# Sedation Policies, Recommendations, and Guidelines Across the Specialties and Continents

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## Introduction

It is the nature of pediatric sedation that the practice involves a wide variety of sedation providers and pediatric medical subspecialists. As such, there is still no consensus on "universally" applicable and acceptable guidelines. A number of guidelines, policies, and recommendations for sedation care have been promulgated by different subspecialty societies over the last 30 years. This chapter will consider some of these guidelines and put them into perspective.

The common dictionary definition of "guideline" is "general rule, principle, piece of advice." With this definition in mind, this chapter will consider several forms of guidelines – including those that come in the form of "statements," "practice advisories," "clinical policies," or "recommendations." These documents range from those that contain broad descriptions of appropriate monitoring and treatment to those that offer specific guidelines on the use of particular drugs or nil per os (NPO) intervals. While different pediatric subspecialties may have slightly different opinions and descriptions when discussing the specifics of sedation care, the common elements and considerations largely outweigh the differences.

Before beginning, it should be noted that the methodologies used to produce these guidelines vary from organization to organization. For example, the American Academy of Pediatrics (AAP) guidelines were put together by a workgroup on sedation from the Committee on Drugs [1–4]. While these guidelines were based on a careful consideration of the available literature, the exact nature of how studies were "weighted" and how conclusions were drawn is not explicitly described. The most recent guidelines of American Society of Anesthesiologists (ASA) [4] and American College of Emergency Physicians (ACEP) [5–7] are founded on an evidence-based review of pediatric sedation literature.

This chapter reviews the most recently published sedation guidelines of the various specialties in the United States and then presents the guidelines from some international societies in order to provide comparison and contrast.

## American Academy of Pediatrics Guidelines

In the United States, the AAP guidelines are the most widely applied guidelines with respect to pediatric sedation. While other statements from the AAP have expanded on the importance of the

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use of sedation and analgesia for children [8–10], these guidelines still remain the standard for the AAP and have influenced the creation of safe sedation systems around the USA and internationally. Much of their lexicon and recommendations have been largely adopted by The Joint Commission in evaluating institutional compliance for safe sedation standards. The first AAP guideline for pediatric sedation was written in response to three dental deaths in 1983 (published in 1985) [1] on behalf of the American Academy of Pediatrics Section on Anesthesiology. Written in collaboration with the American Academy of Pediatric Dentistry (AAPD) and the ASA, the purpose was to develop a framework from which improved safety could be developed for children requiring sedation in order to perform a needed procedure. This initial guideline emphasized standardization on issues such as the need for informed consent, appropriate fasting prior to sedation, frequent measurement and charting of vital signs, the availability of age and size appropriate equipment, the use of physiologic monitoring, the need for basic life support (BLS) skills, and proper recovery and discharge procedures. The concept of an independent observer whose only responsibility is to monitor the patient was introduced for deeply sedated pediatric patients. Advanced airway and resuscitation skills were encouraged but not specifically required for deep sedation providers. These original guidelines defined three terms for depth of sedation: conscious sedation, deep sedation, and general anesthesia. The descriptive term "conscious sedation" was defined as "A medically controlled state of depressed consciousness that allows the protective reflexes to be maintained; retains the patient's ability to maintain a patent airway independently and continuously; and permits an appropriate response by the patient to physical stimulation or verbal command, e.g. 'open your eyes.'"

In 1992 the Committee on Drugs of the AAP revised the 1985 guideline [2]. The new iteration recognized that a patient could readily progress from one level of sedation to another and that the practitioner should be prepared to increase vigilance and monitoring as indicated. Pulse oximetry was recommended for all patients undergoing sedation. This new guideline also discouraged the practice of administering sedation at home by parents – a practice which was not infrequent in dental and radiologic sedation at that time. An addendum to the guideline was produced by the same Committee on Drugs of the AAP 2002 [11] ending the use of the term "conscious sedation" and clarifying the fact that these guidelines apply to any location where children are sedated – in or out of the hospital. The current guidelines use the terminology of "minimal sedation, moderate sedation, deep sedation, and anesthesia." These descriptions of sedation levels have been adopted by the ASA and The Joint Commission. The addendum emphasized that sedatives be administered only by those skilled in airway management and cardiopulmonary resuscitation [11].

The most current iteration of the AAP sedation guidelines was published in Pediatrics in December 2006 [3]. This set of guidelines represents a significant landmark for the field of pediatric sedation. For the first time, with the publication of this document, the Joint Commission, ASA, AAP, and the AAPD officially adopted common language to define sedation categories (minimal, moderate, deep, and anesthesia) and the expected physiologic responses for each category. The authors emphasize the concept that sedation is a continuum and that the sedation provider must be capable of rescuing a patient for a level of sedation one step deeper than that which is intended. They recommend "ongoing maintenance of critical skills for airway rescue" and reference some resources, but stop short of specific directions for how best to teach or maintain critical competencies. Deep sedation requires special expertise and personnel resources.

Credentials required to administer deep sedation [3]:

1. There must be one person available whose sole responsibility is to constantly observe the vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration.
2. At least one individual, trained and competent to provide advanced pediatric life support,

airway management, and cardiopulmonary resuscitation, must be present.

This iteration of the guidelines emphasizes that as the recommendations apply to all sites where sedation is given, clear plans for rescue by Emergency Medical Systems (EMS) must be put in place for settings such as a free standing clinic or office.

The guidelines include an interesting section on drug interactions and cautions on alternative medications such at St. John's Wart, Kava, and Echinacea and their possible impact on sedation provision. The guidelines do not make any statement nor recommendation on the administration of propofol, either by anesthesiologists or nonanesthesiologists.

These guidelines distinguish monitoring requirements based on the depth of sedation as well as the setting. Pulse oximetry, heart rate, and intermittent blood pressure should be followed during moderate sedation. For deep sedation, "precordial stethoscope or capnography should be implemented for patients who are difficult to observe (i.e., MRI) to aid in monitoring adequacy of ventilation." Capnography is "encouraged" but not required, particularly in situations where other means of assessing ventilation are limited.

These guidelines make recommendations on fasting (NPO) status which continue to be followed today:

### ASA/AAP NPO Guidelines

1. Clear liquids: 2 h: include water, fruit juices without pulp, carbonated beverages, clear tea, black coffee.
2. Breast milk: 4 h.
3. Infant formula, nonhuman milk.
4. Light meal and solid food: 6 h.

Recovery criteria and considerations are also enumerated, including a suggestion for the use of (new) simple "wakefulness" measures as part of the discharge criteria (where a child is simply observed for his/her ability to remain awake for a specified period of time (15–20 min) prior to discharge) [3].

## American Society of Anesthesiologists (ASA) Policies and Recommendations

While the ASA has not produced a document specific for pediatric sedation, issues relating to pediatric patients are mentioned in almost all of the sedation-related publications it has produced. The ASA has many statements and guidelines that address sedation by nonanesthesia providers including *Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists* [4]. *Continuum of Depth of Sedation – Definition of General Anesthesia and Levels of Sedation/Analgesia; Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners who are not Anesthesia Professionals; 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; Statement on Safe Use of Propofol; and Statement on Granting Privileges to Nonanesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who are not Anesthesia Professionals.* (All statements and other documents are available at: http://www.asahq.org/publicationsAndServices/sgstoc.htm.)

The Sedation Practice Guidelines for Practitioners who are not Anesthesiologists [4] is probably the most widely quoted document concerning sedation that the ASA has produced. The latest iteration of this document was published in 2002 as an update/revision of the original 1995 guidelines [4, 12]. The stated purpose of the guideline is to "allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks." These guidelines were developed by a task force using an evidence-based "strength of the evidence" methodology.

The ASA guidelines are consistent with the AAP in many respects. They describe the sedation levels identical to the AAP and The Joint Commission guidelines. They require that the sedation provider be able to rescue patients from a level deeper than intended. The authors also apply the current ASA recommendations on NPO times

(2 h for clear fluids, 4 h for breast milk, 6 h for light meals and formula, 8 h for full meals) to elective sedation. The ASA guidelines are similar to those of AAP in their recommendation for ECG, blood pressure, and pulse oximetry for all deep sedation patients. Continual monitoring of sedation depth through stimulation/response analysis is recommended. Until 2011, the ASA emphasized but did not require capnography, stating that capnography should be considered, but is not required, for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. The American Society of Anesthesiologists updated in July, 2011 the Standards for Basic Anesthetic Monitoring. These standards specify that "during moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure or equipment." This updated ASA standard is landmark- the first time that end-tidal carbon dioxide monitoring has been made a standard of care for moderate as well as deep sedation [13].

In 2005 the ASA produced the "Statement on granting privileges for administration of moderate sedation to practitioners who are not anesthesia professionals." This is a detailed statement that defines the different groups/qualifications of sedation providers: The Anesthesia Professional (anesthesiologist, Certified Registered Nurse Anesthetist (CRNA), Anesthesiologist Assistant (AA), Nonanesthesiologist Sedation Practitioner (other physicians, dentists, podiatrists), Supervised Sedation Professional (licensed registered nurse, advanced practice nurse, etc.)). This grouping has raised some controversy, as the term "nonanesthesiologist" can represent physicians of various levels of skill, training, and experience [14].

The ASA defines the rescue capabilities that are required for sedation providers at each level of sedation. In 2006 they deviated from the AAP in that they restricted the administration of deep sedation to those of particular qualifications: To practitioners who are qualified to administer general anesthesia or to appropriately supervise anesthesia professionals (http://www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx). This individual should have no other responsibilities except to deliver sedation and monitor the patient throughout. This "Statement on granting privileges to non-anesthesiologist practitioners for personally administering deep sedation or supervising deep sedation by individuals who are not anesthesia professionals" was supplanted on October 20, 2010 by the ASA Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners [15]. It recommends that the nonanesthesiologist be able to bag-valve-mask ventilate, insert an oro/pharyngeal airway and laryngeal mask airway, and perform an endotracheal intubation. Training should include a minimum of 35 patients, inclusive of simulator experience. Practitioners should be familiar with the use and interpretation of capnography. Deep sedation of children requires PALS and ACLS certification as well as separate education training and credentialing. The ASA recognizes the Center for Medicare and Medicaid Services (CMS) as defining those qualified to administer deep sedation. The Hospital Anesthesia Services Condition of Participation 42 CFR 482.52 (a) of 2010 [16] limits deep sedation to be delivered only by an anesthesiologist, nonanesthesiologist MD or DO, dentist, oral surgeon, podiatrist, CRNA, or Anesthesia Assistant (AA) [16, 17].

These CMS guidelines toward nonanesthesia providers of sedation were revised in January 2011 in the PUB 100–07 State Operations Provider Certification which revises Appendix A for various provisions of 42 CFR 482.52 concerning anesthesia services. These revisions were made in response to feedback from practitioners. Important changes in these guidelines stem from the CMS acknowledgement that the individual hospitals may establish their own policies and procedures with respect to the qualifications of analgesia providers and the clinical situations which distinguish anesthesia from analgesia. The policies must follow nationally recognized guidelines and can include guidelines of one or more specialty societies.

The ASA "Statement on the Safe Use of Propofol" first published in 2004 and amended in 2009, advises that "the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to rescue patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia [18]."

The distinction between sedation, deep sedation, and Monitored Anesthesia Care (MAC) is frequently misunderstood. To clarify these definitions, the ASA in 2009 amended the document entitled: Distinguishing "MAC" from Moderate Sedation/Analgesia (Conscious Sedation) to differentiate between the two levels of care. Important distinctions were that MAC entails an anesthesia assessment and the delivery of sedation by a provider who is prepared and qualified to assess and manage physiological or medical issues and to convert to a general anesthetic. In general, those who administer moderate sedation would not expect to progress to a condition in which the patient could not maintain his own airway [19].

## The Joint Commission: Where We Stand Now

Issues relating to sedation (in general) and pediatric sedation in specific are found in a variety of locations in the *The Joint Commission Handbook* and website (www.jointcommission.org). The JCAHO 2004 Comprehensive Accreditation Manual for Hospitals was intended to set the standards for sedation and anesthesia care for patients in any setting [20].

The Joint Commission recommendations are important when considering the credentialing and privileging of sedation providers. The Joint Commission requires that hospitals define the scope of practice for practitioners. It is important to distinguish the term "credentialing" from "privileging." "Credentialing" is the process whereby designated hospital appointees assure that physicians who work in the hospital have the appropriate education, training, and licensure to practice in the institution. "Privileging" specifically gives permission to hospital staff to provide care in various clinical settings or perform particular procedures in a given institution. With regard to sedation privileging, each healthcare facility is mandated by The Joint Commission to approve a plan to provide sedation and anesthesia care. Each institution must outline the criteria for determining which practitioners are qualified to provide the service.

It is important to recognize the evolution of the role of the Anesthesiology Department in the delivery of sedation as outlined by The Joint Commission. Earlier Joint Commission publications placed responsibility for sedation oversight on the Department of Anesthesiology and its Chairman [19]. Subsequent revisions of this document have revised the language: The Anesthesiology Department plays an important advisory role but is not directly responsible for sedation care, privileging, or quality assurance.

In the current 2007 Joint Commission manual, there are recommendations for the training that may be provided for other sedation providers: "Individuals administering moderate or deep sedation and anesthesia are qualified and have the appropriate credentials to manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally [21]." Referring specifically to deep sedation it states, "individuals must be qualified to rescue patients from general anesthesia and are competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation [21]." It goes on to specify "Each organization is free to define how it will determine that the individuals are able to perform the required types of rescue. Acceptable examples include, but are not limited to, ACLS certification, a satisfactory score on a written examination developed in concert with the department of anesthesiology, a mock rescue exercise evaluated by an anesthesiologist [21]."

Although the Joint Commission still believes that Anesthesiology Departments should play a role in the development of training and privileging programs for sedation, they no longer hold the central role of being "in charge" of sedation

services. Key roles in sedation oversight may be filled by qualified specialists of many different subspecialties.

## American College of Emergency Physicians Guidelines

The American College of Emergency Medicine (ACEP [7]) has put forward a wide range of statements, clinical practice advisories, and clinical policy statements concerning sedation. The 2008 ACEP Policy Compendium includes an important statement *Procedural Sedation in the Emergency Department* (www.acep.org/practres.aspx?id=29644). This statement begins with a strongly worded sentence: "Emergency physicians and nurses under their supervision are qualified to provide procedural sedation/analgesia in the emergency department, and ACEP is the authoritative body for the establishment of guidelines for procedural sedation and analgesia (PSA) by emergency physicians."

In 1998 and 2005 the ACEP produced *Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department* [7]. Similar to the ASA guidelines, the ACEP guidelines apply to all patients, adults, and children who receive sedation. They recognize that sedation is a continuum and maintain that practitioners should possess competence in cardiovascular resuscitation and airway management which should include a patient who has achieved general anesthesia. The ACEP considers these skills, including the administration of propofol and deep sedation, to be a fundamental part of the emergency medicine training curriculum and inclusive of the training required of all board-certified emergency physicians [7, 22].

The ACEP guidelines deviate from those of the AAP and ASA with respect to NPO guidelines. Both the AAP and ASA recommend fasting intervals for elective cases similar to those required for general anesthesia – specifically 2 h for clear liquids, 4 h for breast milk, 6 h for formula, and 8 h for full meals. These guidelines do not make recommendations for the non-elective sedation case. The ASA and ACEP differ in their consideration of NPO status in emergent situations. The ASA guidelines state "Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure. In urgent, emergent, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed, or (3) whether the trachea should be protected by intubation." The AAP guidelines are a bit less specific stating only "for emergency procedures the risks of sedation and the possibility of aspiration must be weighed against the benefits of performing the procedure promptly."

By the very nature of their work, emergency medicine sedation providers must cope with patients who do not meet approprite NPO criteria and are not having "elective" procedures. In the last 10 years, there have been several studies in the emergency medicine literature that have reported very low rates of aspiration or pulmonary complications in patients who were sedated without meeting the NPO recommendations from the AAP or ASA [23, 24]. Previous publications from the ACEP have concluded that there is insufficient evidence to conclude that fasting actually changes outcome for sedation (see above) [25].

In 2006, the ACEP produced a document on fasting prior to sedation [26]. This clinical practice advisory is titled "Fasting and Emergency Department Procedural Sedation and Analgesia: A Consensus-Based Clinical Practice Advisory." The paper begins with an extensive review of the guidelines that have been set forth by the ACEP, AAP, and ASA concerning NPO status, and considers them in the context of the Emergency Department setting. This consensus-based clinical advisory concludes that there is actually scarce literature to document the perceived risk that various NPO times pose with respect to sedation complications. The authors suggest that the issue of NPO interval needs to be considered in the context of the urgency and duration of the procedure as well as the risk stratefication of the patient, nature of food intake, and depth/type of sedation targeted. The result is a somewhat complex strategy

**Standard-risk patient**[a]

| Oral intake in the prior 3 hours | Procedural Urgency[b] | | | |
|---|---|---|---|---|
| | *Emergent Procedure* | *Urgent Procedure* | *Semi-Urgent* | *Non-Urgent* |
| *Nothing* | All levels of sedation | All levels of sedation | All levels of sedation | All levels of sedation |
| *Clear liquids only* | All levels of sedation | All levels of sedation | Up to and including brief deep sedation | Up to and including extended moderate sedation |
| *Light snack* | All levels of sedation | Up to and including brief deep sedation | Up to and including dissociative sedation; non-extended moderate sedation | Minimal sedation only |
| *Heavier snack or meal* | All levels of sedation | Up to and including extended moderate sedation | Minimal sedation only | Minimal sedation only |

**Higher-risk patient**[a]

| Oral intake in the prior 3 hours | Procedural Urgency[b] | | | |
|---|---|---|---|---|
| | *Emergent Procedure* | *Urgent Procedure* | *Semi-Urgent* | *Non-Urgent* |
| *Nothing* | All levels of sedation | All levels of sedation | All levels of sedation | All levels of sedation |
| *Clear liquids only* | All levels of sedation | Up to and including brief deep sedation | Up to and including extended moderate sedation | Minimal sedation only |
| *Light snack* | All levels of sedation | Up to and including dissociative sedation; non-extended moderate sedation | Minimal sedation only | Minimal sedation only |
| *Heavier snack or meal* | All levels of sedation | Up to and including dissociative sedation; non-extended moderate sedation | Minimal sedation only | Minimal sedation only |

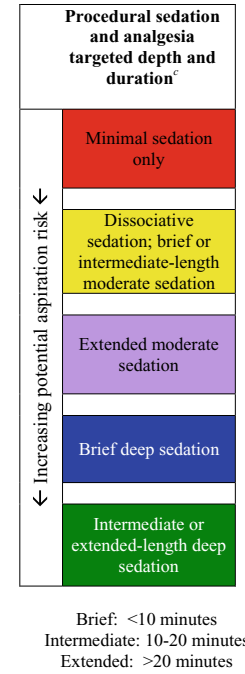


**Figure.** Prudent limits of targeted depth and length of ED procedural sedation and analgesia according to presedation assessment of aspiration risk

**Fig. 3.1** ACEP NPO considerations and aspiration risk. (Adapted from Green et al. [26], Reprinted with permission from Elsevier)

that weighs NPO time vs. Emergent/Urgent/Semiurgent nature of the case vs. duration of the procedure. Figure 3.1 schematically describes the recommendations that result from these guidelines [26]. Important however, is their guidelines for non-elective sedation of patients who are not considered NPO by ASA or AAP standards. The guidelines state that although "recent food intake is not a contraindication for administering Procedural Sedation and Analgesia (PSA), the emergency physician must weigh the risk of pulmonary aspiration and the benefits of providing PSA in accordance with the needs of each individual patient [7]." The NPO recommendations state that "recent food intake is not a contraindication for administering PSA, but should be considered in choosing the timing and target level of sedation [7, 26]."

In 2004 and 2008, the ACEP published evidence-based guidelines on the use of specific medications for use in pediatric sedation: *Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department*; [5] and *Clinical policy: Critical issues in the sedation of pediatric patients in the emergency department* [25]. The "Critical Issues" statement supported earlier recommendations on NPO status and reviewed the use of sedatives which included nitrous oxide, chloral hydrate, and sucrose. Important statements include "Procedural sedation may be safely administered to pediatric patients in the ED who have had recent oral intake [25]."

Other ACEP publications include a clinical practice advisory on Propofol use in the Emergency Department [22], and a clinical practice guideline on ketamine use in the Emergency Department [6]. Both of these documents support the use of these drugs for sedation in the Emergency Department, expanding on the evidence-based guideline recommendations from the Clinical Policy on pharmacological agents mentioned above [5]. The ACEP recommendations

for physiological monitoring deviate from the ASA and AAP with respect to pulse oximetry application: Pulse oximetry is not mandatory. The guidelines advise that pulse oximetry may not be necessary when the patient's level of consciousness is minimally depressed and verbal communication can be continually monitored. Pulse oximetry is recommended, however, when there is an increased risk of developing hypoxemia, such as when high doses of drugs or multiple drugs are used, or when treating patients with significant comorbidity. Capnography, although not required, is acknowledged by ACEP to be a monitor which may allow more rapid identification of hypoventilation than pulse oximetry alone [27].

## American Dental Association Sedation Guidelines

The American Dental Association (ADA) guidelines regarding sedation are posted on their website at www.ada.org/sections/professionalResources/pdfs/anesthesia_guidelines.pdf. The guidelines acknowledge the depths of sedation consistent with that described by the AAP and the ASA. It contains descriptions of routes of administration for sedative medications, ASA classification for sedation patients, and monitoring guidelines for sedated patients. There is a very specific outline of the training required for dentists regarding various levels of sedation, including specific educational programs and life support training. In this regard the guidelines are more detailed than those provided by other organizations. Deep sedation requires the presence of a minimum of three individuals: one dentist who is credentialed to administer deep sedation or anesthesia and two additional personnel who have current certification of successfully completing a BLS Course for the Healthcare Provider. There are two requirements to qualify for deep sedation certification: Completion of an advanced education program on the administration and management of deep sedation or anesthesia, which must be accredited by the ADA Commission on Dental Accreditation, and a current certification in both BLS for Healthcare Providers and Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course. The dentist administering deep sedation or general anesthesia must remain within the facility until the patient meets discharge criteria (or is discharged) and must monitor the patient continuously until the patient meets the criteria for recovery. Those who provide pediatric sedation must have Pediatric Advanced Life Support (PALS) in addition to directed pediatric training and education [28, 29].

The guidelines are presented in sections, each of which iterates a sedation level: Minimal, Moderate, and Deep Sedation sections. Specific recommendations are given for training of sedation providers, preoperative preparation of patients, monitoring and documentation, recover and discharge criteria, and personnel/equipment requirements. The document is intended for adults and for children 12 years of age and below. The ADA refers to the AAP/AAPD *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* and *Use of Deep Sedation and General Anesthesia in the Pediatric Dental Office* [3, 30]. These guidelines address some issues unique to the office-based dental practice and to the special needs child. If the dental patient undergoing deep sedation or general anesthesia is mentally and/or physically challenged, it may not be possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. In these situations, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative assessment prior to administering sedation [3]. Nitrous oxide is a recognized and acceptable sedative, alone or in combination with other sedatives [3].

## American Society of Gastroenterologists

The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy has recently published guidelines for deep sedation, the administration of propofol by nonanesthesiologists and pediatric sedation for

gastrointestinal procedures and endoscopy [31]. All of these guidelines were written after a review of the MEDLINE and PubMed database. The recommendations are rated "A," "B," or "C" based on the weight of the evidence available. A level identifies statements supported by prospective randomized trials and C level identifies expert opinion in the absence of peer-reviewed evidence. The chronological history leading up to these 2009 guidelines will be detailed below [31, 32].

The first guideline was published in 2002 and entitled *Guidelines for the Use of Deep Sedation and Anesthesia for GI Endoscopy* [32]. This guideline reviews the levels of sedation and the importance of presedation assessment in order to customize sedation for the needs of the patient. Planning is identified as particularly important for those with specific emotional issues, drug use history, and those who are undergoing extensive procedures. There are no specific references to, or recommendations for, the pediatric population.

Pharmacologic agents are reviewed and include guidelines for the indications and use of droperidol (in addition to midazolam and fentanyl). This guideline is unique in its recommendation for droperidol as a third drug if needed. There is an accompanying warning about cardiac issues related to droperidol and the need for extended ECG monitoring when it is utilized.

The majority of this guideline is devoted to the role of propofol and the relative risks vs. benefits of its use in endoscopy. Personnel preparation and monitoring requirements for propofol sedation are carefully delineated [32]:

1. At least one person who is qualified in both basic and advanced life support skills (i.e., tracheal intubation, defibrillation, use of resuscitation medications).
2. Physiologic monitoring should include pulse oximetry, electrocardiography, and automated blood pressure measurement. Monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.
3. Equipment for airway management and resuscitation.
4. Trained personnel dedicated to the continuous and uninterrupted monitoring of the patient's physiologic parameters and administration of propofol.
5. Extended monitoring with capnography should be considered as it may decrease the risks during deep sedation.

Published in 2002, this guideline concludes that although propofol does not appear to offer a significant advantage over standard benzodiazepine/opiate techniques for routine endoscopy procedure, it does confer significant advantages for longer and more complicated procedures (Level "A" recommendation). The authors also discuss the provision of propofol sedation by nonanesthesiologists including other physicians and registered nurses. Anesthesiology assistance is recommended for specific situations including prolonged or therapeutic endoscopic procedure requiring deep sedation, anticipated intolerance to standard sedatives, increased risk for complication because of severe comorbidity (ASA class III or greater), and increased risk for airway obstruction because of anatomic variant. These final recommendations are included at a "C" level.

A second publication entitled *Guidelines for Conscious Sedation and Monitoring During Gastrointestinal Endoscopy* was published in 2003 in the journal Gastrointestinal Endoscopy [33]. They refer to "conscious sedation" as a level of equivalence to "moderate sedation." These guidelines review the data on endoscopy-related complications – noting that over 50% of complications are related to cardiopulmonary side effects with the majority relating to aspiration, oversedation, hypoventilation, vasovagal episodes, and airway obstruction. They note that the risk of cardiovascular complications is dependent on the patient's underlying medical condition and the procedure to be performed – The combination of high-risk patients and high-risk procedures represent the highest risk.

These guidelines support the monitoring recommendations of the ASA and AAP: Required monitoring during sedation for endoscopy includes recording of the heart rate, blood pressure, respiratory rate, and oxygen saturation. Capnography is advised for prolonged cases but not required.

Several drugs are mentioned for conscious sedation during endoscopy. Benzodiazepines and opiates (along with reversal agents) are mentioned in detail along with droperidol and promethazine. Unique to this set of guidelines, "pharyngeal" anesthesia is reviewed. Specific mention is made of the risk of methemoglobinemia with benzocaine administration. In reference to deep sedation, the authors suggest that propofol is superior to standard benzodiazepine/opiate sedation for complex procedures and acknowledge that its use in routine upper and lower endoscopic procedures is controversial with little proven benefit over standard moderate sedation [33].

The most recent and pertinent publication regarding sedation specifically for pediatric endoscopy was published in 2008 as *Modifications in Endoscopic Practice for Pediatric Patients* [34]. This document addresses many issues relating to sedation in children and for pediatric endoscopy. For example, the authors review indications and contraindications for endoscopy in children, the appropriateness of pediatric vs. adult endoscopists for various procedures in children, and the appropriate preparation of patients for these studies. They include discussions of the proper equipment to use for pediatric endoscopy and the indications for antibiotic prophylaxis.

Important cautions are that airway obstruction is more common in children and because of higher oxygen consumption, it can lead to the rapid onset of hypoxia in the face of apnea (and therefore recommend the routine use of oxygen during endoscopic sedation in this age group). The authors note that general anesthesia is often used for pediatric endoscopy and that the number of centers using propofol sedation or general anesthesia for endoscopy appears to be increasing [34, 35]. One study from 1995 cites equivalent safety and efficacy when using a standardized procedural sedation protocol (opiate plus benzodiazepine) when compared to general (potent inhalation) anesthesia [36]. The authors also note that when propofol sedation is compared to "general anesthesia," it has been found to result in less total time for sedation/anesthesia and equal safety [37].

In 2009, the American Society of Gastroenterologists published their position statement for nonanesthesiologist administration of propofol for GI endoscopy [31]. The guidelines state that clinically important benefits of propofol in average-risk patients undergoing upper endoscopy and colonoscopy have not been consistently demonstrated with regard to patient satisfaction and safety. It supports that propofol can be safely and effectively given by nonanesthesiologist physicians and nurses provided they have undergone appropriate training and credentialing in administration and rescue from potential pulmonary and cardiovascular complications. The summary section makes specific recommendations for sedation for pediatric endoscopy. They generally follow AAP and ASA standards [31]:

1. All pediatric patients should receive routine oxygen administration and should be monitored with a minimum of pulse oximetry and heart rate monitoring.
2. In deeply sedated patients one individual having no other responsibilities should be assigned to monitor the patient's cardiac and respiratory status and to record vital signs.
3. The presence of personnel trained specifically in pediatric life support and airway management during procedures requiring sedation is strongly recommended.

## The Debate: Granting Privileges for Sedation to Non-Anesthesiologists

An ongoing area of debate revolves around the credentialing and privileging of non-anesthesiologists to administer sedation. In October 2010, the ASA issued a Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners [15]. The ASA Statement recommends that non-anesthesiologists be proficient in advanced airway management for rescue when they deliver deep sedation. This proficiency and competency would be determined by the Director of Anesthesia Services of the facility in which the sedation is delivered [15]. In addition, the ASA specified that performance evaluation and a performance improvement program would be required for privileging- both of which would be developed

with and reviewed by the Director of Anesthesia Services [15].

In response to the above ASA Statement, in July 2011 the American College of Emergency Physicians released a policy statement entitled Procedural Sedation and Analgesia in the Emergency Department (ED): Recommendations for Physician Credentialing, Privileging, and Practice [38]. This Policy iterated that the chief of the emergency medicine service at each institution will be responsible for establishing criteria for credentialing and recommending emergency physicians for sedation privileges. Sedation training should "focus on the unique ED environment". Furthermore, the capability of qualified ED nurses to administer propofol, ketamine, and other sedatives under the direct supervision of a privileged emergency physician is condoned. The Policy acknowledges that deep sedation may be accomplished with the ED physician both administering sedation and performing the procedure.

The training, credentialing and privileging process and requirements for non-anesthesia specialists will likely remain an area of ongoing debate. Regardless, the introduction and implementation of structured sedation training, regardless of the specialty which initiates and is responsible for the training program, will only serve to benefit the practice and delivery of sedation.

## International Guidelines

A wide variety of sedation guidelines specific to pediatrics or with application to pediatrics have been published by various specialty societies and international organizations. Some are largely consistent with the recommendations of the AAP, others are not. It is not possible to review and highlight all of the similarities and differences between the existing sedation guidelines worldwide. Chapters 14, 17, and 18 detail the most recent sedation guidelines published by the National Institute of Health (NICE) in the United Kingdom (2011) [39], the Dutch Institute of Healthcare Improvement in the Netherlands (2011) [40], the Endoscopy Section of the German Society for Digestive and Metabolic Diseases (2009) [41], and the adult and pediatric guidelines of the South African Society of Anesthesiologists (2010 and 2011) [42, 43]. A sample of sedation statements and guidelines published worldwide include the following:

1. Scottish Intercollegiate Guidelines Network [44].
2. Australasian College for Emergency Medicine, Australian and New Zealand College of Anaesthetists [45].
3. Canadian Consensus Guidelines. Canadian Association of Emergency Physicians [46].
4. British Society of Gastroenterology [47].
5. Standing Dental Advisory Committee – UK [48].
6. NeuroAnesthsia and Neruointensive Study Group of the Italian Society of Anesthesia [49].
7. Standing Dental Advisory Committee, Department of Health – UK. *Conscious Sedation in the Provision of Dental Care. Report of an Expert Group on Sedation for Dentistry 2003*. Available at: www.dh.gov.uk/PublicationsandstatisticsPublications. Accessed 2 Jan 2008.
8. The Working Group on Endoscopy, Austrian Society of Gastroenterology and Hepatology [50].
9. South African Society of Anaesthesiologists (SASA) Sedation Guidelines [43].
10. South African Society of Anaesthesiologists (SASA) Paediatric Procedural Sedation and Analgesia (PSA) Guidelines [42].
11. National Institute for Health and Clinical Excellence. Sedation for diagnostic and therapeutic procedures in children and young people (Clinical guideline 112) 2010 [39] (http://guidance.nice.org.uk/cg112).
12. Sedation Guidelines for Gastrointestinal Endoscopy 2008 of German Society for Digestive and Metabolic Diseases [41].
13. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anesthesiology Guideline: Non-Anesthesiologist Administration of Propofol for G1 Endoscopy [51].
14. Dutch Institute for Healthcare Improvement (CBO), Pediatric Guidelines for Sedation

and/or Analgesia (PSA) at Locations Outside the Operating Theatre from the Netherlands Society of Anesthesiologists and the Dutch Society of Pediatrics [40].

Even within Europe, there is a lack of consensus and agreement between the guidelines, particularly with respect to pediatrics, deep sedation, and propofol. One example of this is the sedation guidelines of Scotland. The Scottish National Guidelines of 2004 were written only for minimal and moderate sedation, as anything beyond (deep sedation included) requires an anesthesiologist and is treated as a general anesthetic [44]. Propofol is limited to anesthesiologist administration only. Scotland offers a unique acknowledgement on the role of the child and parent in the sedation process. In 1995, the Child Scotland Act specified that an informed consent be obtained from the child when appropriate. The presence of the parents is recommended during the sedation, in hopes of providing emotional support [52].

## Summary

The practice of sedation for children has advanced considerably over the last 40 years. Sedation guidelines have evolved, with new editions, updates, and addendums in order to reflect the change in practice and the published literature. As outlined in this chapter, there are a large number of guidelines that address pediatric sedation. There is a general lack of consensus on NPO status for sedation and on whether nonanesthesiologists should administer deep sedation or propofol. In general, however, all of the guidelines are congruent with regard to the need for patient assessment and preparation and for appropriate competency-based training and credentialing for sedation providers. Future efforts should be aimed at designing clinical studies with defined endpoints and outcomes. Worldwide participation in these studies, involving all specialties, will establish safety data which could direct the creation of more unified sedation guidelines. Particularly with children, unified recommendations from the AAP, ASA, AAPD, ADA, The Joint Commission, ACEP, and American Society of Gastroenterologist together with a consensus among the different specialties worldwide, would offer a landmark first step in the advancement of pediatric sedation.

## References


1. Committee on Drugs, American Academy of Pediatrics. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatrics. 1985;76:317–21.
2. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. Pediatrics. 1992;89(6 Pt 1):1110–5.
3. Cote CJ, Wilson S. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. Pediatrics. 2006;118(6):2587–602.
4. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology. 2002;96(4):1004–17.
5. Mace SE, Barata IA, Cravero JP, et al. Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. Ann Emerg Med. 2004;44(4):342–77.
6. Green SM, Krauss B. Clinical practice guideline for emergency department ketamine dissociative sedation in children. Ann Emerg Med. 2004;44(5):460–71.
7. Godwin SA, Caro DA, Wolf SJ, et al. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005;45(2):177–96.
8. Zempsky WT, Cravero JP. Relief of pain and anxiety in pediatric patients in emergency medical systems. Pediatrics. 2004;114(5):1348–56.
9. Committee on Fetus and Newborn, Committee on Drugs, Section on Anesthesiology, Section on Surgery, Canadian Paediatric Society, Fetus and Newborn Committee. Prevention and management of pain in the Neonate: an update. Pediatrics. 2006;118:2231–41.
10. Committee on Psycosocial Aspects of Child and Family Health. The assessment and management of acute pain in infants, children, and adolescents. Pediatrics. 2001;108:793–7.
11. Committee on Drugs, American Academy of Pediatrics. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: addendum. Pediatrics. 2002;110(4):836–8.
12. Practice guidelines for sedation and analgesia by non-anesthesiologists. A report by the American Society of Anesthesiologists Task Force on Sedation and

Analgesia by Non-Anesthesiologists. Anesthesiology. 1996;84(2):459–71.
13. Standards for Basic Anesthetic Monitoring. Committee of Origin: Standards and Practice Parameters (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010 with an effective date of July 1, 2011) http://www.asahq.org/For-Healthcare-Professionals/Standards-Guidelines-and-Statements.aspx.
14. Green SM, Krauss B. Replacing the outmoded term "nonanesthesiologist". Anesth Analg. 2005;100:1862.
15. Granting privileges for deep sedation to non-anesthesiologist sedation practitioners. (Approved by the ASA House of Delegates on 20 October 2010). http://www.asahq.org/publicationsAndServices/sgstoc.htm.
16. Department of Health & Human Services. Centers for Medicare & Medicaid Services. Revised hospital anesthesia services interpretive guidelines – state operations manual (SOM) Appendix A Ref: S&C-10-09-Hospital. Revised 2 May 2010. https://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter10_09.pdf. Accessed 14 Feb 2011.
17. Department of Health & Human Services. Centers for Medicare & Medicaid Services. CMS Manual System. Pub. 100–07 State Operations Provider Certification. Transmittal 59. Clarification of the interpretive guidelines for the anesthesia services condition of participation. 21 May 2010. https://www.cms.gov/transmittals/downloads/R59SOMA.pdf. Accessed 20 Jan 2011.
18. Statement on Safe Use of Propofol. (Approved by the ASA House of Delegates on 27 October 2004, and amended on 21 October 2009). http://www.asahq.org/publicationsAndServices/sgstoc.htm.
19. Distinguishing Monitored Anesthesia Care ("MAC") From Moderate Sedation/Analgesia (Conscious Sedation). (Approved by the ASA House of Delegates on October 27, 2004 and last amended on 21 October 2009) http://www.asahq.org/publicationsAndServices/sgstoc.htm.
20. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Comprehensive accreditation manual for hospitals: the official handbook. Oakbrook Terrace, IL: JCAHO; 2004.
21. Joint Commission for Accreditation of Hospitals (JCAHO). Operative or other high-risk procedures and/or the administration of moderate or deep sedation or anesthesia. The Comprehensive accreditation manual for Hospitals: official handbook. Oakbrook Terrace, IL: JCAHO; 2007. p. PC-41.
22. Miner JR, Burton JH. Clinical practice advisory: emergency department procedural sedation with propofol. Ann Emerg Med. 2007;50(2):182–7, 187.e1.
23. Roback MG, Bajaj L, Wathen JE, Bothner J. Preprocedural fasting and adverse events in procedural sedation and analgesia in a pediatric emergency department: are they related? Ann Emerg Med. 2004;44(5):454–9.
24. Agrawal D, Manzi SF, Gupta R, Krauss B. Preprocedural fasting state and adverse events in children undergoing procedural sedation and analgesia in a pediatric emergency department. Ann Emerg Med. 2003;42(5):636–46.
25. Mace SE, Brown LA, Francis L, et al. Clinical policy: critical issues in the sedation of pediatric patients in the emergency department. Ann Emerg Med. 2008;51(4):378–399, 399 e1–57.
26. Green SM, Roback MG, Miner JR, Burton JH, Krauss B. Fasting and emergency department procedural sedation and analgesia: a consensus-based clinical practice advisory. Ann Emerg Med. 2007;49(4):454–61.
27. Miner JR, Heegaard W, Plummer D. End-tidal carbon dioxide monitoring during procedural sedation. Acad Emerg Med. 2002;9(4):275–80.
28. Guidelines for the use of sedation and general anesthesia by dentists: as adopted by the October 2007 ADA House of Delegates. The American Dental Association. http://www.ada.org/sections/about/pdfs/anesthesia_guidelines.pdf. Accessed 2010.
29. Guidelines for teaching pain control and sedation to dentists and dental students: as adopted by the October 2007 ADA House of Delegates. The American Dental Association. http://www.ada.org/sections/professionalResources/pdfs/anxiety_guidelines.pdf. Accessed 2010.
30. Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures. American Academy of Pediatrics and the American Academy of Pediatric Dentistry. http://www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf. Accessed 2011.
31. Vargo JJ, Cohen LB, Rex DK, Kwo PY. Position statement: nonanesthesiologist administration of propofol for GI endoscopy. Hepatology. 2009;50(6):1683–9.
32. Faigel DO, Baron TH, Goldstein JL, et al. Guidelines for the use of deep sedation and anesthesia for GI endoscopy. Gastrointest Endosc. 2002;56(5):613–7.
33. Waring JP, Baron TH, Hirota WK, et al. Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy. Gastrointest Endosc. 2003;58(3):317–22.
34. Lee KK, Anderson MA, Baron TH, et al. Modifications in endoscopic practice for pediatric patients. Gastrointest Endosc. 2008;67(1):1–9.
35. Koh JL, Black DD, Leatherman IK, Harrison RD, Schmitz ML. Experience with an anesthesiologist interventional model for endoscopy in a pediatric hospital. J Pediatr Gastroenterol Nutr. 2001;33(3):314–8.
36. Squires Jr RH, Morriss F, Schluterman S, Drews B, Galyen L, Brown KO. Efficacy, safety, and cost of intravenous sedation versus general anesthesia in children undergoing endoscopic procedures. Gastrointest Endosc. 1995;41(2):99–104.
37. Kaddu R, Bhattacharya D, Metriyakool K, Thomas R, Tolia V. Propofol compared with general anesthesia for pediatric GI endoscopy: is propofol better? Gastrointest Endosc. 2002;55(1):27–32.
38. O'Connor RE, Sama A, Burton JH, et al. Procedural Sedation and Analgesia in the Emergency Department: Recommendations for Physician Credentialing, Privileging, and Practice. Ann Emerg Med. 2011.

39. Sury M, Bullock I, Rabar S, Demott K. Sedation for diagnostic and therapeutic procedures in children and young people: summary of NICE guidance. BMJ. 2010;341:c6819.
40. Summary of draft guidelines on sedation and/or analgesia (PSA) at Locations Outside the Operating Theatre. Part III: In Children. initiators: Netherlands Society of Anesthesiologists and Dutch Society of Pediatrics. Utrecht: Dutch Institute for Healthcare Improvement (Central Accompaniment Organization (CBO)); 2011.
41. Riphaus A, Wehrmann T, Weber B, et al. S3 Guideline: sedation for gastrointestinal endoscopy 2008. Endoscopy. 2009;41(9):787–815.
42. Reed A, Thomas J, Roelofse JA, Gray R, de Kock M, Piercy J. Paediatric procedural sedation and analgesia (PSA) guidelines. Cramerview: South African Society of Anaesthesiologists; 2011.
43. South African Society of Anaesthesiologists. SASA Sedation Guidelines 2010. S Afr J Anaesthesiol Analg. 2010;161(2).
44. Scottish Intercollegiate Guidelines Network. SIGN Guideline 58: safe sedation of children undergoing diagnostic and therapeutic procedures. Paediatr Anaesth. 2008;18(1):11–2.
45. Australasian College for Emergency Medicine, Australian and New Zealand College of Anaesthetists; Faculty of Pain Medicine and Joint Faculty of Intensive Care Medicine. Statement on clinical principles for procedural sedation. Emerg Med (Fremantle). 2003;15(2):205–6.
46. Innes G, Murphy M, Nijssen-Jordan C, Ducharme J, Drummond A. Procedural sedation and analgesia in the emergency department. Canadian Consensus Guidelines. J Emerg Med. 1999;17(1):145–56.
47. Bell GD, McCloy RF, Charlton JE, et al. Recommendations for standards of sedation and patient monitoring during gastrointestinal endoscopy. Gut. 1991;32(7):823–7.
48. Standing Dental Advisory Committee. Conscious sedation in the provision of dental care: new guidelines. SAAD Dig. Spring 2004;21(1):20–2.
49. Levati A, Paccagnella F, Pietrini D, et al. SIAARTI-SARNePI guidelines for sedation in pediatric neuroradiology. Minerva Anestesiol. 2004;70(10):675–97; 698–715.
50. Schreiber F. Austrian Society of Gastroenterology and Hepatology (OGGH) – guidelines on sedation and monitoring during gastrointestinal endoscopy. Endoscopy. 2007;39(3):259–62.
51. Dumonceau JM, Riphaus A, Aparicio JR, et al. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anaesthesiology Guideline: non-anesthesiologist administration of propofol for GI endoscopy. Endoscopy. 2010;42(11):960–74.
52. SIGN. Safe sedation of children undergoing diagnostic and therapeutic procedures. A national clinical guideline. Edinburgh: Scottish Intercollegiate Guidelines Network; 2004.