Abstract
The provision of sedation for children undergoing tests or procedures outside of the operating room has evolved significantly over the last 40 years. Professional societies around the globe have helped make this area of care safer by providing recommendations or guidelines for practitioners. Some organizations, such as the American Academy of Pediatrics (AAP), have published a series of these guidelines over the years that have adopted the most relevant information and newest technologies as they have developed. Most of the guidelines share common elements. They are intended to maximize the safety and effectiveness of sedation by defining the appropriate evaluation of patients, recommending strategies for sedation, outlining appropriate monitors for patients during sedation, and defining discharge criteria after the procedure/sedation is completed. In this chapter there is a detailed discussion of several of the historically most cited sedation guidelines for children and a brief review of a number of other organizational guidelines from around the world.

Keywords
Sedation • Children • Guidelines • International • Monitoring • Recommendations • American Academy of Pediatrics (AAP) • American Academy of Pediatric Dentistry (AAPD) • American Society of Anesthesiologists (ASA) • American College of Emergency Physicians (ACEP) • Joint Commission • Deep sedation • Monitored Anesthesia Care (MAC) • Center for Medicare and Medicaid Services (CMS) • American Dental Association (ADA) • American Society of Gastroenterologists (ASG) • Scottish Intercollegiate Guidelines Networks (SIGN) • Society for the Advancement of Anesthesia in Dentistry (SAAD) • South African Society of Anesthesiologists (SASA)

Introduction
The practice of pediatric sedation involves a wide variety of sedation providers and pediatric medical subspecialists. There are no “universally” applicable and acceptable guidelines that apply to all the physicians and nurses who are taking part in sedating children. 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 the evolution of North American and international guidelines, and put them into context and 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...
offering specific guidelines on the use of particular drugs or nil per os (NPO) intervals. There is variability in the manner in which different pediatric subspecialties (and different countries) have addressed the specifics of sedation care, but the common elements and considerations largely outweigh the differences.

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 [1–3]. 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 the American Society of Anesthesiologists (ASA) [4] and American College of Emergency Physicians (ACEP) [5–8] are founded on an evidence-based review of pediatric sedation literature and the methodologies are quite explicit. Even in these cases, however, the lack of definitive or comparative data on outcomes from sedation encounters necessitates that many of the guidelines are based on “consensus” rather than evidence.

This chapter will review the most recently published sedation guidelines of the various specialties in the United States and will then present the guidelines of some international specialties in order to provide comparison and contrast.

American Academy of Pediatrics Guidelines

In the United States, the AAP’s guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures [9] are the most widely 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 [10, 11], these guidelines remain of primary importance and have influenced the creation of safe sedation systems around the United States and internationally. Much of their lexicon and recommendations have been largely adopted by the Joint Commission and regulatory bodies in Europe and Australia 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 AAP 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 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”” [1].

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 that 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” and clarifying the fact that these guidelines apply to any location where children are sedated—in or out of the hospital. This set of guidelines use the terminology of “minimal sedation, moderate sedation, deep sedation, and anesthesia.” These descriptions of sedation levels have been adopted by the ASA, the Joint Commission, and multiple international organizations (see later). The addendum emphasized that sedatives should only be administered by those skilled in airway management and cardiopulmonary resuscitation [9].

The most current iteration of the AAP sedation guidelines was published in Pediatrics in December 2006 [3]. This document represents a significant landmark for the field of pediatric sedation. For the first time, 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.
The authors contend that 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 patient’s 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 [3].

This iteration of the guidelines emphasizes that 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 also include an interesting section on drug interactions and cautions on alternative medications such as St. John’s wort, kava, and echinacea and their possible impact on sedation provision. In regard to propofol, they do not make any statement or recommendation on its administration, either by anesthesiologists or nonanesthesiologists.

Monitoring requirements are based on the depth and setting of sedation. 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., magnetic resonance imaging (MRI)) to aid in monitoring adequacy of ventilation” [3]. Capnography is “encouraged” but not required, particularly in situations where other means of assessing ventilation are limited.

These guidelines suggest that predicting the exact depth of sedation (other than minimal sedation) that will result from the administration of a sedative drug is impossible. In light of this fact, the authors make recommendations on fasting (NPO) status, which assume airway protective reflexes could be lost at any time during a moderate or deep sedation and therefore mirror the recommendations made for patients undergoing anesthesia.

**NPO Guidelines**

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

*Note:* These guidelines state that in urgent/emergent sedation situations, the benefit of waiting for appropriate NPO intervals must be weighed against the necessity of the procedure [3].

Finally, recovery criteria and considerations are 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).

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### American Society of Anesthesiologists 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 non-anesthesia 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”
- “Standards for Basic Anesthesia Monitoring”
- “Statement onGranting Privileges to Nonanesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who Are Not Anesthesia Professionals”

The “Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists” [4] is probably the most widely quoted document concerning sedation the ASA has produced. The latest iteration of this document was published in 2002 [4] as an update/revision of the original 1996 guidelines [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 electrocardiogram (ECG), blood pressure, and pulse oximetry for all deep sedation patients. In contrast to the AAP, the ASA places more emphasis on capnography, stating that capnography should be considered, but is not required, for all patients receiving deep sedation and for patients whose

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1. All statements and other documents available at: [http://www.asahq.org/publicationsAndServices/sgstoc.htm](http://www.asahq.org/publicationsAndServices/sgstoc.htm).
ventilation cannot be directly observed during moderate sedation. Continual monitoring of sedation depth through stimulation/response analysis is also recommended.

In 2005 the ASA published 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:

1. Anesthesia Professional—anesthesiologist, certified registered nurse anesthetist (CRNA), anesthesiologist assistant (AA)
2. Nonanesthesiologist Sedation Practitioner—other physicians, dentists, podiatrists
3. 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 [13].

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 advocated the limitation of the administration of deep sedation to those practitioners with anesthesia training: Specifically they state that this practice should be limited to those practitioners who are qualified to administer general anesthesia or to appropriately supervise anesthesia professionals [14]. This individual should have no other responsibilities except to deliver sedation and monitor the patient throughout. The “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 advisory 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 oropharyngeal airway and laryngeal mask airway, and perform an endotracheal intubation. The advisory states that training for these individuals should include a minimum of 35 patients, inclusive of simulator experience. Practitioners should be familiar with the use and interpretation of capnography. Finally, this document recommends that deep sedation of children requires Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) certification as well as separate education training and credentialing in sedation.

Most recently, in October of 2012, the ASA passed an amendment of its original (2006) advisory on deep sedation by nonanesthesiologists. In this iteration the statement is 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” [16]. This guideline goes on to advise against nonanesthesiologists delegating or supervising the administration of sedation by individuals who are not similarly qualified [16].

In 2011, the ASA amended the Standards for Basic Anesthesia Monitoring (first published in 1986) to specify that during moderate and deep sedation, ventilation should be followed by clinical observation and capnography [17]. Exceptions to capnography would be situations whereby patient, procedure, or equipment precludes or invalidates the monitoring.

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 [18] limits deep sedation to be delivered only by an anesthesiologist, nonanesthesiologist MD or DO, dentist, oral surgeon, podiatrist, CRNA, or anesthesia assistant [18, 19].

The CMS guidelines regarding nonanesthesiologist 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 that 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 Safe Use of Propofol” first published in 2004 and amended in 2009, 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” [20].

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 Monitored Anesthesia Care (‘MAC’) from Moderate Sedation/Analgesia (Conscious Sedation)” to differentiate between the two levels of care [21]. 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 as well as to convert to a general anesthetic. This is distinguished from those who administer moderate sedation where one would not expect progression to a condition in which the patient could not maintain his own airway [21].
The Joint Commission: Where We Stand Now

Issues relating to sedation (in general) and pediatric sedation (specifically) are found in a variety of locations in the Joint Commission Handbook and website. The JCAHO 2004 Comprehensive Accreditation Manual for Hospitals was intended to set the standards for sedation and anesthesia care for patients in any setting [22].

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 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 [22]. 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” [23]. 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” [23]. 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” [23].

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) has put forward a wide range of statements, clinical practice advisories, and clinical policy statements concerning sedation. The 2008 American College of Emergency Physicians Policy Compendium includes a statement “Procedural Sedation in the Emergency Department” [24]. 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 by emergency physicians.”

In 1998 and 2005 the ACEP published “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 that should include a patient who has achieved general anesthesia. The ACEP considers these skills, including the administration of deep sedation, to be a fundamental part of the emergency medicine training curriculum of all board-certified emergency physicians [7, 25].

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 nonelective sedation case. 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

2http://www.jointcommission.org
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 appropriate 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 [26, 27]. Previous publications from the ACEP have concluded that there is insufficient evidence to conclude that fasting actually changes outcome for sedation (see previous) [28].

In 2006, ACEP produced a document on fasting prior to sedation [29]. 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 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 versus emergent/urgent/semiurgent nature of the case versus duration of the procedure.

Table 2.1 schematically describes the recommendations that result from these guidelines [29]. It is important to note the guidelines for nonelective 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, the emergency physician must weigh the risk of pulmonary aspiration and the benefits of providing procedural sedation and analgesia in accordance with the needs of each individual patient” [7, 29].

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” [28]. The “Critical Issues” statement supported earlier recommendations on NPO status and reviewed the use of sedatives including 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 [30, 31].

Other ACEP publications include a clinical practice advisory on propofol use in the emergency department [25], 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 previously [5]. The ACEP recommendations for physiological monitoring also differ 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 to be a monitor that may allow more rapid identification of hyperventilation than pulse oximetry alone [32].

In February 2014, the ACEP released the most recent clinical policy to date. Entitled “Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department,” it updates the 2005 policy [33]. This paper highlights the value of designing studies to specifically examine patient-specific outcomes. It also recognizes that unique patient-care environments and high-risk patient populations may pose unique challenges which may require modification of the clinical policy. Reviewing the literature, the College of Emergency Physicians Clinical Policies Committee made evidence-based recommendations for important clinical questions. The following questions were addressed [33]:

1. Is preprocedural (nil per os/NPO) fasting necessary to decrease risk of emesis and aspiration during sedation in the emergency department?
2. Does capnography decrease risk of adverse events?
3. How many personnel are necessary to manage sedation-related complications?
4. Are ketamine, propofol, etomidate, dexmedetomidine, alfentanil, and remifentanil appropriate sedatives for the emergency department?

The clinical policy was based on literature review, with recommendations identified as levels A, B, and C. The levels were determined from the degree of clinical certainty after review of the literature. High certainty, moderate certainty, and inadequate/absence evidence corresponded to levels A, B, and C recommendations, respectively. The importance of NPO was a level B recommendation, advising that there was no evidence to support preprocedural fasting of children for procedural sedation in the emergency department. The routine use of capnography was assigned a level B recommendation,
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**HIGHER RISK**

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**Procedural Sedation and Analgesia Targeted Depth and Duration**

- **Brief**: <10 min
- **Intermediate**: 10–20 min
- **Extended**: >20 min
recognizing that as an adjunct to pulse oximetry, it may detect hypoventilation and apnea earlier than pulse oximetry or clinical assessment. The recommendation for the number of personnel necessary to manage sedation-related complications was a level C—without supporting evidence, the recommendation was that in addition to the provider performing the procedure, a nurse or other qualified individual needed to be continuously present. The final recommendations with respect to sedatives were levels A, B, and C. Ketamine and propofol were considered level A recommendations, deemed safe for pediatric sedation in the emergency department. Etomidate for children was considered level C, supported with expert consensus, despite absent/inadequate supporting published literature. The combination of ketamine and propofol was considered level B for safe pediatric sedation in the emergency department. No recommendations could be made for dexmedetomidine, as there is only one case report of its use in the emergency department.

**American Dental Association Sedation Guidelines**

The American Dental Association (ADA) guidelines regarding sedation are posted on its website [34]. The guideline acknowledges 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 Basic Life Support (BLS) Course for the Healthcare Provider. There are two requirements 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 (2) a current certification in both BLS for Healthcare Providers and 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 PALS in addition to directed pediatric training and education [35, 36].

The guidelines are presented in sections, each of which relates to a sedation level: minimal, moderate, and deep sedation. Specific recommendations are given for training of sedation providers, preoperative preparation of patients, monitoring and documentation, recover and discharge criteria, and personnel/equipment requirements. For children 12 years of age and under, the ADA refers to the AAP/American Academy of Pediatric Dentists (AAPD) Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures that was discussed earlier in the AAP section [3, 37]. These guidelines address some issues unique to the office-based dental practice and to the special needs child. If the dental patient 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 should document the reasons preventing the recommended preoperative assessment prior to administering sedation [3]. In addition, recognizing the long history of nitrous oxide use in dentistry, this document specifically mentions it as an acceptable sedative, alone or in combination with other sedatives [3].

In 2012, AAPD published a revision of its “Guideline on Use of Anesthesia Personnel in the Administration of Office-based Deep Sedation/General Anesthesia to the Pediatric Dental Patient” [38]. This document reaffirms 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. It further recognizes that when this 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. The authors are careful to define the aspects of training that are required in order to deliver this care. Specifically, the provider must have completed a 1- or 2-year dental anesthesia residency approved by the ADA or a medical anesthesia residency as approved by the AMA. This provider must be licensed in the state where the care is provided. Emergency preparedness must be updated and practiced on a regular basis and recovery must be monitored by an experienced provider at all times until the patient has met discharge criteria. There is a directive that the facility must meet the standards for anesthesia delivery as set by state or local codes and the “Guidelines on Monitoring and Management of Pediatric Patients During and after sedation for Diagnostic and Therapeutic Procedures.” The new document concludes by reinforcing the need for appropriate pre-, intra-, and postoperative documentation as well as ongoing quality assurance standards.
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 [39]. 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 as follows.

The first guideline was published in 2002 and entitled “Guidelines for the Use of Deep Sedation and Anesthesia for GI Endoscopy” [40]. 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 including guidelines for the indications and use of droperidol (in addition to midazolam and fentanyl) and propofol for deep sedation during endoscopy. 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 versus benefits of its use in endoscopy. Personnel preparation and monitoring requirements for propofol sedation are carefully delineated [40]:

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, it 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), increased risk for airway obstruction because of anatomic variant. These final recommendations are included at a “C” level.

A second publication, “Guidelines for Conscious Sedation and Monitoring during Gastrointestinal Endoscopy,” was published in 2003 in the journal *Gastrointestinal Endoscopy* [41]. It 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. The authors 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 reviewed along with droperidol and promethazine. Unique to this set of guidelines, “pharyngeal” anesthesia is reviewed. Specific mention is made of the risk of methemoglobinemia when excessive benzocaine is administered to the mucosa. In reference to deep sedation, the authors suggest that propofol is superior to standard benzodiazepine/opiate sedation for complex procedures. On the other hand, the authors recognize that its use in routine upper and lower endoscopic procedures is controversial with little proven benefit over standard moderate sedation [41].

The most recent and pertinent publication regarding sedation specifically for pediatric endoscopy was published in 2008 as “Modifications in Endoscopic Practice for Pediatric Patients” [42]. 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 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 included, such as the fact 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. Therefore the routine use of oxygen is recommended 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 [42, 43]. 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 [44]. 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 [45].

In 2009, the American Society of Gastroenterologists (ASG) published their position statement for nonanesthesiologist administration of propofol for GI endoscopy [39]. 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 [39]:

1. All sedation 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.

**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 of these guidelines are consistent with the recommendations from the AAP and ASA, others are not. 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) [46]. This document was written after a comprehensive review of the best available evidence and expert opinion. The recommendations are wide ranging and include the mandate for a full presedation 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 presedation assessment. These referral indications include ASA status 3 or greater, airway difficulties, and all infants and newborns. Notably, these recommendations include an extensive description of available sedation techniques. The authors include a section that recommends specific drugs and drug combinations for sedation encounters based on the targeted level of sedation, the procedure, and patient/family preference. Contraindications for sedatives are also covered. Recommendations concerning other elements of sedation practice, such as choosing appropriate resuscitation equipment, personnel, and informed consent, follow closely with the guidelines put forward by the AAP and ASA.

Chapters 18 and 25 detail the most recent sedation guidelines from the Dutch Institute of Healthcare Improvement in the Netherlands (2011) [47], the Endoscopy Section of the German Society for Digestive and Metabolic Diseases (2009) [48] and the adult and pediatric guidelines of the South African Society of Anesthesiologists (2010 and 2011) [49, 50].

Notable sedation statements and guidelines published worldwide include:


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 versus dentistry versus radiology versus emergency medicine. There is also 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.

**Australasian College for Emergency Medicine, Australian and New Zealand College of Anesthetists. “Statement on clinical principles for procedural sedation”** [52]

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.
Canadian Consensus Guidelines. Canadian Association of Emergency Physicians “Procedural sedation and analgesia in the emergency department” [53]

This is a slightly dated consensus statement conceived in conjunction with the Canadian Association of Anesthesiologists. It outlines general principles of safe sedation in line with those mentioned previously, including assessment of the patient, facility preparation, training of providers, fasting status, and recovery. This document also includes an example of a sedation record, which is somewhat unique. While no specific sedation regimens are recommended, there are useful links to other publications that involve sedation recommendations.

British Society of Gastroenterology “Recommendations for standards of sedation and patient monitoring during gastrointestinal endoscopy” [54]

An older set of recommendations for sedation that is intended for a general population, not strictly for children. This document is focused primarily on basic safety issues including the use of appropriate monitoring, record keeping, equipment, and personnel. There is a specific recommendation to evaluate patients for “risk factors” and the authors include a helpful checklist to aid in this assessment. Strategies for sedation are not outlined, although there are general statements that the dosage of all drugs should be kept to the “minimum necessary” and antagonists (for benzodiazepines and opiates) should be available.

Society for the Advancement of Anesthesia in Dentistry (SAAD) Standards in Conscious Sedation for Dentistry [55]

This is a set of general standards that were written for adult and pediatric patients care. The standards are meant to apply to any setting in which “conscious” sedation is being provided for dental patients. The authors define conscious sedation as “A technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The level of sedation must be such that the patient remains conscious, retains protective reflexes, and is able to understand and respond to verbal commands.” The standards do not define other levels of sedation except to point out that “Any technique resulting in the loss of consciousness or abolition of protective reflexes is defined as General Anesthesia.”

General guidelines for education and training of providers include the need for “practical training in the use of drugs and equipment.” There is also a mandate for training in the management of conscious sedation-related complications, although no guidance is given as to how or what situations should be tested. All members of the sedation team are recommended to have basic life support training. Supervised, hands on experience must be acquired by the sedation providers and their assistants in each of the conscious sedation techniques used. The setting, timing, and number of these experiences will vary with local circumstances but the authors advise that the experience should be commensurate with those specified by “appropriate authorities.”

These standards also contain general recommendations for specific equipment—such as the inhalation relative analgesia machines and intravenous equipment that could be used for sedation. The authors of these standards go further to state that a clinical assessment of the patient is required and should result in an ASA classification as well as consideration of any “absolute contraindications” for sedation, although these are not defined. Consent for sedation is outlined along with a detailed description of the need for supervision and transportation requirements after sedation.

A sizable portion of these standards is left to a discussion of techniques for sedation, which include oral, inhalation, or intravenous sedation. Inhalation sedation is limited to titrated doses of nitrous oxide. Intravenous sedation is described as a dose of benzodiazepine, however the authors mention that propofol infusion “has become popular in recent years.” (No warnings about this practice or special requirements are included.) Oral/intranasal/transmucosal sedation is mentioned, and midazolam and temazepam are cited as drugs that produce sedation by this route.

Monitoring is mentioned in general terms. Clinical monitoring of “color, pulse, and respiration is of particular importance.” No electromechanical devices are required for this purpose for inhalation induction—few other details are offered.

For the purposes of this document, “children” are considered as any patient under the age of 16. There is very little detail offered concerning special requirements for the care of children except the warning that children have different responses to sedation and teams that deliver sedation to children should be trained and have experience in this age group.

Neuroanesthesia and Neurointensive Study Group of the Italian Society of Anesthesia “SIAARTI-SARNePI Guidelines for sedation in pediatric neuroradiology” [56]

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 presedation evaluation. NPO 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 during procedures performed on children. Capnography is recommended, although the authors recognize the lack of clear evidence for outcome improvement with this monitor. 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, computed tomography (CT) scans, and MRI.


This is a very brief guideline of sedation specific to the gastroenterology field. There are many references, but the methodology involved in coming up with specific statements is not explained. The authors include a brief discussion of risk factors for patients (and those that might be designated “difficult”) and a review of the specific procedures and terminology that is involved in gastroenterology. The authors include a significant section on the use of propofol and cite several studies that support the use of propofol by nonanesthesiologists (including trained nurses) for endoscopic procedures. The document concludes with some specific comments on the need to assure full recovery prior to discharge.

South African Society of Anesthesiologists “Guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2010” [58]

This is a 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.

These guidelines begin with an interesting listing of the defined levels of sedation that is a blending of the AAP and ACEP levels of sedation. The list includes the various levels defined by the AAP and ASA, but adds the level of “dissociative sedation” which is aimed at the sedation provided by ketamine. The state is defined as one where spontaneous breathing and cardiovascular stability are maintained. The section includes the statement that this anesthetic state “does not operate on the sedation continuum.” The statement goes on to define “simple sedation” as that provided by single oral or transmucosal medications and contrasts this to “advanced sedation,” which includes sedation with multiple medications or that given by the intravenous or inhalational route. “Failed sedation” is also defined and includes sedation that fails to achieve the desired level of sedation and results in the procedure being abandoned. The guidelines go on to specifically define patients that require a presedation evaluation by an anesthesiologist or a “highly experienced sedation practitioner.” These patients include those of young age <1 year, as well as those with specific comorbidities such as congenital syndromes or congenital heart disease. The balance of the document includes an extensive section on the presedation patient assessment, NPO guidelines (same as AAP), and a detailed description of a wide variety of sedation medications—ranging from minimal sedation with oral midazolam to deep sedation/anesthesia (propofol). There is a review of the key elements of the sedation environment—which are independent of the setting (office versus hospital)—and monitoring requirements. The authors advise that even patients who are under simple sedation require someone other than the procedure operator to monitor the patient and those undergoing advanced sedation should have a separate individual who is responsible for the administration, monitoring, and rescue of the patient. This individual is recommended to be a medical practitioner. Discharge criteria are described. These are the most safety oriented and conservative of any guidelines currently published. They include the recommendation of the use of maintenance of wakefulness criteria such as the ability to keep eyes open for at least 20 min. The authors include a unique and thought-provoking discussion of the various adverse events associated with the sedation of children and subdivide these events into those attributable to the procedure, the skills of the sedation provider, and the environment. The final portion of the document includes a discussion of strategies for sedation aimed at specific procedures or tests.

Sedation Guidelines for Gastrointestinal Endoscopy (2008) of German Society for Digestive and Metabolic Diseases [59]

This is a very detailed document available only in German. The authors begin with a discussion of all safety-related issues such as patient evaluation, monitoring, and resuscitation concepts. The majority of these guidelines involve a detailed discussion of the use of various drugs and combinations for sedation. Propofol is featured with a significant section to the literature supporting nurse-delivered propofol sedation as well as a review of literature comparing propofol to other sedatives for endoscopic procedures. There is further discussion of propofol target-controlled
infusions for endoscopic sedation as well as propofol computer-assisted personalized sedation. Later sections review the use of benzodiazepines and opiates alone or in combination with other medications. The guidelines conclude with a discussion of complications of sedation for endoscopy and treatment of complications. The authors include 232 references.

“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 GI Endoscopy” [60]

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.

Lago P, Garetti E, Merazzi D, Pieragostini L, Ancora G, Pirelli A. “Guidelines for procedural pain in the newborn” [61]

These guidelines were written with the intent of informing the Italian neonatology community about the most up-to-date, evidence-based information on the management on neonatal patients who are undergoing procedures. While not strictly sedation related, the guidelines do address the management of procedural stress and pain—and some sedatives are described. The authors outline a very careful review of the current literature at the time of publication and their methodology for “weighting” the evidence. They outline sensible “principles” for management of neonates during procedures—such as optimizing the environment, use of sucrose, and distraction techniques. Finally, they advise waiting for a baseline state of quiet restfulness prior to beginning a procedure and limiting the number of sequential procedures that a neonatal patient experiences in any one time period. The bulk of these guidelines describe optimal management of one procedure at a time starting with heel lancing, venipuncture, central venous catheter insertion, tracheal intubation, lumbar puncture, chest tube insertion, and ending with screening examinations for ROP. In each case, the pertinent literature on environmental, behavioral, and pharmacologic interventions are cited and rated according to significance. There is a sensible emphasis on the use of local anesthetics and titration of pharmacological agents as needed.

In an era where the appropriate treatment for pain in this age group is uncertain, these guidelines offer a well-researched and reasonable approach to management.

Consideration of these various guidelines leads to the inevitable conclusion that there is more agreement than disparity among the opinions and recommendations that are presented internationally. Almost all of the guidelines focus on careful assessment and risk stratification of patients. All are careful to advise appropriate monitoring, rescue systems, and recovery when sedating children. The primary area where there is lack of agreement lies in the use of specific medications for sedation—and in particular with deep sedation involving potent opioids and propofol. As an example, we can consider the Scottish National Guidelines of 2004, which were written only for minimal and moderate sedation, as anything beyond this (deep sedation included) is recommended for an anesthesiologist and is treated as a general anesthetic [51]. On the other hand, guidelines from the Austrian Society of Gastroenterology and the German Society for Digestive and Metabolic Diseases [57] point specifically to literature that supports the use of propofol by nonanesthesiologists for endoscopic procedures and recommends the practice.

Conclusion

The delivery of sedation for children has advanced considerably over the last 40 years. Similarly, 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. Most agree on the important aspects of sedation safety and monitoring. On the other hand, there is a lack of consensus on the duration of NPO status for sedation and whether nonanesthesiologists should administer deep sedation with propofol. Future efforts should be aimed at designing clinical studies with defined endpoints and outcomes. Worldwide participation in these studies, involving all specialties, could establish safety data that would allow the creation of more unified sedation guidelines. Unified recommendations from the AAP, ASA, AAPD,
ADA, the Joint Commission, ACEP, and American Society of Gastroenterologist, together with the different specialty societies worldwide, would offer a landmark first step in the advancement of pediatric sedation.

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