for younger patients, age-appropriate behaviors (eg, crying) occur and are expected. Reflex withdrawal, although a normal response to a painful stimulus, is not considered as the only age-appropriate purposeful response (eg, it must be accompanied by another response, such as pushing away the painful stimulus so as to confirm a higher cognitive function). With moderate sedation, no intervention is required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. However, in the case of procedures that may themselves cause airway obstruction (eg, dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway. If the patient is not making spontaneous efforts to open his/her airway so as to relieve the obstruction, then the patient should be considered to be deeply sedated.
- "Deep sedation" ("deep sedation/analgesia"): a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully (see discussion of reflex withdrawal above) after repeated verbal or painful stimulation (eg, purposefully pushing away the noxious stimuli). 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.

- “General anesthesia”: 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.

### Goals of Sedation

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are: 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 control 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 safe discharge from medical supervision, as determined by recognized criteria, is possible (Appendix A).

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 goal of the procedure are essential for safe practice.<sup>53,88,91-93,95-97</sup> For example, analgesic medications such as opioids 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 commonly are used. Anxiolysis and amnesia are additional goals that should be considered in selection of agents for particular patients. However, the potential for an adverse outcome may be increased when 3 or more sedating medications are administered.<sup>44,98</sup> Knowledge of each drug’s time of onset, peak response, and duration of action is essential. Although the concept of titration of drug to effect is critical, one must know whether the previous dose has taken full effect before administering additional drug. Such management will improve safety and outcomes. Drugs with long durations of action (eg, chloral hydrate, intramuscular pentobarbital, phenothiazines) will require longer periods of observation even after the child achieves currently used recovery and discharge criteria.<sup>45,99,100</sup> This concept is particularly important for infants and toddlers transported in car safety seats who are at risk of re-sedation after discharge because of residual prolonged drug effects with the potential for airway obstruction.<sup>45,46</sup>

## General Guidelines

### Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Appendix B). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or extreme tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.<sup>51</sup> 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 or more 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>101</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, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from inadequate recognition and treatment of respiratory compromise. Other rare complications may also include seizures and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

### Back-up Emergency Services

A protocol for access to back-up emergency services shall be clearly identified, with an outline of the procedures necessary for immediate use. For nonhospital facilities, a protocol for ready access to ambulance service and immediate activation of the EMS system for life-threatening complications must be established and maintained. It should be understood that the availability of EMS services does not replace the practitioner’s responsibility to provide initial rescue in managing life-threatening complications.

### On-Site Monitoring and Rescue Equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain equipment to provide the necessary age- and size-appropriate drugs and equipment 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 facility or to another area within a medical facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Appendices C and D 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 oximeter probes), end-tidal carbon dioxide monitors, and defibrillators (with size-appropriate defibrillator paddles), must have a safety and function check on a regular basis as required by local or state regulation.

### Documentation Before Sedation

Documentation shall include, but not be limited to, the guidelines that follow:

1. Informed consent. The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.<sup>102</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. 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 so as to avoid airway obstruction. Transportation by 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.<sup>45,46,100,103</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 or a severe underlying medical condition. 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. Therefore, it is prudent that before sedation, the practitioner evaluate preceding food and fluid intake. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulation.<sup>104,105</sup> However, because the absolute risk of aspiration during procedural sedation is not yet known, guidelines for fasting periods before elective sedation generally should follow those used for elective general anesthesia. For emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly (see below). Further re-search is needed to better elucidate the relationships between various fasting intervals and sedation complications.

### Before Elective Sedation

Children receiving sedation for elective procedures should generally follow the same fasting guidelines as before general anesthesia (Table 1). It is permissible for routine necessary medications to be taken with a sip of 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 and necessity for completing the procedure. In this circumstance, the use of sedation must be preceded by an evaluation of food and fluid intake. There are few published studies with adequate statistical power to provide guidance to the practitioner regarding safety or risk of pulmonary aspiration of gastric contents during procedural sedation.<sup>104-109</sup> When protective airway reflexes are lost, gastric contents may be regurgitated into the airway. Therefore, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity, pregnancy, or bowel motility dysfunction, require careful evaluation before 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. The use of agents with less risk of depressing protective airway reflexes may be preferred.<sup>110</sup> Some emergency patients requiring deep sedation may require protection of the airway before sedation.

### Use of Immobilization Devices

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction. 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. The purpose of this evaluation is not only to document baseline status but also to determine whether patients present specific risk factors that may warrant additional consultation before sedation. This evaluation will also screen out patients whose sedation will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

A new 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, echinacea) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations.<sup>111-116</sup> Kava may increase the effects of sedatives by potentiating gamma-aminobutyric acid inhibitory neurotransmission, and valerian may itself produce sedation that apparently is mediated through modulation of gamma-aminobutyric acid neurotransmission and receptor function.<sup>117,118</sup> Drugs such as erythromycin, cimetidine, and others also may inhibit the cytochrome P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.<sup>119-122</sup> Medications used to treat human immunodeficiency virus infection, some anticonvulsants, and some psychotropic medications also may produce clinically important drug-drug interactions.<sup>123-125</sup> Therefore, a careful drug history is a vital part of the safe sedation of children. The clinician should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.<sup>126</sup>

The health evaluation should include:

- Age and weight
- Health history, including: 1) 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, and neurologic impairment that might increase the potential for airway obstruction, such as a history of snoring or obstructive sleep apnea;<sup>127,128</sup> 4) pregnancy status; 5) a summary of previous relevant hospitalizations; 6) history of sedation or general anesthesia and any complications or unexpected responses; and 7) relevant family history, particularly related to anesthesia
- Review of systems with a special focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications
- Vital signs, including heart rate, blood pressure, respiratory rate, 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 occurrence)
- Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy—eg, mandibular hypoplasia) to determine whether there is an increased risk of airway obstruction<sup>54,129,130</sup>
- Physical status evaluation (ASA classification [see Appendix B])
- Name, address, and telephone number of the child's medical home

For hospitalized patients, the current hospital record may suffice for adequate documentation of presedation health;

however, a brief 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 benefit of direct supervision by trained medical personnel.** Administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats.<sup>46</sup>

### Documentation During Treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage, 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 site of the procedure.<sup>43</sup> During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administrations, special attention must be paid to calculation of dosage (ie, mg/kg). 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, and oxygen saturation were monitored until the patient attained predetermined discharge criteria (see Appendix A). A variety of sedation scoring systems are available and may aid this process.<sup>70,100</sup> Adverse events and their treatment shall be documented.

### Documentation After Treatment

The time and condition of the child at discharge from the treatment area or facility shall be documented; this 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 A). 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>45,103,131,132</sup> some patients might benefit from a longer period of less-intense observation (eg, a step-down observation area) before discharge from medical supervision.<sup>133</sup> Several scales to evaluate recovery have been devised and validated.<sup>70,134,135</sup> A recently described and 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>100</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.<sup>137-141</sup> Therefore, each facility should maintain records that track adverse events, such as desaturation, apnea, laryngospasm, the need for airway interventions including jaw thrust, positive pressure ventilation, prolonged sedation, unanticipated use of reversal agents, unintended or prolonged hospital admission, and unsatisfactory sedation/analgesia/anoxiolysis. Such events can then be examined for assessment of risk reduction and improvement in patient satisfaction.

## Preparation and Setting up for Sedation Procedures

Part of the safety net of sedation is to use 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**:

- S** = Size-appropriate **suction** catheters and a functioning **suction** apparatus (eg, Yankauer-type suction)
- O** = An adequate **oxygen** supply and functioning flow meters/other devices to allow its delivery
- A** = **Airway**: size-appropriate airway equipment (nasopharyngeal and oropharyngeal airways, laryngoscope blades [checked and functioning], endotracheal tubes, stylets, face mask, bag-valve-mask or equivalent device [functioning])
- 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>141,142</sup> and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, end-tidal carbon dioxide, 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 “anoxiolysis”) 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>57</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 following light tactile stimulation (see Definition of Terms for This Report). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function usually is maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation. The drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness highly 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.<sup>57</sup>

### 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 provided in this guideline, 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 provide rescue should the child progress to a level of deep sedation. The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops airway obstruction or apnea. Training in, and maintenance of, advanced pediatric airway skills is required; regular skills reinforcement is strongly encouraged.

#### Support Personnel

The use of moderate sedation shall include 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.<sup>44</sup> This individual must be trained in and capable of providing pediatric basic life support. 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 and practice drills of the facility’s emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.

### *Monitoring and Documentation*

#### Baseline

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

#### During the Procedure

The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. There shall be continuous monitoring of oxygen saturation and heart

rate and intermittent recording of respiratory rate and blood pressure; these should be recorded in a time-based record. Restraining devices 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 checked frequently to ensure airway patency. A functioning suction apparatus must be present.

#### After the procedure

The child who has received moderate sedation must be observed in a suitably equipped recovery facility [eg, the facility must have functioning suction apparatus as well as the capacity to deliver more than 90% oxygen and positive-pressure ventilation (eg, bag and mask with oxygen capacity as described previously)]. The patient's vital signs should be recorded at specific intervals. 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 A). 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 (eg, a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical supervision (see also Documentation Before Sedation for instructions to families).<sup>45,103,131,132</sup> A recently described and 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>100</sup> Patients who have received reversal agents, such as flumazenil or naloxone, will also require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, which can lead to re sedation.

### **Deep Sedation**

Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (see Definition of Terms for this report). The state and risks of deep sedation may be indistinguishable from those of general anesthesia.

#### *Personnel*

There must be 1 person available 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. At least 1 individual must be present who is trained in, and capable of, providing advanced pediatric life support, and who is skilled in airway management and cardiopulmonary resuscitation; training in pediatric advanced life support is required.

#### *Equipment*

In addition to the equipment previously cited for moderate sedation, an electrocardiographic 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 and Documentation*

A competent individual shall observe the patient continuously. The monitoring shall include all parameters described for moderate sedation. Vital signs, including oxygen saturation and heart rate, must be documented at least every 5 minutes in a time-based record. The use of a precordial stethoscope or capnograph for patients difficult to observe (eg, during MRI, in a darkened room) to aid in monitoring adequacy of ventilation is encouraged.<sup>143</sup> The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. 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."

## **Special Considerations**

### **Local Anesthetic Agents**

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular attention should be paid to dosage in small children.<sup>64,66</sup> To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (ie, 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 narcotics (see Tables 2 and 3 for limits and conversion tables of commonly used local anesthetics).<sup>64,144-157</sup> In general, when administering local anesthetic drugs, the practitioner should aspirate frequently so as to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.<sup>158</sup>

### **Pulse Oximetry**

The new generation of pulse oximeters is less susceptible to motion artifacts and may be more useful than older oximeters that do not contain the updated software.<sup>159-163</sup> Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. It is essential that any oximeter probe is positioned properly; clip-on devices are prone to easy displacement, which may produce artifactual data (eg, under- or overestimation of oxygen saturation).<sup>141,142</sup>

### **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 magnetic resonance imaging or computerized axial tomography devices or darkened rooms.<sup>47,49,50,143,164-173</sup> The use of expired carbon dioxide monitoring devices is encouraged for sedated children, particularly in situations where 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.<sup>164,165</sup> 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.<sup>166,168,173</sup>

### 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, and bag-mask-valve ventilation. Occasionally, endotracheal intubation is required for more prolonged ventilatory support. In addition to standard endotracheal intubation techniques, a number of new devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the laryngeal mask airway (LMA), the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.

The largest clinical experience in pediatrics is with the LMA, which is available in a variety of sizes and can even be used in neonates. Use of the LMA is now being introduced into advanced airway training courses, and familiarity with insertion techniques can be life saving.<sup>174,175</sup> The LMA also can serve as a bridge to secure airway management in children with anatomic airway abnormalities.<sup>176,177</sup> Practitioners are encouraged to gain experience with these techniques as they become incorporated into pediatric advanced life support courses.

An additional emergency device with which to become familiar is the intraosseous needle. Intraosseous needles also are available in several sizes and can be life saving in the rare situation when rapid establishment of intravenous access is not possible. Familiarity with the use of these adjuncts for the management of emergencies can be obtained by keeping current with resuscitation courses, such as Pediatric Advanced Life Support and Advanced Pediatric Life Support or other approved programs.

### Patient Simulators

Advances in technology, particularly patient simulators that allow a variety of programmed adverse events (eg, apnea, bronchospasm, laryngospasm), response to medical interventions, and printouts of physiologic parameters, are now available. The use of such devices is encouraged to better train medical professionals to respond more appropriately and effectively to rare events.<sup>178-180</sup>

### 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. Pulse oximeters 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; avoid coiling the oximeter wire and place the probe as far from the magnetic coil as possible to diminish the possibility of injury. Electrocardiogram monitoring during magnetic resonance imaging has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.<sup>181-184</sup> Expired carbon dioxide monitoring is strongly encouraged in this setting.

### 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 to oxygen and that has a delivery system 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.<sup>185</sup> 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.<sup>15,186-210</sup> The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide (50% or less) with the balance as oxygen, without any other sedative, narcotic, 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 greater than 50%, the likelihood for moderate or deep sedation increases.<sup>211,212</sup> In this situation, the clinician must be prepared to institute the guidelines for moderate or deep sedation as indicated by the patient's response.<sup>213</sup>

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
Breast 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

\* 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. A Report of the American Society of Anesthesiologists. Available at: "<http://www.asahq.org/publicationsAndServices/npoguide.html>".

Table 2. COMMONLY USED LOCAL ANESTHETIC AGENTS: DOSES, DURATION, AND CALCULATIONS\*

Local Anesthetic	Maximum Dose with Epinephrine (mg/kg)†		Duration of Action (min) ‡
	Medical	Dental	
<i>Esters</i>			
Procaine	10.0	6	60-90
Chlorprocaine	20.0	12	30-60
Tetracaine	1.5	1	180-600
<i>Amides</i>			
Lidocaine	7.0	4.4	90-200
Mepivacaine	7.0	4.4	120-240
Bupivacaine	3.0	1.3	180-600
Levobupivacaine	3.0	2	180-600
Ropivacaine	3.0	2	180-600
Articaine		7	60-230

\* Maximum recommended doses and duration of action. Note that lower doses should be used in very vascular areas.

† 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 months. 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.

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

Table 3. LOCAL ANESTHETIC PERCENT CONCENTRATION: CONVERSION TO mg/mL

Concentration (%)	mg/mL
3.0	30.0
2.5	25.0
2.0	20.0
1.0	10.0
0.5	5.0
0.25	2.5
0.125	1.25

## Appendix A. Recommended Discharge Criteria

1. Cardiovascular function and airway patency are satisfactory and stable.
2. The patient is easily arousable, and protective reflexes are intact.
3. The patient can talk (if age appropriate).
4. The patient can sit up unaided (if age appropriate).
5. For a very young or handicapped child incapable of the usually expected responses, the premedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved.
6. The state of hydration is adequate.

## Appendix B. ASA Physical Status Classification

Class I	A normally healthy patient.
Class II	A patient with mild systemic disease (eg, controlled reactive airway disease).
Class III	A patient with severe systemic disease (eg, a child who is actively wheezing).
Class IV	A patient with severe systemic disease that is a constant threat to life (eg, a child with status asthmaticus).
Class V	A moribund patient who is not expected to survive without the operation (eg, a patient with severe cardiomyopathy requiring heart transplantation).

## Appendix C. Drugs\* That May Be Needed to Rescue a Sedated Patient<sup>44</sup>

Albuterol for inhalation  
 Ammonia spirits  
 Atropine  
 Diphenhydramine  
 Diazepam  
 Epinephrine (1:1000, 1:10 000)  
 Flumazenil  
 Glucose (25% or 50%)  
 Lidocaine (cardiac lidocaine, local infiltration)  
 Lorazepam  
 Methylprednisolone  
 Naloxone  
 Oxygen  
 Fosphenytoin  
 Racemic epinephrine  
 Rocuronium  
 Sodium bicarbonate  
 Succinylcholine

\* The choice of emergency drugs may vary according to individual or procedural needs.

## Appendix D. Emergency Equipment<sup>†</sup> That May Be Needed to Rescue a Sedated Patient<sup>‡</sup>

### Intravenous Equipment

Assorted IV catheters (eg, 24-, 22-, 20-, 18-, 16-gauge)  
 Tourniquets  
 Alcohol wipes  
 Adhesive tape  
 Assorted syringes (eg, 1-, 3-, 5-, 10-mL)  
 IV tubing  
     Pediatric drip (60 drops/mL)  
     Pediatric burette  
     Adult drip (10 drops/mL)  
     Extension tubing  
     3-way stopcocks  
 IV fluid  
     Lactated Ringer solution  
     Normal saline solution  
     D<sub>5</sub> 0.25 normal saline solution  
 Pediatric IV boards  
 Assorted IV needles (eg, 25-, 22-, 20-, and 18-gauge)  
 Intraosseous bone marrow needle  
 Sterile gauze pads

### Airway Management Equipment

Face masks (infant, child, small adult, medium adult, large adult)  
 Breathing bag and valve set  
 Oropharyngeal airways (infant, child, small adult, medium adult, large adult)  
 Nasopharyngeal airways (small, medium, large)  
 Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)  
 Laryngoscope handles (with extra batteries)  
 Laryngoscope blades (with extra light bulbs)  
     Straight (Miller) No. 1, 2, and 3  
     Curved (Macintosh) No. 2 and 3  
 Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0 uncuffed and 6.0, 7.0, and 8.0 cuffed)  
 Stylettes (appropriate sizes for endotracheal tubes)  
 Surgical lubricant  
 Suction catheters (appropriate sizes for endotracheal tubes)  
 Yankauer-type suction  
 Nasogastric tubes  
 Nebulizer with medication kits  
 Gloves (sterile and nonsterile, latex free)

<sup>†</sup> The choice of emergency equipment may vary according to individual or procedural needs.

<sup>‡</sup> The practitioner is referred to the SOAPME acronym described in the text in preparation for sedating a child for a procedure.

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