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

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## Introduction

The practice of pediatric sedation involves a wide variety of pediatric surgical and medical sub-specialists. There are no "universally" applicable and acceptable guidelines that apply to all the physicians and nurses who are take part in sedating children for procedures. A number of guidelines, policies, and recommendations for sedation care have been promulgated by different subspecialty societies over the last 40 years. This chapter will consider development of these guidelines and put them into context and perspective.

There are several forms of guidelines – those that come in the form of "statements," "practice advisories," "clinical policies," clinical practice guidelines," or "recommendations." These documents range from those that contain general descriptions of appropriate monitoring and treatment to those that offer very specific guidelines on the use of particular drugs or pre-sedation nil per os (NPO) intervals. There is variability in the recommendations that pediatric subspecialty societies make concerning the specifics of sedation care, but the most important elements are remarkably similar. It should also be noted that the methodologies used to produce these guidelines vary from organization to organization. For example, in the American Academy of Pediatrics (AAP), guidelines are put together by a workgroup on sedation from the Committee on Drugs [1–3].While these guidelines are based on a careful consideration of the available literature and review by a number of experts in pediatric specialties, the exact nature of how studies were "weighted" and conclusions are drawn is not explicitly described. On the other hand, the most recent guidelines from the British National Institute for Healthcare and Clinical Excellence (see International Guidelines section), American Society of Anesthesiologists [3] (ASA), and American College of Emergency Physicians (ACEP) [4] are founded on a structured, evidence-based, review of pediatric sedation literature, and the methodologies are explicit. Even in publications such as this, the absence of high-quality controlled trials in pediatric sedation necessitates that many of the most important aspects of these guidelines are based on "consensus" (or some interpretation of the data) rather than strictly on the evidence. This chapter will review a number of sedation guidelines from organizations centered in the United States and internationally. Some are published in peer-reviewed literature, and some are available on society websites. As the comparison of guidelines can be quite subtle, and the acronyms for various organizations are incredibly confusing, the various guidelines in this chapter will be organized by their sponsoring organization.

## American Academy of Pediatrics (AAP) Guidelines

"The AAP *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures*" are the most widely cited, and applied, guidelines with respect to pediatric sedation. While other statements from the AAP have expanded on the importance of the use of sedation and analgesia for children [5–7], the sedation guidelines specifically address the clinical provision of sedation for children. They have influenced the creation of safe sedation systems across the USA and internationally. Much of their lexicon and recommendations have been largely adopted by The Joint Commission (TJC) and by regulatory bodies in Europe and Australasia 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) [8] on behalf of the American Academy of Pediatrics (AAP) Section on Anesthesiology. Written in collaboration with the American Academy of Pediatric Dentistry (AAPD) and the

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American Society of Anesthesiologists (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 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 [1]. This 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 [9] ending the use of the term "conscious sedation" (described above) and clarifying the fact that these guidelines apply to any location where children are sedated – in or out of the hospital. These guidelines use the terminology of "minimal sedation, moderate sedation, deep sedation, and anesthesia." These levels have been adopted by the ASA, The Joint Commission, and various international organizations. The addendum emphasized that sedatives should only be administered by those skilled in airway management and cardiopulmonary resuscitation [9].

A subsequent iteration of the AAP sedation guidelines was published in December 2006 [10]. 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 idea 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 [10]:

(i) There must be one person available whose sole responsibility is to constantly observe the patients vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration.
(ii) 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 freestanding clinic or office.

The authors included a section on drug interactions and cautions on alternative medications such at St. John's wort, Kava, and *Echinacea* and their possible impact on coagulation and sedation provision.

This version of the AAP guidelines distinguished monitoring requirements based on the depth of sedation as well as the setting. Pulse oximetry, heart rate, and intermittent blood pressure were recommended during moderate sedation. For deep sedation, "precordial stethoscope or capnography was advised 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 maintain the suggestion (from previous versions) that predicting the exact depth of sedation (other than minimal sedation) that will result from the administration of a sedative drug is not possible. In light of this fact, the authors make recommendations on fasting (NPO) durations prior to sedation (Table 2.1) which assume airway protective reflexes could be lost at any time during a moderate or deep sedation and therefore should mimic those that are applied to general anesthesia.

Recovery criteria and considerations are also enumerated in these guidelines, including a suggestion for the use of 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).

The next version of the guidelines *AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016* expanded on the previous versions of these guidelines [2]. The concepts outlined in previous iterations were continued in this version. The authors continue to stress the fact that, since the level of sedation may vary over time, providers of sedation must be able to

rescue patients from a level of sedation that is at least one level deeper than the intended level. So, if the sedation providers intend to deliver deep sedation, they must have the skills required to rescue a patient from general anesthesia. "They must have the ability to recognize the various levels of sedation and have the skills and age and size-appropriate equipment necessary to provide appropriate cardiopulmonary support if needed" [2]. This guideline goes on to be very specific about the competencies required to rescue a child with apnea, laryngospasm, and/or airway obstruction – including the ability to open the airway, suction, perform bag-mask ventilation, insert an oral airway, nasopharyngeal airway, and laryngeal mask airway, and perform endotracheal intubation. This version of the guidelines is more specific in advising that these competencies are best maintained by frequent simulation and team training for rare events. In addition to these skills, the guidelines advise that (for non-hospital facilities) a protocol for the immediate activation of the EMS system for life-threatening complications must be established and maintained.

New to this version of the guidelines is a clear outline of the monitoring and oversight requirements for moderate vs. deep sedation (Table 2.2), which is helpful since the differences are subtle. It is notable that capnography is recom-

**Table 2.1** NPO guidelines

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

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**Table 2.2** Requirements for moderate versus deep sedation

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

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mended for moderate sedation and required for deep sedation. The guidelines end with a very thorough review of local anesthetics and their pharmacology and recommendations for treatment of local anesthetic toxicity with intralipid.

The most recent iteration of the AAP sedation guidelines was published in 2019 [3]. Once again, most of the content is carried over from the previous guidelines – particularly those from 2016. Notably, although the authors recognize that the incidence of aspiration is likely different for sedation activity vs. anesthesia, these guidelines continue the admonition that the NPO intervals for sedation should mimic those of anesthesia since the actual incidence of aspiration is not known for procedural sedation. For emergency procedures, the guidelines advise that the need for the procedure must be weighed against the possible risk imposed by the lack of fasting [3].

In this version of the AAP/AAPD guidelines, there is a recommendation that during deep sedation/general anesthesia for a patient in a dental facility, there must be at least two individuals present with the patient throughout the procedure. Furthermore, the guideline requires both of these individuals to have appropriate training and up-to-date certification in patient rescue. This training should include Pediatric Advanced Life Support (PALS) or Advanced Pediatric Life Support (APLS). The recommendation is that one of the two must be an independent observer who is not performing or assisting with the procedure – this position can be filled by a physician anesthesiologist, certified registered nurse anesthetist, a second oral surgeon, or a dentist anesthesiologist. Similar recommendations are made for delivery of deep sedation/anesthesia in a hospital or surgicenter setting.

## 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 or referenced in many of the sedation-related publications it has produced. Perhaps the most pertinent of these documents is the recent "Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018" [11] which replaced the previous guidelines titled "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: An Updated Report by the American Society of Anesthesiologists (ASA) Task Force on Sedation and Analgesia by Non-Anesthesiologists" [12]. These guidelines were developed by a multispecialty group of authors including representation from the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dental Anesthesiologists, and the Society of Interventional Radiology. These recommendations are specifically meant to apply to moderate sedation, which is defined (like the AAP guidelines) as a state in which the patient is experiencing a depression of consciousness but is purposefully responsive to voice or light touch, and airway patency should not be impaired. The authors describe a rigorous and systematic review of the literature for these guidelines. Their findings are graded based on the quality of the evidence available to base the recommendations on. Each section of the document also includes a survey of experts in the field intended to augment the conclusions in areas where the published evidence was insufficient to support firm conclusions. These guidelines cover several aspects of sedation – including the pre-sedation assessment, monitoring standards (including capnography to supplement standard monitoring of pulse oximetry), personnel requirements (trained observer), a review of medications for sedation, recovery criteria, and required QA/QI processes. While they do not address issues specifically related to children, there is a clear indication, from the inclusion criteria and the searches described, that they are intended to apply to children as well as adults. There is an extensive section on various drug combinations that may be used for moderate sedation. The authors very specifically point out the use of dexmedetomidine and its potential to be substituted for a benzodiazepine when providing moderate sedation. They also take pains to advise careful titration of medications for sedation with the requirement for knowledge of pharmacokinetics in order to avoid stacking of doses and excessive sedation. It is a bit difficult to follow some of the discussion regarding medications since they involve combinations such as propofol and remifentanil, as well as ketamine (and combinations of sedatives with ketamine) – none of which would seem to apply very well to a set of guidelines addressing only "moderate sedation." In spite of this somewhat incongruous section, the guidelines are clearly written and align with the AAP recommendations in most dimensions.

The ASA has many other statements that relate to sedation – they are published on their website at https://www.asahq.org/standards-and-guidelines. The statements that pertain to sedation include *Distinguishing Monitored Anesthesia Care from Moderate Sedation Analgesia*, *Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners*, *Statement on Granting Privileges to Non-anesthesiologist Physicians Supervising Deep Sedation*, and the *Statement on the Safe Use of Propofol*. The ASA also has produced a number of Expert Consensus Documents; the purpose of these is to disseminate "policies, positions, suggestions, and definitions to promote the practice of anesthesiology." These Expert Consensus Documents are found on the same ASA website and include *Advisory on Granting Privileges for Deep Sedation to Non Anesthesiologist*

*Physicians*, *ASA Physical Classification System*, *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, and *Guidelines for Delineation of Clinical Privileges in Anesthesiology*.

Several of these statements/guidelines deserve particular mention and review. The *Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners* begins by declaring that non-anesthesiologist sedation practitioners should supervise moderate sedation only if they are qualified by "education, training, and licensure to administer moderate sedation" (It should be noted that some experts have objected to the term "non-anesthesiologist" since it has been proposed that this terminology inappropriately includes physicians of various levels of skill, training, and experience in one cohort.) [13]. The statement goes on to define various core competencies for the sedation professional including obtaining consent, medical history, assessment of risk of aspiration, knowledge of pharmacology of sedative medications, issues related to oxygen supplementation, proficiency with airway management, knowledge of appropriate monitors for sedation, knowledge of documentation principles, and appropriate resuscitation skills. The authors include a description of appropriate licensure, practice patterns, and performance improvement for these practitioners.

The *Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation* was updated in October of 2017. This statement is very brief and worded "Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges for deep sedation should be granted only to non-anesthesiologist physicians who are qualified and trained in the medical practice of deep sedation and the recognition of and rescue from general anesthesia." This guideline goes on to advise against non-anesthesiologists delegating or supervising that administration of sedation by individuals who are not similarly qualified. At the same time, the ASA *Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologist Physicians* is a much more detailed document that outlines the training, competencies, and licensure that an individual should have in order to deliver deep sedation. This document quotes the current CMS statements about practitioners who are qualified to deliver this form of sedation and the organization for sedation oversight that should be in place in any organization where this care is being delivered.

The ASA "*Statement on the Safe Use of Propofol*" last amended in 2019 and advises "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." This document goes on to describe the education and training requirements for this care along with the appropriate monitoring and equipment that should be present for this type of care.

The distinction between sedation, deep sedation, and monitored anesthesia care (MAC) is frequently misunderstood. To clarify these definitions, in 2018, the ASA amended the document entitled *Distinguishing Monitored Anesthesia Care (MAC) From Moderate Sedation/Analgesia (Conscious Sedation)* to differentiate between the two levels of care. Important distinctions are noted – 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 as well as to convert to a general anesthetic. Conversely, patients receiving moderate sedation would *not* be expected to progress to a condition in which the patient could not maintain his/her own airway.

In 2019 the ASA published a useful document that addresses some common (controversial) issues in procedural sedation – under the title *Principles for Hospital-based Sedation, Analgesia and Anesthesia*. This statement is available at https://www.asahq.org/quality-and-practice-management/quality-improvement/qmda-regulatroy-toolkit/guide-to-anesthesia-department-administration. This document reviews the US Center for Medicaid and Medicare Services recommendations for sedation oversight. It then outlines strategies for Anesthesiology Departments to work with colleagues in other departments to meet the mandates for oversight and quality improvement that are part of the standards put forward by the US federal government (CMS). In this rather unique recommendation, the ASA gives a point-by-point outline for how anesthesiologists should negotiate with colleagues to establish common ground and productive discussion on sedation issues. A large portion of the document specifically addresses a new recommendation from the American College of Emergency Physicians (ACEP) concerning "unscheduled sedation" (reviewed below) and contrasts the language in that document to the language the ASA has promoted around the same issues. While there are few firm conclusions for how to resolve the differences between the different organizations' take on sedation principles, the presence of a discussion of the various topics involved is evidence of a recognition that conflicting standards exist and that these should be resolved through dialogue in order to optimize care delivery.

## Center for Medicare and Medicaid Services (CMS)

The US federal government Center for Medicare and Medicaid Services (CMS) has written *The Hospital Anesthesia Services Condition of Participation* 42 CFR 482.52 (a) of 2010 [14] in which it outlines several concepts

involved in the delivery of sedation services and how these services should be organized in hospitals that receive reimbursement through CMS. While this is not pertinent to international readers, this agency is critical to reimbursement for US hospitals and organizations; thus its recommendations carry significant weight throughout the country. The guidelines can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74SOMA.pdf. Perhaps the most notable part of this guideline is the recommendation that all anesthesia services be organized under one individual and that the standards for anesthesia care be consistent across an organization. The document goes on to point out that the individual in charge of sedation services would most logically be the Chair of Anesthesiology, but other qualified individuals could fill this position. They outline the various levels of sedation and the distinction between "anesthesia" and "analgesia." This document also includes very specific language around the need for quality improvement activity with respect to all areas of sedation/anesthesia and the necessity for a pre-sedation/anesthesia evaluation and a post-sedation/anesthesia evaluation.

These CMS guidelines regarding non-anesthesia 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 these recommendations (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 acknowledgment 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 Joint Commission

Issues relating to sedation regulations and guidelines (in general) and pediatric sedation (in specific) are found in a variety of locations in the *The Joint Commission Handbook* and website (http://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.

The Joint Commission recommendations are important when considering the credentialing and privileging of sedation providers. They require 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 directly on the Department of Anesthesiology and its chairman. Subsequent revisions of this document have revised the language: the Anesthesiology Department play an important advisory role but is not directly responsible for sedation care, privileging, or quality assurance.

In the current 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." 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." It goes on "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."

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 (ACEP) Guidelines

The American College of Emergency Medicine (ACEP) has put forward a wide range of statements, clinical practice advisories, and clinical policy statements concerning sedation of children for procedures. The 2019 American College of Emergency Physicians Policy Compendium includes a statement *Procedural Sedation in the Emergency Department* which has been updated several times since it was first pub-

lished in 1992 (https://www.acep.org/globalassets/new-pdfs/policy-statements/procedural.sedation.in.the.ed.pdf). This statement emphasizes the importance of procedural sedation – improving the quality and safety of emergency department care. It mentions a variety of medications and non-pharmaceutical interventions that improve care during procedures. Importantly, this document clearly states that "NPO status has not been demonstrated to reduce risk of emesis or aspiration in ED procedural sedation." It also establishes that "the American College of Emergency Physicians is the authoritative body for the establishment of guidelines for sedation in emergency department patients." This could be interpreted as a challenge to the CMS guidelines (outlined above) which places oversight for all sedation at a given institution under one individual.

There are multiple other sedation statements from this organization. In 2005 and 2014, the ACEP published *Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department* [4, 15]. Similar to the ASA guidelines, the ACEP guidelines apply to all patients, (adults and children) who receive sedation. They were developed based on a structured literature review, and the recommendations are graded based on the strength of the evidence. 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. 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 [15, 16].

The ACEP guidelines differ slightly 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. Those guidelines do not make recommendations specifically for the nonelective sedation case. As mentioned above, emergency medicine sedation providers must cope with patients who do not meet appropriate NPO criteria and are not having "elective" procedures. In the last 20 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 [17–19]. Previous publications from the ACEP have concluded that there is insufficient evidence to conclude that fasting actually changes outcome for sedation (see above) [20]. This clinical policy recommends that providers "do not delay procedural sedation in adults or pediatrics in the ED based on fasting time." It also includes a recommendation in favor of capnography for procedural sedation and recommends the use of various potent sedatives in emergency department practice [4].

In 2007 ACEP produced a guideline specifically addressing the issue of fasting prior to sedation [21]. This clinical practice advisory is titled "Fasting and Emergency Department Procedural Sedation and Analgesia: A Concensus-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 stratification of the patient, nature of food intake, and depth/type of sedation targeted. The result is a somewhat complex strategy that weighs NPO time vs. emergent/urgent/semiurgent nature of the case vs. duration of the procedure. Figure 2.1 schematically describes the recommendations that result from these guidelines [21]. These NPO recommendations conclude that "recent food intake is not a contraindication for administering procedural sedation and analgesia, but should be considered in choosing the timing and target level of sedation" [15, 21].

In 2004 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* [22] was a thorough document that has not been updated and (perhaps) replaced by separate clinical policy statements on the use of drugs such as propofol and ketamine (see below). Another well-researched publication, *Clinical Policy: Critical Issues in the Sedation of Pediatric Patients in the Emergency Department* [20] was published 4 years later. The "critical issues" statement supported earlier recommendations on NPO status and reviewed the use of sedatives such as nitrous oxide, chloral hydrate, and sucrose. Their recommendations have been accepted by a wide range of surgical and nursing organizations and have been published in corresponding journals [23, 24].

The ACEP website includes a position statement titled *Procedural Sedation and Analgesia in the Emergency Department: Recommendations for Physician Credentialing, Privileging, and Practice.* https://www.acep.org/globalassets/uploads/uploaded-files/acep/clinical-and-practice-management/resources/sedation/acep-sedation-position.pdf. This document defines various states of sedation/anesthesia and goes on to state that "Graduates of emergency medicine residency and fellowship programs…are qualified for all forms of analgesia and all levels of sedation in all ages." For providers who are not trained in emergency medicine, it advises that the chief of the unit (or section) will need to set

**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 |

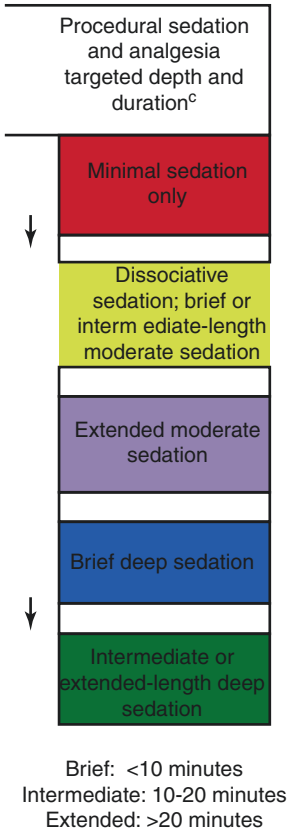


**Fig. 2.1** ACEP NPO considerations and aspiration risk. (Reproduced from Green et al. [21]. Epub 2006 Nov 1. Reprinted with permission from Elsevier)

the standards for training and proctoring of practice prior to privileging these practitioners for sedation practice.

ACEP recently updated a clinical practice advisory on propofol use in the emergency department [16, 25]. This guideline is consistent with other ACEP publications in that it does not consider lack of an NPO interval as a contraindication to administration of propofol. It notes providers who deliver propofol sedation must be qualified for deep sedation. As a departure from the AAP or ASA guidelines, this practice advisory allows for a single provider to both deliver sedation with propofol and perform the procedure – as long as that individual is "prepared to interrupt the procedure to perform resuscitation." There are also some recommendations for dosing of propofol as a single agent and in combination with ketamine or opioids.

ACEP also has a practice guideline on ketamine use in the emergency department which was originally written in 2004 and updated in 2011 [26, 27]. The authors point out the unique sedative qualities of ketamine and have a separate "level" of sedation termed "dissociative" sedation as applied to the state that is induced by ketamine. (This definition is not recognized by other major organizations that have issued guidelines on sedation practice). Because of its unique properties, the authors argue a separate clinical policy is needed outside of other recommendations on sedative administration in the emergency department [22]. This document outlines best use (minor painful procedures) and enumerates some possible contraindications ("airway instability"). Two providers are recommended for dissociative sedation, although IV access is unnecessary when the drug is given by the intramuscular route. Recommendations for recovery and discharge are also included.

In 2019, ACEP published a guideline specifically aimed at addressing issues related to the administration of unscheduled procedural sedation. Titled *Unscheduled Procedural Sedation: A Consensus Practice Guideline*, this extensive document reviews most issues associated with procedural sedation with special attention to the unscheduled case situation. The guideline was based on clinical analysis of existing literature between 2000 and 2018 and endorsed by multiple organizations (Fig. 2.2) [28]. Most of the document's 21 pages outline concepts that are similar to the ACEP recommendations for general procedural sedation. Two sedation providers are required, a sedation provider and a sedation

Organizations that participated and endorsed the guideline

- American College of Emergency Physicians
- American Academy of Emergency Medicine
- American Board of Emergency Medicine
- American College of Cardiology
- American College of Medical Toxicology
- American College of Osteopathic Emergency Physisians
- Association of Academic Chairs of Emergency Medicine
- Emergency Medicine Residents' Association
- Emergency Nurses Association
- Society for Academic Emergency Medicine
- Society for Pediatric Sedation

Organizations that participated and provided input

- American Academy of Pediatrics
- American Academy of Pediatrics Section on Critical Care
- American Academy of Pediatrics Section on Pediatric Emergency Medicine
- American Society for Gastrointestinal Endoscopy
- Council of Emergency Medicine Residency Directors
- American Association of Oral and Maxillofacial Surgeons
- Society of Critical Care Medicine
- Society of Interventional Radiology

Organizations that participated review comments

- American Association of Nurse Anesthetists

Eigth other organizations representing general medicine, anesthesiology, dentistry, and gastroenterology were invited to participate, but either declined or did not respond.

**Fig. 2.2** Organizations that approved the ACEP consensus practice guideline on unscheduled sedation. (Reproduced from Green et al. [28] with permission from Elsevier)

monitor. The recommendations in this document vary slightly from the AAP, and ASA guidelines in that the qualifications for the "procedural sedation monitor" are less complex and not directed at the specific level of sedation. This individual is described as "a nurse, respiratory therapist, or other health care professional who is privileged based upon local oversight, training, and verification of skills." These skills required are limited to monitoring the patient, being able to assist the sedation provider (who may be performing the procedure) in resuscitation and summon to effectively summon help. Furthermore they allow for some dual tasking of the sedation monitor – "the sedation monitor can assist with minor, interruptible tasks as long as they do not materially interfere with the effective procedural sedation monitoring." Given the nature of the unscheduled procedures addressed in this document and the lack of data relating aspiration to NPO duration, the authors conclude that given the exceptionally low risk of pulmonary aspiration with procedural sedation and absent evidence of an impact from fasting, reform is appropriate for recommendations regarding pre-procedural oral intake [28].

## International Committee for the Advancement of Procedural Sedation Consensus Statement on Fasting for Procedural Sedation

Almost all of the general guidelines on sedation that have been published include some mention of the duration of fasting that is required prior to providing procedural sedation. As outlined above in the AAP, ASA, and ACEP section of this chapter, these recommendations do not always align perfectly. This is largely due to the lack of very high-quality data on the topic. To attempt to address this issue and other topical issues in sedation, an International Collaborative of experts were formed, the International Committee for the Advancement of Procedural Sedation (ICAPS). This group used a review of the available literature, along with a Delphi methodology, to come up with a set of consensus recommendations regarding fasting duration prior to sedation [29]. These experts concluded that there is "no association between aspiration and compliance with fasting guidelines." They suggest that fasting guidelines for procedural sedation should be less restrictive than those for general anesthesia, and their suggested algorithm for fasting prior to procedures is presented in Fig. 2.3.

## American Dental Association Sedation Guidelines

As mentioned in the section on the AAP guidelines on sedation (above), the American Academy of Pediatric Dentistry (AAPD) has been involved in the writing and dissemination of the AAP/AAPD [3] guidelines on sedation from their inception. Most of the versions of the AAP guidelines have been co-written with the AAPD over the years – including the current version. The most important addition in the current iteration is the inclusion of the recommendation that *two* providers with specific sedation rescue training and credentials (Pediatric Advanced Life Support) should be present for

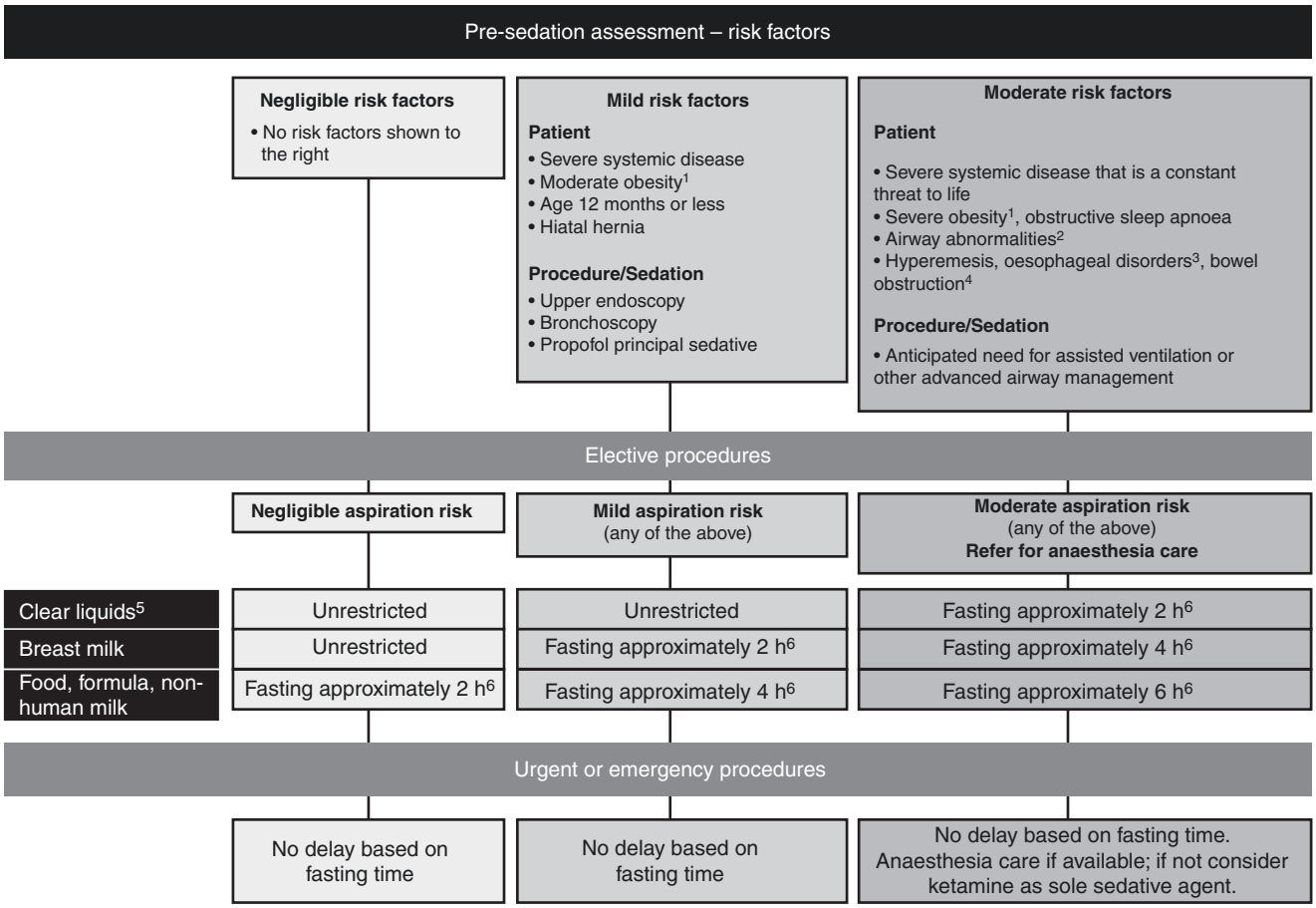


**Fig. 2.3** Pre-procedural sedation algorithm from the International Committee for the Advancement of Procedural Sedation. (Reproduced from Green et al. [29] with permission from John Wiley and Sons)

sedation in a dental office. This is a significant change from the earlier versions which only recommended one such qualified sedation provider to be present for sedation of this kind.

In addition to the collaborative guidelines (above), the American Dental Association (ADA), independently, published general guidelines regarding sedation titled "Guidelines for the Use of Sedation and General Anesthesia by Dentists." They were last updated in October of 2016, and they are available at https://www.ada.org/~/media/ADA/Education%20and%20Careers/Files/ADA_Sedation_Use_Guidelines.pdf. The guideline outlines depths of sedation consistent with that described by the AAP/AAPD 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 educational requirements for dentists regarding various levels of sedation, including specific 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 in Basic Life Support (BLS) Course for the Healthcare Provider. There are two pathways for dentists to qualify for deep sedation certification: (1) 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 (2) an appropriate dental sedation/anesthesia emergency management course. This guideline goes on to recommend that dentists 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.

This set of ADA guidelines is presented in sections, divided by 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 over. The ADA refers to the (AAP/AAPD) *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* for guidelines concerning sedation of young children, infants, and toddlers [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 [10]. Nitrous oxide is a recognized and acceptable sedative, alone or in combination with other sedatives.

In 2018 AAPD published an update of its 2012 *Guideline on Use of Anesthesia Personnel in the Administration of Office-based Deep Sedation/General Anesthesia to the Pediatric Dental Patient* [31]. It affirms the fact that there are several categories of pediatric patients, such as those with developmental delays and autism, who require deep sedation for dental interventions. Further, this manuscript recognizes that when sedation/anesthesia care is provided in the dental office, it is much more cost-effective and convenient to schedule than when it is delivered in a large hospital setting. This guideline is careful to define the aspects of training that are required in order to deliver this care. Specifically, this policy details the different types of sedation and anesthesia providers along with their permissible responsibilities and training (Fig. 2.4). Emergency preparedness must be updated and practiced on a regular basis, and recovery must be moni-

Table, ANESTHESIA EDUCATION AND TRAININGCOMPARISON

| Anethesia provider | Permitted to function independent of supervivion by anesthesiologist | Mininum duration of program required for certification | Min. # of DAGA cases | Min. # of pediatric cases | Definition of pediatric patient | Min. # of DAGA cases involving patients with SHCN | National examination/ certification organization |
|---|---|---|---|---|---|---|---|
| Certified anesthesiologis t assistant[3] | No | 24 months | 400GA cases | 50 | 0-18 | N/A | National Commission for Certification of Anesthesiologist Assistants |
| Certified registered nurse anesthetis[5] | In some states | 24 months | 25/400 | <2 yrs: 10<br>2-12 yrs:30 | ≤12 yrs | N/A | National Board of Certification and Recertification for Nurse Anesthetists |
| Dentist anesthesiologist T | N/A | 36 months | 800 | 125 | ≤7 yrs | 75 | American Dental Board Anesthesiology and/or National Dental Board of Anesthesiology |
| Medical anesthesiologist s | N/A | 48 months | N/A | 100 | ≤12 yrs | N/A | American Biard of Anesthesiology |
| Pediatric medical anesthesiologist[9] | N/A | 12 month-fellowship following medical anesthesiology residency | N/A | N/A | N/A | N/A | American Biard of Anesthesiology (Pediatic Anesthesiology Examination[10]) |
| Oral and maxillofacia l surgeon" | N/A | Five months anesthesia service supplemented by CMFS service* | 300 | 50 | ≤18 yrs | N/A | National Dental Board of Anesthesiology for anesthesia certification |
| | | 48 months | | | | | American Biard of Oral and Maxillofacial Surgery for surgery certification |

DS/GA=Deep sedation/General anesthesa, SHON=Special heel care reeds CMFS=Oral and maxllofacial surgery

* During the ord and maxllofacial surgery training program, a resictent's assignment to the department of anesthesiology "must be for a minium of five months should be consective and one of the these months should be dedicated to pediatric anesthesia"." This anethesia experience is supplemented through the training program to ensure competance in deep sedation/general anesthesia on adult and pediatric patients.

**Fig. 2.4** Dental Guidelines for Education and Training of Sedation Providers. (Reproduced from American Academy of Pedodontics and American Academy of Pediatric Dentistry [32], with permission from the American Academy of Pediatric Dentistry)

tored by an individual experienced in recovery care at all times until the patient has met discharge criteria. The authors are also careful to point out that the facility must meet the standards for anesthesia delivery as set by state or local codes and the AAP/AAPD guidelines. The new document concludes by reinforcing the need for appropriate pre-, intra-, and postoperative documentation as well as ongoing quality assurance standards.

## British National Health Service Dental Sedation Standards

The National Health Service Office of the Chief Dental Officer in Great Britain published *Commissioning Dental Services: Service Standards for Conscious Sedation in a Primary Care Setting* in 2017. These guidelines are available at https://www.england.nhs.uk/wp-content/uploads/2017/06/dental-commissioning-guide-service-standards-conscious-sedation-2.pdf. They are notable for the use of the term "conscious sedation" that has been abandoned in the guidelines produced by organizations in many countries, notably the USA. The standards are written specifically with the desire to promote equality and eliminate discrimination in healthcare delivery across populations. Sedation is described as being a key component of adequate dental care for any population in order to control anxiety. In this case, the level of sedation is such that the patient remains conscious, retains protective reflexes, and is able to understand and respond to verbal commands. The provision of sedation requires informed consent, and the document describes the methods of sedation. For patients between 12 and 16 years of age, this is either with nitrous oxide or midazolam. For patients under 12 years of age, sedation is strictly limited to inhalation sedation with nitrous oxide and/or intravenous, oral, or intranasal midazolam.

These guidelines describe the training required for anyone providing sedation with the approved agents, including the completion of a specific training program in sedation and a continuing activity of at least 50 administrations per year. There are very specific requirements for equipment, including scavenging equipment for inhaled nitrous oxide. Finally, this document requires sedation providers to collect quality and outcome measures, including patient-reported outcomes concerning the adequacy and quality of the sedation provided.

## Intercollegiate Advisory Committee for Sedation in Dentistry

A somewhat similar effort (as the NHS Dental Sedation Standards above) to outline recommendations for sedation in dentistry was produced by the Intercollegiate Advisory Committee for Sedation in Dentistry from the Royal College of Surgeons and the Royal College of Anesthetists in Scotland in 2015. They are available at https://www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/standards-for-conscious-sedation-in-the-provision-of-dental-care-and-accreditation/. Once again, these are comprehensive (over 100 pages long) guidelines for practice that include a definition of conscious sedation in dentistry and the training required for providers to qualify to deliver sedation in dentistry (similar to that described in the NHS guidelines). These guidelines are unique in that they set standards for specific medications, the patient population for whom they may be administered, and the experience and training of the provider as well as the necessary monitoring (Table 2.3). Like the NHS guidelines outlined above, these standards recommend a systematic strategy for reporting adverse outcomes and documenting ongoing experience in sedation for credentialing purposes. Finally, these recommendations include a mandate to inspect locations where sedation is being delivered to document adherence to guidelines. This mandate for inspection of sedation locations is unique and could be a future standard for other organizations.

## American Society of Gastroenterologists

The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy has written guidelines for sedation for endoscopic procedures after a review of the MEDLINE and PubMed database. Specific recommendations are graded based on the weight of the evidence available. The first endoscopy sedation guideline was published in 2002 and then updated in 2018 entitled *Guidelines for the Use of Deep Sedation and Anesthesia for GI Endoscopy* [33, 34]. This guideline reviews the levels of sedation and the importance of pre-sedation assessment in order to customize sedation for the needs of the patient. Most of the evaluation and monitoring recommendations are in line with the ASA guidelines outlined above. Planning is identified as particularly important for those with specific emotional issues, drug use history, and those who are undergoing extensive procedures. The authors review a variety of drugs available for moderate sedation. There are no specific references to or recommendations for the pediatric population. A unique aspect of these recommendations is the description of various strategies for the delivery of propofol sedation including non-anesthesiologist-administered propofol sedation (NAAP), nurse-administered propofol sedation (NAPS), and balanced propofol sedation (BPS). There are numerous references of the positive outcome data in the GI literature concerning each of these strategies. The authors outline the requirements for propofol sedation and note that consistent evidence has shown more rapid recovery after propofol sedation for

**Table 2.3** Requirements for clinical sedation techniques

| | Initial theory and skills training | Additional theory and skills training | Recommended minimum clinical experience in monitored practice to achieve competency (number of cases appropriate to age group) | Life support training for all team members | Other rescue measures (vi) | Monitoring (in addition to clinical) | Operator-sedationist (with second appropriate person) | Dental nurse training (viii) | Environment (primary = 1; secondary = 2) (ix) |
|---|---|---|---|---|---|---|---|---|---|
| Nitrous oxide / oxygen (i)(ii) | Y | N | 10 | ILS<br>PILS | Resp dep airway | | Y | CDSN/ equivalent | 1/2 |
| Midazolam. intravenous(i)(ii) | Y | Adults; N<br>Peds:Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Y | CDSN/ equivalent | 1/2 |
| Temazepam, oral (i) (ii) | Y | Adults: N<br>Peds:Y | 10 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Adults: Y<br>Peds: N/A | CDSN/ equivalent | 1/2 |
| Midazolam, oral (i)(ii) | Y | Adults: N<br>Peds:Y | 10 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Y | CDSN/ equivalent | 1/2 |
| Midazolam, intranasal(i)(ii) | Y | Adults: N<br>Peds:Y | 10 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Y | CDSN/ equivalent | 1/2 |
| Opioid + midazolam (i)(ii)(iii) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Adults: Y<br>Peds: N | CDSN+ | Adult: 1/2<br>Peds: 2 |
| Ketamine (all routes) (i)(ii)(iv) | Y | Y | 20 | ILS<br>PILS | Resp dep Airway | NIBP<br>Pulse oximetry | N | CDSN+ | Adult: 1/2<br>Peds: 2 |
| Midazolam, PCS (i)(ii)(v) | Y | Y | 20 | ILS<br>PILS | Resp dep Airway | NIBP<br>Pulse oximetry | Adults: Y<br>Paeds: N/A | CDSN+ | 1/2 |
| Propofol, PCS (i) (ii)(v) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | Adults: Y<br>Peds: N/A | CDSN+ | 1/2 |
| Propofol, TCI (i) (ii) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | N | – | 2 |
| Midazolam + propofol (i)(ii) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP | N | – | 2 |
| Sevoflurane (i)(ii) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | N | _ | 2 |
| Sevoflurane + nitrous oxide / oxygen (i)(ii) | Y | Y | 20 | ILS<br>PILS | Resp dep airway | NIBP<br>Pulse oximetry | N | – | 2 |

Permission to come from Royal College of Surgeons

*Cap* capnography, *CDSN* Certificate in Dental Sedation Nursing, *ILS* immediate Life Support, *N/A* not applicable, *NIBP* non-invasive blood pressure monitoring, *PCS* patient-controlled sedation, *PILS* Pediatric Immediate Life Support, *Resp dep* respiratory depression, *TCI* target-controlled infusion

endoscopy when compared to benzodiazepine/opioid moderate sedation.

Specifically with respect to propofol sedation, this document outlines personnel, preparation, and monitoring requirements [33]:

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. Age appropriate 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. A physician should be present throughout propofol sedation and must remain immediately available until the patient meets discharge criteria.

The issue of propofol sedation has been addressed in other documents from the gastroenterology subspecialty. A position statement on the administration of propofol by non-anesthesiologists and pediatric sedation for gastrointestinal procedures and endoscopy was published in 2009 and has not been updated since [35]. This position statement came from the multiple interested organizations including the American College of Gastroenterology, American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy. The document reviews the evidence published on the topic and concludes that the safety profile for non-anesthesiologist administered propofol is equivalent to that of standard sedation. It also concludes that the use of propofol is more cost-effective because of efficiency gains. Finally, the document notes the special skills needed to perform propofol sedation and outlines specific training strategies.

An older publication *Guidelines for Conscious Sedation and Monitoring During Gastrointestinal Endoscopy* was published in 2003 in the journal *Gastrointestinal Endoscopy* [36]. This manuscript refers 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 – high-risk patients and high-risk procedures at 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.

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. In reference to deep sedation, the authors suggest that propofol is superior to standard benzodiazepine/opiate sedation for complex procedures and acknowledges that its use in routine upper and lower endoscopic procedures is controversial with little proven benefit over standard moderate sedation [36].

Another pertinent publication regarding sedation specifically for pediatric endoscopy was published in 2008 and updated in 2014 titled *Modifications in Endoscopic Practice for Pediatric Patients* [37, 38]. This document addresses many issues relating to the general practice of endoscopy in children, but it also addresses issues specifically related to sedation in children and for pediatric endoscopy. The authors review indications and contraindications for endoscopy in children, the appropriateness of pediatric versus 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 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 guideline advises adherence to AAP/AAPD sedation guidelines and notes that while pediatric gastroenterologists are qualified to provide moderate sedation, most endoscopies in children involve deeper levels of sedation, and therefore sedation providers who are prepared to provide deep sedation should be present. 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 [37, 39]. The authors also note that when propofol is compared to "general anesthesia," it has been found to result in less total time for anesthesia and equal safety [40].

## 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. Most are

largely consistent with the most widely quoted recommendations from the AAP. It is not possible to review all of the published guidelines and highlight the similarities and differences between the existing sedation guidelines worldwide, but there are some guidelines that deserve specific discussion. Of particular interest are the "Recommendations on effective and safe sedation of children and young people undergoing common diagnostic and therapeutic procedures" from the National Institute of Health and Clinical Excellence (NICE) in the United Kingdom (2011) [41]. A recent update of this publication was made in 2019 and available at https://www.nice.org.uk/guidance/cg112/evidence/full-guideline-136287325. The NICE sedation guidelines are largely unchanged since their original publication, however, the fasting guidelines, have been updated to reflect an NPO recommendation of 1 hour which is in line with the current recommendations for pediatric surgical patients in the United Kingdom [42]. These NICE guidelines are presented as a comprehensive review (almost 400 pages) of the best available evidence and expert opinion. The recommendations are wide-ranging and include the mandate for a full pre-sedation evaluation that incorporates medical condition, current medications, airway assessment, ASA physical status, and an evaluation of the psychosocial makeup of the child. In addition, there is a clear outline of indications for seeking advice from a specialist before undertaking sedation based on the pre-sedation assessment. These indications include ASA status three or greater, airway difficulties, and all infants and newborns. Notably, these recommendations include an extensive description of available sedation techniques. The authors recommend specific drugs or combinations of drugs for sedation based on the targeted level of sedation, the procedure, contraindications to drugs based on patient characteristics, and patient/family preference. An algorithm for choosing a sedation method is also included as shown in Fig. 2.5. Other elements such as choosing appropriate resuscitation equipment, personnel, and informed consent follow closely with the guidelines put forward by the AAP and ASA.

Chapters 21 (Lightdale) and 31 (Roelofse) of this text detail the most recent sedation guidelines from the Dutch Institute of Healthcare Improvement in the Netherlands (2011), the Endoscopy Section of the German Society for Digestive and Metabolic Diseases (2009), and the adult and pediatric guidelines of the South-African Society of Anesthesiologists (2010 and 2011).

Several notable examples of sedation/anesthesia statements and guidelines published worldwide include:

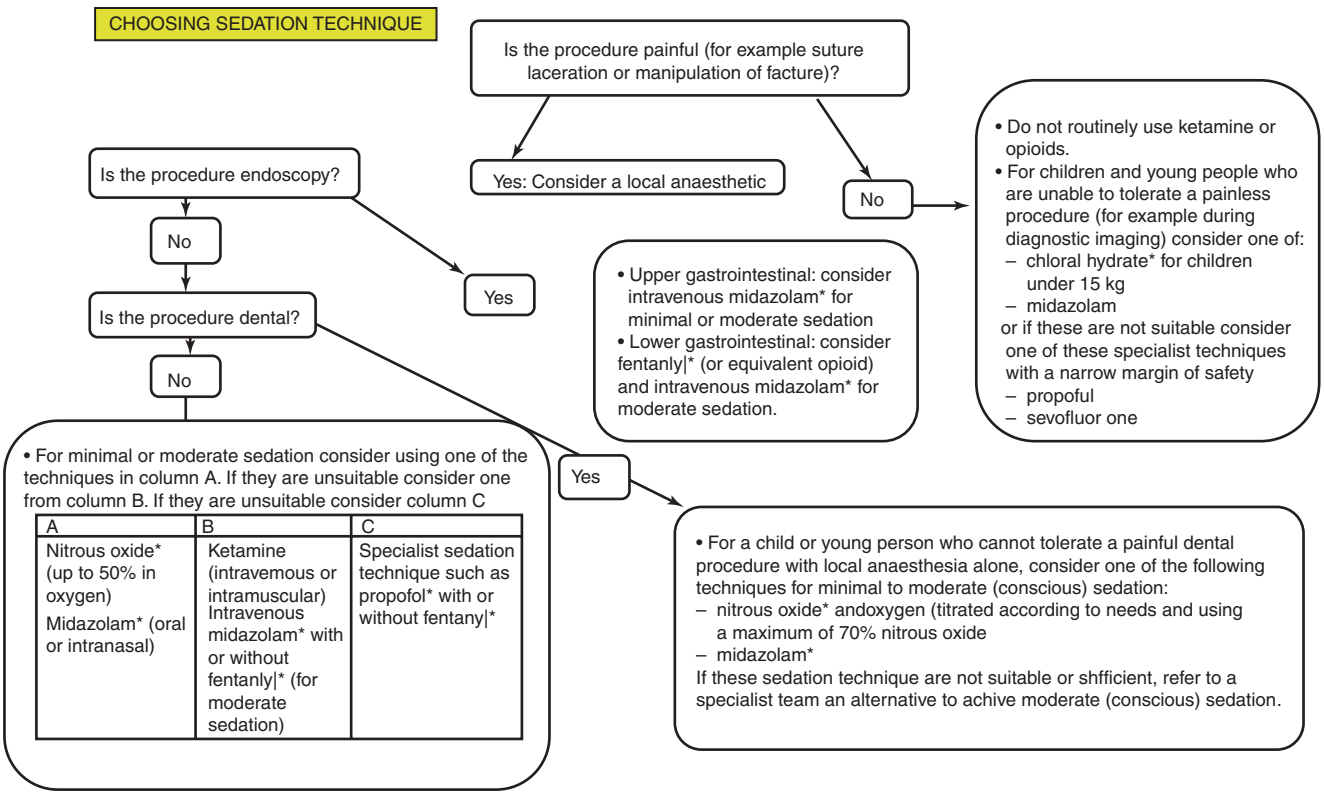


**Fig. 2.5** Strategy for Choosing Sedation from the NICE Guidelines for Sedation. (Source: National Guideline Centre [2010], Sedation in under 19s: using sedation for diagnostic and therapeutic procedures, Clinical guideline 112, Published by the National Guidelines Centre at The Royal College of Physicians, 11 St. Andrews Place, Regent's Park, London, NW11 4LE. Copyright © NGC. Reproduced by permission. https://pathways.nice.org.uk/pathways/sedation-in-children-and-young-people)

1. *New South Wales Government Health. Paediatric Procedural Sedation – Guide for Emergency Departments, Wards, Clinics, and Imaging(2018)* (https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_011.pdf). This comprehensive guideline was written as a resource to apply to all areas where sedation is provided with the understanding that adaptation would be needed for some settings. It covers a large number of critical common issues for pediatric sedation. It describes the critical competencies for evaluating patients prior to sedation. Training and credentialing guidelines follow that of the Australian and New Zealand College of Anaesthetists (ANZCA) which recommends 3 months of supervised training for dentists who provide sedation. It outlines criteria for safe sedation starting with the question as to whether or not the procedure is needed. NPO criteria are outlined and quite specific. For example, they differentiate the criteria for nitrous oxide from potent sedatives such as propofol or ketamine.
2. *Australian and New Zealand College of Anaesthetists. Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental, or Surgical Procedures* (https://www.anzca.edu.au/documents/ps09-2014-guidelines-on-sedation-and-or-analgesia). This is another comprehensive document with recommendations for assessment, monitoring, equipment, and recovery. Their recommendations for personnel present during sedation include three individuals – one proceduralist, sedation monitor, and an assistant (available to help the proceduralist or the sedation provider as needed).
3. *Scottish Intercollegiate Guidelines Network. SIGN Guideline 58: Safe Sedation of Children Undergoing Diagnostic and Therapeutic Procedures* [43]. This is a comprehensive, evidence-based, sedation review that includes discussions of appropriate evaluation of pediatric patients as well as recommendations for equipment, environment, recovery, parental information, and quality improvement. There are specific sections addressing the needs of medical pediatrics vs. dentistry vs. radiology vs. emergency medicine. There is a section on sedation techniques that recommends various drugs for certain situations and specifically reserves potent medications such as propofol and short-acting opiates for use by anesthesiologists. This recommendation is distinct from recommendations emanating from US organizations that accept the delivery of propofol by specialists other than anesthesiologists.
4. *Australasian College for Emergency Medicine, Australian and New Zealand College of Anaesthetists. Statement on Clinical Principles for Procedural Sedation* [44]. A very brief statement of basic principles of sedation (preparation, staffing, facilities, medication, recovery) that is in line with recommendations from British and American organizations. Source material is not referenced.
5. *Canadian Consensus Guidelines. Canadian Association of Emergency Physicians Procedural Sedation and Analgesia in the Emergency Department* [45]. Slightly dated consensus statement conceived in conjunction with the Canadian Association of Anesthesiologists. Outlines general principles of safe sedation care in line with those mentioned above including assessment of the patient, facility preparation, training of providers, fasting status, and recovery. This document includes an example of a sedation record which is somewhat unique. No specific sedation regimens are recommended. There are useful links to other sedation publications and guidelines included.
6. *Neuroanesthesia and Neurointensive Study Group of the Italian Society of Anesthesia SIAARTI-SARNePI Guidelines for Sedation in Pediatric Neuroradiology* [46]

   These guidelines are based on a literature review and graded on the basis of the evidence in the literature to support them. In spite of their origins from an Italian professional society, these guidelines use the AAP terminology for levels of sedation. As with the other guidelines reviewed here, there is a detailed discussion of the need for an appropriate pre-sedation evaluation. Nil per os recommendations and monitoring guidelines follow closely with the AAP and ASA. This guideline cites the use of the Pediatric Coma Scale and the Ramsay Scale for monitoring of depth of sedation. Capnography is recommended, although the authors recognize the lack of clear evidence for outcome improvement. There are extensive reviews of emergency equipment required for sedation sites and drug choices/combinations for sedation. Finally, the authors include some helpful thoughts on "special situations" including angiography, endovascular treatment, CT scans, and MRI scanning.
7. *The Working Group on Endoscopy, Austrian Society of Gastroenterology and Hepatology*. Austrian Society of Gastroenterology and Hepatology (OGGH) – guidelines on sedation and monitoring during gastrointestinal endoscopy [47].
8. *Sedation Guidelines for Gastrointestinal Endoscopy 2008 of German Society for Digestive and Metabolic Diseases* [48]. This is a similar guideline to that of the Austrian Society (above) – published in German.
9. *South-African Society of Anaesthesiologists (SASA) Sedation Guidelines*; 2010 [49]. A helpful and extensive sedation guideline but limited to addressing issues related to adult sedation.

10. *South-African Society of Anaesthesiologists (SASA) Paediatric Procedural Sedation and Analgesia (PSA) Guidelines* [50].
11. These extensive guidelines have undergone a recent update in 2016. This is comprehensive document that reviews multiple aspects of the provision of sedation of children. It represents the most complete guidelines/review of pediatric sedation produced by any national organization or policy-making entity. The introduction of the document clearly identifies those responsible for authoring the guidelines, but there is no description of the manner in which evidence was used to formulate the recommendations. The authors do not reference the document in a way that would allow one to check or review the sources of their recommendations.
12. *Consensus Statement on Clear Fluids Fasting for Elective Pediatric General Anesthesia. Association of Paediatric Anaesthetists of Great Britain and Ireland*, *the European Society for Paediatric Anaesthesiology*, *and L'Association Des Anesthesistes-Reanimateurs Pediatriques d'Expression Fancaise* [42]

    This is a very well-thought-out document that follows the current evidence on fasting and concludes that fasting from clear fluids for 1 h is sufficient (and actually preferable) to the 2 h recommendation that is commonly quoted in other guidelines – such as the AAP/AAPD and ASA guidelines reviewed above. The authors cite studies that show the stomach empties water within 30 minutes, clear fluids empty within an hour, and that decreased fasting can lead to better overall hydration states in preoperative patients. Furthermore, they note data that shows aspiration of clear fluids has generally not been shown to cause serious pulmonary sequelae. Notably fasting for non-clear fluids and solids is not substantially changed. While the recommendations are aimed at anesthesia, it is clear that they would also be applied to moderate and deep sedation encounters and would be treated similarly.
13. *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* [51]

    This guideline represents the combined effort of a number of European Societies involved with gastrointestinal endoscopy. The authors have undertaken an evidence and consensus-based guideline on the use of propofol for non-anesthesiologists for GI endoscopy. Recommendations are graded based on the evidence. The guideline concludes that propofol sedation has similar rates of adverse events as more traditional sedation regimens. There is a strong recommendation for appropriate training for propofol sedation. Physicians and registered nurses are considered appropriate candidates for propofol sedation training and practice. Human patient simulation is recommended as an enhancement of the training for propofol sedation. High-risk patient groups are noted including those with high ASA status, risks for airway obstruction, patients who take potent pain medications, and those undergoing prolonged procedures. The combination of propofol with other drugs is neither advised nor discouraged. Monitoring with full ASA monitors and regular assessment of the level of sedation is recommended. Discharge using standardized discharge scoring system is recommended (Table 2.4).
14. *World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) International Standards for a Safe Practice of Anesthesia* [52]

    This document "applies standards to any healthcare facility anywhere in the world… in which… deep sedation or moderate sedation… is administered." This set of standards comes from an organization of anesthesiologists representing 150 countries and the WHO. This document is valuable in that it clearly defines all types of anesthesia providers, each of whom may be qualified to administer moderate or deep sedation (Table 2.5). These standards cover a variety of topics including facilities and equipment, medications and intravenous fluids, monitoring, and the conduct of anesthesia. The conclusions are relatively straightforward and include that idea that there should be a trained and vigilant provider at all anesthetics. In addition these guidelines call for monitoring of tissue oxygenation, perfusion, blood pressure, and airway management. Importantly, this document also advises the use of the Safe Surgery Checklist and a

**Table 2.4** Example of checklist for home discharge after digestive endoscopy under sedation

| |
|---|
| Stable vital signs for at least 1 h |
| Alert and oriented to time, place, and person (infants and patients whose mental status was initially abnormal should have returned to their baseline status) |
| No excessive pain, bleeding, or nausea |
| Ability to dress and walk with assistance |
| Discharged home with a responsible adult who will remain with the patient overnight to report any postprocedure complications |
| Written and verbal instructions outlining diet, activity, medications, follow-up appointments, and a phone number to be called in case of emergency |
| A contact person and circumstances that warrant seeking the assistance of a healthcare professional clearly outlined |
| Tolerating oral fluids not mandatory, unless specified by physician (i.e., patient is diabetic, frail, and/or elderly; not able to tolerate an extended period of NPO status) |

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**Table 2.5** Anesthesia providers, terminology, and training backgrounds

| | Description |
|---|---|
| Anesthesia provider | Any healthcare worker who provides anesthesia care, irrespective of professional background or moderate or deep training |
| Anesthesia | Refers to the administration of general or regional anesthesia or moderate or deep sedation independent of who provides the care |
| Anesthesiologist | A graduate of a medical school who has completed a nationally recognized specialist anesthesia training program |
| Nurse anesthetist | A graduate of a nursing school who has completed a nationally recognized nurse anesthetist training program |
| Non-specialist physician anesthetist | A graduate of a medical school who has not completed a specialist training program in anesthesia but has undergone some anesthesia training |
| Non-anesthesiologist providers | Includes non-specialist physician anesthetists, nurse anesthetists, and other providers |
| Other anesthesia providers | In many countries, anesthesia is provided by other health workers (e.g., anesthetic officers, technicians, or assistants) who have completed training recognized in their own countries |

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system for transfer of care at the end of an anesthetic. These latter two advisories are not often included in the sedation guidelines reviewed in this chapter and could represent a meaningful addition to most of the standards that have been promoted.

## Summary

The practice of sedation for children has advanced considerably over the last 50 years. Guidelines from a number of organizations have helped to guide care and improve safety of sedation provision. Given the variety of individuals involved in formulating these guidelines, it is remarkable that there is general agreement on the critical need for appropriate assessment and monitoring of these patients. There remains variability on the recommendations concerning the need for NPO intervals prior to sedation, but caution is advised by all of those involved in formulating sedation practice guidelines. 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. There continues to be a need for clinical trials with defined endpoints and outcomes that could answer some of the remaining areas of variability. Worldwide participation in these studies, involving all specialties, will establish safety data which could direct the creation of more unified sedation guidelines.

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