

PREFACE

Pharmacologically induced sedation has become pervasive throughout medical practice to accomplish diagnostic and minor therapeutic procedures effectively and humanely. As diagnostic techniques and technical procedures become more complex, the need for sedation in patients with varied co-morbid conditions, in diverse settings produces a series of questions regarding safety and effectiveness. The administration of sedation and analgesia for diagnostic and therapeutic procedures has therefore evolved into a unique discipline that is practiced by clinicians with varying skills and training. Disparities in sedation practices have led regulatory agencies to mandate that patients receive the same standard of care regardless of the location in which the care is provided within an institution. To ensure that the standard of care is of high quality, institutions are required to develop guidelines for the practice of sedation, ensure that these guidelines are followed, and provide quality data and outcome measures. In addition, practitioners who administer sedatives and analgesics specifically for a diagnostic and/or a therapeutic procedure require specific credentials for this practice.

It is the intent of *Sedation and Analgesia for Diagnostic and Therapeutic Procedures* to review sedation and analgesia from a wide variety of perspectives starting with the basic neurobiology and physiology of the sedated state, proceeding through clinical guidelines and practices, and concluding with a section on quality-outcome measures and processes. The practical aspects of this book have been further emphasized by incorporating a series of tables and figures in each chapter that highlight protocols, regulatory requirements, recommended dosages of pharmacologic agents, monitoring requirements, and quality assurance tools. The target audience for this text spans multiple disciplines that range from investigators, physicians, and nurses to hospital administrators.

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Practice Guidelines for Pediatric Sedation

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1. INTRODUCTION

The sedation of children for diagnostic and therapeutic procedures has undergone quite an evolution from the days of “DTP (demerol, thorazine, phenergan) cocktail” without monitoring. Although the use of sedation for infants and children is often motivated by a desire to avoid both physical and psychological trauma, these goals must be tempered by the realities of risk and safety. Prior to the 1980s, there was often little or no awareness of the potential consequences of effects and interactions of sedating drugs, outside the specialty of anesthesiology. Practitioners had minimal recognition of the potential hazards of oversedation, including loss of airway, aspiration, and cardiorespiratory compromise. Concerns about recovery and premature discharge were either rarely acknowledged or ignored. Unfortunately, such an attitude may persist today, although there has been increasing recognition that sedation of infants and children can carry the same inherent risks as general anesthesia. In response to the publicity surrounding “sedation disasters,” specialized societies dedicated to the care and safety of children have developed guidelines to provide a framework for the safe provision of sedation. The guidelines deal with the use of various sedating agents, as well as the environment in which the sedation is administered, monitoring of patients, patient selection, and the responsibilities of practitioners who administer the agents. There has been an attempt to tighten and restrict the use of terminology and definitions that have been used loosely and inaccurately in the medical literature. Several different sets of guidelines have been promulgated by different specialty groups, which have attempted to address the issues of safety and standards of care. These guidelines are not all the same, however, and it is instructive and important to understand the differences between them and to recognize their potential shortcomings and limitations. This chapter examines the practice guidelines written specifically for pediatric sedation and discusses how they should be

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used in developing an institutional policy and plan, and how the systems or organizational approach to the implementation of sedation guidelines may decrease risk and increase safety.

2. HISTORY AND BACKGROUND

Until the 1980s, there was little oversight or attempt to organize and scrutinize the practice of sedation. Prompted by a series of disastrous outcomes following sedation during dental procedures, the American Academy of Pediatrics (AAP) requested that its Section on Anesthesiology offer guidance in developing a set of guidelines that were eventually published by the Academy in 1985. This document was authored by representatives from the Section on Anesthesiology, the Committee on Drugs, and the American Academy of Pediatric Dentistry (AAPD), and was entitled "Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia." This title was chosen to emphasize that there was a continuum between these three states. It became clear to the Academy and to the authors of the original document that a revision was needed to address other concerns and issues that were not adequately clarified. It was apparent that discharge criteria were a major problem, and that a number of adverse outcomes could be blamed on inadequate recognition of when a child was "street ready" (1). For this reason, the title of the revised document was changed to reflect the importance of applying the guidelines both during and after the administration of the sedating agents (2). There were also a plethora of papers appearing in the medical literature on the subject that stretched the definition of "conscious sedation" beyond credulity (3,4). The use of numerous anesthetic agents at doses that result in varying planes of general anesthesia was commonly described as sedation in an apparent attempt to extend the boundaries of practice (5,6). For this reason, the strict definitions of "conscious" and "deep" sedation were given special emphasis. Many other aspects of the guidelines were revised to reflect the reports of complications that were culled from the literature, adverse drug reports, and popular press, in an attempt to address the systems problems that led to adverse outcomes.

The guidelines were not met with uniform acceptance. Many of the prescribers of sedation believed that the guidelines were overly burdensome and represented an intrusion on practices they believed to be safe based on historical impressions, despite mounting data to the contrary. Clearly, the purchase of monitoring equipment and the use of trained observers imposed additional costs on both individual practitioners and institutions. Ever-increasing financial pressures from diminishing third-party reimbursement added to this problem. The reference in the title of the guidelines to "general

anesthesia” unfortunately led to the impression by some physicians that the guidelines did not apply to them because they did not administer general anesthesia (this led to the change in the title of the revised guidelines of 1992). Other specialties and subspecialties published their own sets of guidelines in response to the AAP guidelines (7–9). It is the belief of some physicians that these latter sets of guidelines are attempts to redefine the standards of practice to fit within the traditionally accepted practices of those specialties (10). Whether there are data to support these alternative guidelines, or whether the potential consequences of adopting looser standards are worth the risks in situations where adequate data are not available, will be examined later in this chapter. It should be recognized from the outset that clinical and outcomes-based considerations are clearly not the only factors involved here, and that several specialties have staked out claims to what has traditionally long been the purview of the anesthesiologist. This has created an environment that is laden with political and financial implications, which have tended to cloud the objectivity of much of the “research” that has been published.

3. WHY GUIDELINES?

The need for guidelines has been disputed, in most cases by clinicians who have been prescribing sedating medications for years without recognized or perceived mishaps. In many cases, the development of national guidelines has been viewed as an intrusion and a limitation of medical practice and physician autonomy. There is little outcome-based data on which to base many of the guidelines, and that which exists has significant limitations of power and methodology. So why promote them at all? It is recognized by all that adverse events in sedation are infrequent (11). An individual clinician may see them only rarely, although the precipitating events that have the potential to lead to catastrophic outcomes may occur, albeit unrecognized, far more often (12). This is a particular problem in infants and children, especially in adult or general hospitals, where the volume of pediatric cases may not approach that of a large children’s hospital. Furthermore, adverse events may be defined differently by clinicians with various levels of risk acceptance. At a recent hospital sedation committee meeting, the author was stunned to discover that one group of clinicians did not consider respiratory depression severe enough to require the use of naloxone as an adverse event—this was simply considered routine practice. Such perceptions clearly impact on the reporting of complication rates.

Many of the improvements in patient safety, and the reduction of adverse events in medicine over the past 25 years, have come through advances in

anesthesia practice. The report of the Institute of Medicine (IOM) not only recognizes this, but suggests that similar methodologies and strategies can be generalized to other areas of medical practice as well (13). Two prime factors in the reduction of risk in anesthesia have been (i) the advances in monitoring technology and the routine application of monitoring to provide early detection of adverse events before they affect physiologic stability and (ii) the aggressive use of risk reduction strategies in patient care. The philosophy in anesthesia practice has been to be exceedingly cautious in addressing various potentially risky situations, whether it is the patient with the risk of a full stomach, the use of halothane in adults, or the routine use of succinylcholine in children. This same philosophical view is embodied in the idea of using guidelines for the practice of sedation in pediatric patients. The overriding approach embodies several axioms:

1. Adverse events occur rarely, but inevitably.
2. Although an individual practitioner may not see a significant number of these events, in the national aggregate they occur frequently enough, or have severe enough preventable sequelae, that a change in practice is deemed desirable.
3. Because these events will invariably occur, a systems approach to prevention and detection is most effective.
4. In order to reduce adverse outcomes, practices must be implemented that will reduce the incidence of these events and provide early detection of the events. This means both avoiding and eliminating practices with excessive risk and using appropriate observation and monitors.

Guidelines are a foundation of the systems approach, which seeks to promote safe practices that result in both risk reduction and early detection of adverse events.

4. PRACTICE GUIDELINES

Numerous sedation guidelines have been promulgated in the United States by various organizations. Only two deal specifically with pediatric patients, and both are from physician specialty organizations. There are other guidelines that impact on pediatric patients, two from physician specialty organizations and one from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO). This section examines the AAP guidelines as a prototype—because it was the first document to specifically address the sedation of children, and thus served as template for others that followed, and also because several of the subsequent documents were published as reactions to the AAP guidelines. This chapter examines the AAP guidelines in detail, and discusses the other guidelines and how they differ. The guidelines not written specifically for pediatric patients are addressed elsewhere

in this volume, but issues especially relevant to pediatric practice are discussed here, particularly when they are in conflict with the AAP guidelines.

4.1. American Academy of Pediatrics Guidelines (1992 revision)

The current AAP guidelines, authored by the Committee on Drugs, have attempted to deal with issues that were left ambiguous or were not addressed in the first version. Monitoring—the use of observation and devices for the early detection of adverse events—and the skills and responsibilities of the clinician, are the primary focus of this document. The guidelines emphasize that sedation is a continuum, which ranges from “conscious sedation” to general anesthesia, and that monitoring must be geared to the depth of sedation. The crucial complications of respiratory depression and loss of airway reflexes and stability are explicitly acknowledged as potential events in any infant or child who is sedated. These risks are emphasized, not minimized, so that the practitioner is encouraged to maintain a heightened sense of vigilance at all times. Monitoring standards must not be selected solely on the basis of the anticipated usual effect of the drug administered, but rather based on the actual effect observed. This is an essential point in the AAP guidelines that cannot be overemphasized. The guidelines require that the monitoring reflect the level of consciousness of the child, and that the monitoring be used to detect early events that might progress to significant complications without intervention. The guidelines further recognize the inability of a single person to both perform the procedure and simultaneously closely observe the patient. The importance of an independent observing clinician is emphasized.

The guidelines first clearly define the terms that are used in the document. This is crucial, since ambiguities in terminology, both intentional and unintentional, became a rampant problem in the literature that followed the initial AAP guidelines. The AAP defines three levels of sedation:

- *Conscious sedation*, a state in which consciousness is medically depressed, but a patent airway and protective airway reflexes are maintained independently at all times. The patient exhibits appropriate and purposeful responses to stimuli or verbal command. These responses do not include reflex withdrawal.
- *Deep sedation*, a state in which the patient is not easily aroused and may be unconscious. There may be partial or complete blunting of protective reflexes, and the patient may or not be able to independently maintain a patent airway. Purposeful response to stimuli may not be present.
- *General anesthesia* is defined as “a medically controlled state of unconsciousness accompanied by a loss of protective reflexes, including the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.”

This classification scheme was not promulgated to strictly classify the condition of a sedated patient. The guidelines emphasize that these levels are in reality a continuum, and that a patient may easily pass from one level to the next. The levels are identified in order to define appropriate levels of physiologic monitoring, not to strictly categorize the effects of a particular drug or sedation regimen. This distinction is an important difference from several other sedation guidelines. The AAP guidelines recognize that no particular agent can be expected to produce consistent results in every patient, and that it is the response to an agent, not the use of a specific drug, that determines the patient's level of sedation and thereby dictates the level of monitoring. The definition of general anesthesia may be problematic, as some have inferred from the guidelines that a state of general anesthesia does not exist if a patient has the ability to independently maintain a patent airway, a contention that is obviously not accurate. Such an implication was not the intent of the definition, but it demonstrates that these definitions, even when very carefully crafted, can create ambiguities that the authors did not anticipate. Despite the clarity and precision of the definition of terms, the use of "conscious sedation" remains problematic, because the term has entered the lexicon, where it continues to be frequently misused to describe deeper states of sedation (14). It would probably be best if this oxymoron is retired and replaced with "moderate sedation," the term adopted in the most recent JCAHO standards (15).

The guidelines also clearly define the levels of imperatives in the language of the document: which items are mandated, and which items are suggested, yet may have alternatives that can be employed.

The AAP guidelines are directed at personnel who provide sedation and are not trained in anesthesiology, and thus advise that patients undergoing sedation be American Society of Anesthesiologists (ASA) physical status I or II, and that physical status III and IV patients require special consideration. Back-up facilities and services must also be clearly identified; these systems must be in place so that a defined plan of action can be immediately implemented if complications develop. The proper and appropriately sized equipment to provide resuscitation from both respiratory and circulatory complications is required in the sedating location. These items include a system for the delivery of positive pressure ventilation and supplemental oxygen ($\text{FiO}_2 > 0.90$), suction apparatus, airway equipment in varied sizes, and drugs necessary for resuscitation. It is emphasized that the equipment and supplies must be immediately available to the sedating clinician, and that they must be regularly checked and maintained. A list of suggested drugs and equipment is appended to the guidelines.

Documentation of both the pre-sedation evaluation and the intra-operative events are mandated by the guidelines. Proper informed consent must be obtained, as the administration of sedating drugs is not without risk, and the parent or guardian must understand the benefits and risks in order to permit the administration of these agents. A history, physical examination (with special attention paid to the airway) and review of the patient's medications is required. The ASA Physical Status score (listed in an appendix) should be assigned. The parent or guardian must be issued instructions regarding the care required following the completion of the sedation, and they must be able to contact medical help at any time should problems arise in the post-sedation period.

Fasting (NPO) status is referenced in the appendix of the document. The risks of sedation, loss of airway reflexes, and aspiration of gastric contents are acknowledged. The standard recommendations for NPO times in elective cases are cited, with 2-h fasting times for clear fluids, and 4-, 6-, and 8-h fasting times for other foods and liquids for ages 0–6 mo, 6–36 mo, and greater than 3 yr, respectively. These recommendations are well supported by data in the literature (16–18). The problem of a full stomach in emergency cases is discussed. The AAP guidelines recommend (i) delaying the sedation, (ii) the use of pharmacological means to enhance gastric emptying and raise gastric pH, or (iii) consider securing the airway when the case cannot be postponed and the stomach cannot be effectively emptied.

From the time sedation commences until discharge criteria are met, documentation of vital signs and the level of consciousness, drugs administered, and inspired oxygen concentration is required, using a time-based record. The record must also document any significant clinical events that occur during this period. At recovery, the record must document return to baseline vital signs and level of consciousness, and a note stating that the child is deemed ready for discharge from care must be entered in the chart. The criteria for discharge are found in an appendix to the guidelines, and include the return to baseline mental status and cardiovascular stability. The responsible adult must be issued post-sedation instructions. Strict criteria for discharge are particularly important in view of the number of sedation complications that have been reported from premature discharge and subsequent airway obstruction and respiratory arrest (12).

The AAP document next describes specific guidelines for the three levels of sedation previously defined. The continuum of sedation concept is reiterated, and the clinician is reminded to be prepared to escalate the level of monitoring if that occurs. Both conscious and deep sedation require an independent monitor to observe the patient, assess vital signs, administer drugs,

and attend to the airway. For conscious sedation, the guidelines list this person under the heading of “support personnel”, and for deep sedation this person is listed under “personnel”, implying a greater level of vigilance and dedication to that single task. The conscious sedation requirements include the practitioner performing the procedure in question as part of the monitoring and sedation care team; for deep sedation, the practitioner is not mentioned, and all of the sedation tasks fall to the independent sedating clinician. The emphasis on “constant observation” in the deep sedation section and the emphasis on the observation of the airway further reinforce that idea, and the wording of requirements for conscious sedation imply that the monitoring person may be involved in other tasks during the procedure. The increased vigilance demanded by a deeper state of sedation requires that the monitoring clinician be completely devoted to that task, without distraction. Both deep and conscious sedation require that one person be trained in at least pediatric basic life support. Deep sedation also requires that the monitoring person possess skills in pediatric airway management; pediatric advanced life support skills are “strongly encouraged.” The level of care required during the procedure is described, and should include continuous monitoring of oxygen saturation and heart rate, and intermittent measurement of respiratory rate and blood pressure. Attention to the airway is again emphasized, and for deep sedation, more intensive monitoring of respiration and airway patency is required, such as the use of capnometry or a precordial stethoscope. In settings where it may not be possible to readily detect transitions in the depth of consciousness—for example, in the magnetic resonance imaging (MRI) scanner—it may be prudent to implement a higher level of monitoring even if minimal or conscious sedation is the goal. Documentation of drug administration and vital signs on a time-based record is mandated. Either vascular access or the ability to immediately obtain it is necessary during deep sedation. Cautions about the potential for toxicity from local anesthetics and the special risks entailed with the use of nitrous oxide, especially the problems of synergy when used in conjunction with other sedating agents, are cited. The monitoring problems in MRI are mentioned, but there are no specific cautions about the particular difficulty in assessing adequacy of respiration and airway patency in that environment. The risks of thermal injury caused by induction currents with electronic monitoring cables in the high-gauss magnetic field are noted.

The AAP guidelines do not directly address the issue of credentialing and the qualifications of the personnel administering sedation and monitoring the patient except to advise regarding the training and certification in pediatric life support (mentioned previously). These difficult issues are left to the individual institution to decide (19).

4.2. American Academy of Pediatric Dentistry Guidelines (1998 revision)

AAPD first published its own set of guidelines for sedation in 1985. These were revised in 1996, and further revised in 1998 to include a section on general anesthesia. The document describes the guidelines as “systematically developed recommendations,” which may be “adopted, modified or rejected according to clinical needs and constraints.” The AAPD explicitly states that the guidelines are not to be construed as setting standards or requirements. This caveat is similar or identical to other guidelines, but is in some contrast to the disclaimers in the introduction to the AAP guidelines, which state that they “reflect our current understanding of appropriate monitoring needs,” and that they may be *exceeded* at any time, based on the judgement of the responsible physician” [emphasis added]. The language used in the AAP guidelines appears to be a greater call for compliance by the clinician, although these, are guidelines and not practice standards, and these semantic differences are highly nuanced. The language in the AAPD document, by eliminating the term “exceeded,” may potentially weaken the impact on practice patterns by individual clinicians. The practice settings for pediatrics and for dentistry may be quite different. It is likely that a greater percentage of dental care under sedation is administered in an individual office, unlike the use of sedation in pediatric medical practice, which is more likely to be hospital-based and under the greater oversight mandated by JCAHO standards. There are no data to show if this results in any difference in compliance with the guidelines by dentists.

The guidelines begin with a section of definitions. Like the AAP guidelines, the document is careful to define levels of imperatives contained in the guidelines. They delineate three levels of sedation (conscious, deep, and general anesthesia), but also subdivide the conscious sedation category into three sublevels, thus resulting in five levels. The descriptions of the levels are defined as both behavioral goals and as levels of responsiveness. A table in the appendix to the document details the definition and the personnel and monitoring equipment appropriate for each level. Level 1 is anxiolysis; the patient is totally awake, and only clinical observation is necessary. In Level 2, the patient has a minimally depressed level of consciousness. Their eyes may intermittently close, but the patient is still able to respond to verbal commands. This corresponds to the “conscious sedation” stage described in the AAP guidelines. Pulse oximetry is required, and precordial stethoscope is recommended. The use of the precordial stethoscope to assess aeration is a frequent recommendation (required for levels 3–5) in the AAPD guidelines, and allows the dentist to continually monitor airway patency and

respiratory rate without continual visual observation. The AAPD guidelines are unique in their emphasis on the means of monitoring of airway patency, a prominence that is certainly born from the potential interference with the airway by dental interventions. Emphasis on this device in situations where direct observation of the patient is obscured would probably be advisable in the AAP guidelines as well, and may be underemphasized in that document. Like the auditory signal from a pulse oximeter, which falls in pitch as the saturation declines, the precordial stethoscope permits the clinician to focus the eyes on one task and the ears on another. The limitation, of course, is that for full concentration to be focused on the monitoring of the sedated patient, all the senses must be engaged in a task related to monitoring. In the case of the dentist, attention is likely to be focused on the dental procedure, since the monitoring is a secondary task. This is unlikely to be a problem for patients sedated to Levels 1 and 2, but with Level 3, as discussed in the next paragraph, or for patients who unintentionally descend to a greater depth of sedation, one may be distracted from adequate vigilance. The goal is that the auditory cues will alert the clinician that something is wrong with the airway, which will then result in refocusing of attention. This type of vigilance is a skill that needs development and experience. Furthermore, the noise of the handpiece and suction device may obscure the breath sounds or heart sounds heard through the precordial stethoscope. Capnometry has been validated as an early warning device for airway patency and respiratory depression in several settings, but requires that attention be given to the waveform trace (20–22).

Level 3, which the AAPD still defines as within the boundaries of conscious sedation, results in “moderately depressed levels of consciousness” that “mimics physiologic sleep.” Despite the description of this state as conscious sedation, patients may not respond to verbal stimuli, may respond to moderately painful stimuli with only reflex withdrawal, and may require chin thrust to maintain the airway. It is this part of the AAPD guidelines that most radically differs from the AAP document. The categorization of this state is clearly inaccurate. If the patient is sedated to the point where he or she does not respond to verbal stimuli, the patient is not conscious, and the resulting state cannot honestly be described as conscious sedation. The main problem with this categorization is that although blood pressure and the option of capnometry are added to the monitoring, “conscious sedation” does not require an independent monitoring clinician. Certainly, the use of continuous auscultation via a precordial stethoscope or capnometry is useful, but distractions are a concern when the monitoring clinician is busy concentrating on other complex tasks. The AAP guidelines and JCAHO standards

would require an independent monitoring clinician for children who have reached this stage of sedation.

Level 4 sedation is defined as deep sedation, with the patient expected to require constant monitoring and frequent management of the airway. Recommended monitoring devices include the full array of noninvasive physiologic monitors, including precordial stethoscope, capnometry, ECG, noninvasive blood pressure, and oximetry. The presence of emergency equipment, such as a defibrillator, is recommended. Patients in this state of sedation have a “deeply depressed level of consciousness” and are not expected to be responsive to most stimuli, but may respond to pain with reflex withdrawal. An independent monitoring clinician with training in airway management is required.

Level 5 is general anesthesia. According to the guidelines, a dentist who has completed training in oral and maxillofacial surgery is qualified to administer general anesthesia. The duration of training in general anesthesia for these practitioners is usually about 3 mo. The adequacy of such training to qualify an individual to administer general anesthesia is an issue that is beyond the scope of this chapter.

A preoperative evaluation is required for all patients, and standard NPO recommendations are cited. Consent is required, and must be documented. The guidelines permit the administration of minor pre-procedure tranquilizers such as diazepam or hydroxyzine by a responsible adult at home, but not chloral hydrate or narcotics. Because even these drugs may have considerable variation in effect from patient to patient, there is some risk in permitting the use of benzodiazepines in younger children and in many older children with developmental or neurological problems. The use of sedating medications outside of a medical facility was one of the risk factors cited by Coté et al. that increases the risk of adverse sedation events (12). Record keeping is mandated for all levels of sedation, and adequacy of recovery must be documented prior to discharge. The criteria for discharge are similar to the AAP guidelines, and continuous observation and monitoring during recovery by a qualified individual experienced in recovery care is emphasized. A responsible parent or guardian must be given appropriate discharge instructions. Explicit and proactively determined emergency procedures are mandated. This is particularly important for the dental setting, where sedation is commonly administered in a private office, remote from a hospital where additional assistance such as a “code team” is readily available.

One would not think that the differences between the AAP and AAPD guidelines are difficult to reconcile, and that the acceptance by the AAPD of the few additional aspects of the AAP guidelines would be so onerous. There

are clearly “turf” issues at play here, but the most glaring difference—that of the definition of AAPD Level 3 as conscious sedation—actually has greater implications, both financial and logistic, than one would notice at first glance. Level 3 sedation has considerable latitude and breadth of definition, and it is not difficult to stretch most deeper levels of sedation to fit within this rubric. It is likely that a large proportion of sedation performed in the dental office may fall under this category. Levels 1 and 2 are often inadequate to deal with the needs of the majority of children who require more intensive dental interventions. Thus, the additional requirement of an independent monitoring clinician actually imposes an obligation on the dentist that has significant financial and personnel implications. We are faced with the decision of risk vs expediency, and must decide how much risk one is willing to accept to prevent or allow early detection of a relatively uncommon event. Since those events have the potential for serious or life-threatening complications, and they are preventable with commonly available technology or procedures, both the AAP and JCAHO have come down on the side of minimizing risk, and the AAPD guidelines appear to offer some degree of compromise in this regard.

4.3. The American College of Emergency Physicians (ACEP)

The American College of Emergency Physicians (ACEP) guidelines were designed to cover sedation of all patients in the emergency room, not just infants and children (9). The ACEP has also published a position paper on the use of sedation and analgesia in pediatrics, but this policy statement is not a set of guidelines, and makes no specific recommendations regarding management, monitoring, or personnel, other than in very broad generalities (8). There are no statements in the ACEP clinical policy that address the unique needs of children or consider them separately from adults. Much of the data referenced in the document are from adult studies, and may not be applicable to infants and children. They have entitled their document a clinical policy,” and acknowledge that many of the statements in the policy are at odds with JCAHO criteria. They offer the clinical policy as a challenge, as it were, to the JCAHO and others, to reinterpret which criteria should be considered in sedation standards.

The ACEP clinical policy is clearly an outgrowth of the unique needs of emergency physicians, who are called upon to provide care for unprepared patients in urgent situations. The patients are often frightened or uncooperative, and either require interventions that cannot be postponed, or the logistics and management issues in running the emergency room are considered to take precedence over the ability to postpone an intervention. The emer-

gency room is a rapid turnover environment in which efficiency is crucial to avoid unmanageable back-ups and delays in care for other unstable patients. Several of the cornerstones of the AAP document are at odds with these administrative matters, and thus the ACEP was faced with either having common practices in many emergency rooms be out of compliance with the AAP and JCAHO guidelines, or write new standards of their own that contested those that had been promulgated by others. Again, the questions that arise are in many ways related to this central issue: at what point is one willing to draw the lines that set the boundaries between patient safety and expediency? Does one give priority to protecting a status quo standard of practice over preventing an infrequent but possible adverse event? How much risk is one willing to accept? These are the real questions posed by the ACEP clinical policy, but they are not discussed in this document. Rather, the ACEP document attempts to refocus the discussion in evidence-based terms, and contest the authenticity of those risks.

The ACEP document begins with a statement that charges other guidelines with not being evidence-based, and implies that at least some of the recommendations contained in those other documents are biased. The authors claim that the ACEP clinical policy will be evidence-based, and will only make recommendations that are founded on such data. However, under scrutiny, there is a clear agenda underlying much of this document. The authors clearly wish to shift the emphasis of guidelines from minimizing risk to permitting certain practices because they have not, in the eyes of the ACEP, been definitively proven as hazardous. Unfortunately, many of the statements made in the document in this regard are not well-supported by the cited data, or do not consider relevant data from the non-emergency medicine literature. It appears from the description of methodology that the ACEP views the Emergency Room as fundamentally different from any other venue in medicine, and therefore excludes virtually all data obtained in other settings from consideration in their “evidence-based” policy statement. This enables them to state repeatedly that there are no evidence-based standards for numerous issues. The two areas of greatest deviation from the AAP guidelines are with regard to the unprotected airway in a patient with a full stomach, and in issues of airway management. Other issues that are contested are informed consent, monitoring standards, personnel and drug choice, and administration.

The ACEP does not accept the long-held contention that the full, or potentially full stomach, is a sufficient risk to avoid using deeper levels of sedation without a secured airway. They believe that there are inadequate data to prove that an unfasted patient in the emergency room is at increased risk of

aspiration during sedation. This is in large part based on the assertion that “procedural sedation and analgesia in the [emergency department] is not reasonably expected to result in the loss of protective reflexes.” This statement is based on studies that do not specifically look at that question, or contain a requisite number of patients from which to draw that conclusion. A Type II statistical error, in which it is assumed that a numerator of zero implies absence of risk, is the problem here (23). They also assume that the clinician is able to predict with a reasonable degree of certainty whether a given sedation technique is likely to result in the loss of airway reflexes, thus minimizing risks of aspiration. The data do not provide adequate evidence to prove that the risk is as negligible as the clinical policy or original papers imply.

Airway issues, such as oxygen desaturation and respiratory depression, are largely dismissed by the ACEP policy, as they do not accept the contention that hypoxia has a significant potential to lead to adverse outcomes during sedation. This has particular implications for pediatric patients, as the majority of cardiac arrests in children outside of the operating room setting begin as respiratory events. The policy again largely ignores the problem of inferring safety from studies of small numbers of patients.

4.4. American Society of Anesthesiologists (ASA)

The ASA published *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists* in 1996 (24). They have been referenced by JCAHO (15) and adopted by the Governing Board of the American Society for Gastrointestinal Endoscopy. The guidelines use similar language to the AAPD guidelines in the preamble defining their goals and limitations, but insert the term “exceed” with regard to the recommendations. They also clearly reject the term “conscious sedation” in favor of “sedation and analgesia.” The ASA guidelines are unique in that a comprehensive review of over 1,300 scientific articles was undertaken by the authors. 269 Articles selected from all disciplines were found to have direct linkage to evidence to support or reject the hypotheses regarding fourteen parameters of sedation care, including pre-procedure evaluation, monitoring, training of personnel, record keeping, drug administration, oxygen administration, airway management, and special considerations. These papers were subject to review and statistical analysis to determine recommendations for clinical practice. In addition, these recommendations were reviewed by non-anesthesiologists who were asked to evaluate the effect on their practices, including time and effort. Even economic impact was considered, although the personnel costs may be considerably underestimated, depending on the particulars of a given insti-

tution (25). It must be emphasized that the depth of sedation that is intended by this set of guidelines would have the patient remain communicative at all times. This has some limits in its applicability in pediatrics, where greater depths of sedation are often needed, but further emphasizes the need for diligence in monitoring and care.

There are no pediatric-specific recommendations in the ASA guidelines, other than in general terms the need to consider special patient needs at the extremes of age. The importance of this document, however, is that a painstaking methodology was applied to evaluating the need for a wide range of care parameters that cut across all medical disciplines. This document remains the most scientifically rigorous set of sedation guidelines published to date.

4.5. Joint Commission for Accreditation of Healthcare Organizations (JCAHO)

The JCAHO standards (15) differ in both scope and purpose from the guidelines discussed thus far. Like the ASA and ACEP guidelines, they do not specifically address the care of pediatric patients. Their primary distinction is that unlike the guidelines, these are a set of standards that a hospital or institution must adhere to in order to obtain accreditation. The JCAHO also maintains a policy regarding patient safety and the institutional responses to sentinel events. Such events are defined as:

unexpected occurrence[s] involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome (15).

This standard has clear implications for an institutional policy regarding sedation, in that it mandates a review and quality assurance program, and requires continual significant oversight of all sedation practices within an institution. Failure to follow this mandate can result in punitive action by the JCAHO both when accreditation is reviewed, and, were an adverse event to occur, if an investigation is begun. Guidelines such as those promulgated by the ACEP are not alternatives that the JCAHO accepts. The JCAHO references the ASA guidelines as the prototype document that should be used by institutions in setting up their own sedation guidelines.

The JCAHO has defined four levels of sedation. They have chosen to dispose of the term “conscious sedation” and have replaced it with terms that are more descriptive. The first level, called *minimal sedation or anxiolysis*, describes a drug-induced state of altered cognition in which consciousness is not impaired, hemodynamic and ventilatory responses and

equilibrium are not affected, and patients maintain verbal responsiveness. *Moderate sedation* replaces the category previously termed conscious sedation. In this state, patients still respond purposefully as described for minimal sedation, although consciousness is more impaired. The airway remains stable without intervention, and hemodynamic status is “usually” unaffected. During *deep sedation/analgesia*, patients “cannot be easily aroused but respond purposefully following repeated or painful stimulation.” Although hemodynamic function is usually unaffected, airway patency and adequacy of ventilation may be adversely impacted, resulting in the need for ventilatory intervention. The last level, *anesthesia*, consists of general and major regional anesthesia. The most important characteristic of general anesthesia in this framework is the inability to be aroused even in response to a painful stimulus. The importance of this classification system is that the most important characteristic of “grading” the level of sedation is the response of the patient to stimulus. The idea that a given patient is not anesthetized because certain drugs were or were not used, or because the airway and ventilation remains intact without intervention is rejected. The guidelines also note that reflex withdrawal to stimulus is not considered a purposeful response.

The JCAHO mandates seven specific standards for moderate and deep sedation and anesthesia, spanning the entire continuum of the patient’s care.

1. The individual providing the care must be “qualified.” The standards for qualification must include the following criteria:
 - training in the administration of drugs to produce a desired sedation level, i.e., titration of sedating drugs to effect, and in carefully monitoring of patients in order to maintain a stable and appropriate level of sedation.
 - appropriate credentialing for the management of patients “at whatever level of sedation or anesthesia is achieved, *either intentionally or unintentionally*” [emphasis added]. This means that a clinician that is administering moderate sedation must be qualified to rescue a patient who unintentionally becomes deeply sedated, including the ability to manage an unstable airway. The clinician who is permitted to administer deep sedation must be qualified to rescue a patient who enters the level of general anesthesia.
 - competency-based education, training, and experience commensurate with the skills described here.
 - There must be adequate staffing of trained personnel in addition to the clinician performing the procedure so that pre-sedation medical evaluation, drug administration, and monitoring during the procedure, and recovery and discharge can be executed.
2. There must be appropriate resuscitation and monitoring equipment available. Monitoring must include continuous measurement of heart rate, pulse oximetry, and respiratory rate and adequacy of ventilation, and blood pressure mea-

surement at regular intervals. Electrocardiogram monitoring is required for patients with cardiovascular disease or in situations where dysrhythmias might occur.

3. All patients must undergo an evaluation before receiving moderate or deep sedation in order to assess the patient's status and formulate the sedation plan. Each patient must have a plan of sedation individualized for his or her underlying medical condition and appropriate for the procedure to be performed.
4. The JCAHO requires that the plans, options, and risks of the sedation plan are discussed with the patient or guardian and that informed consent is obtained.
5. While the sedation is administered, monitoring of the patient's physiologic status appropriate to the patient's condition, the level of sedation, and the complexity of the procedure must be performed.
6. The patient's status must similarly be assessed during the emergence period in an appropriate post-anesthesia or post-sedation recovery area.
7. The patient must be discharged from care by a "qualified licensed independent practitioner, or according to criteria approved by the medical staff."

Compliance with these standards is evaluated during the JCAHO site visits for accreditation. Revisions and updates to the standards occur frequently. These, and clarifications of the intent of the standards, can be found at the JCAHO website (www.jcaho.org).

5. EFFICACY

Has the use of guidelines led to changes in outcome for sedated children? Are there data to suggest that the implementation of risk-reduction strategies, improved monitoring, or observation by trained personnel have decreased the incidence of adverse events? (11) At this time, hard data are still lacking. Because the incidence of those events is relatively small, virtually all of the studies that purport to demonstrate the safety of various sedation recipes or sedation systems lack the statistical power to draw those conclusions. Until a controlled study measuring the incidence of complications and outcome in many tens of thousands of patients can be performed, we are not likely to have population-based information about safety that is meaningful. Furthermore, studies that focus on incidence alone may not provide the information necessary to draw conclusions about the application of guidelines in clinical practice. It may, however, be more useful to focus on a different approach to determining best or safest practice, by using a systems approach to analyze various practices and determine which are best able to minimize risk. The best available data using this approach come from the study by Coté et al., a retrospective analysis of adverse outcomes in children who underwent sedation (12). This study did not intend to measure incidence, prevalence, or the "safety" of any one system, but instead focused on determining if there were specific systems or practices that could be associated with adverse outcomes.

The authors, a group of pediatric anesthesiologists, pediatric intensivists, and emergency pediatrics specialists, analyzed 95 reports of critical incidents during sedation, and sought to define practices that were shared among the adverse events. In addition to identifying problematic practices, the authors sought to identify factors that led to positive outcomes. This is particularly important, since, as discussed earlier, adverse events inevitably occur, and it is a primary goal of guidelines to maximize the likelihood of rescue from a complication. Factors that were recognized as common to adverse outcomes included sedation in a non-hospital setting, inadequate medical evaluation prior to sedation, lack of an independent observer, medication errors, and inadequate recovery procedures. The use of monitoring devices alone, despite their warning of oxygen desaturation, were associated with better outcomes specifically only when the alarms were answered by trained personnel. In respiratory arrests that occurred in non-hospital facilities, the risk of permanent neurological injury or death was three times as likely as in a hospital, suggesting that the availability of trained personnel responding to an emergency had a major impact on outcome. This conclusion was strengthened by the finding that out of hospital respiratory events were much more likely to be followed by cardiac arrests and inadequate resuscitation than in hospital events. This was the case even though the initiating respiratory events occurred equally among hospital and non-hospital patients. These findings appear to validate the systems and practices recommended in the AAP guidelines. They add strength to the idea that such systems have universal application, and that they should be applied across specialties and settings. The institution of such systems is likely to have the greatest impact on safety and outcome if done as an integrated approach with all departments and practitioners so that every patient will benefit.

6. CONCLUSIONS

Sedation guidelines are likely to engender controversy and opposition until all groups of physicians and practitioners acknowledge that there is an advantage to working from the common viewpoint of a systems approach to minimizing risk. This has been designed as a primary goal in the current decade by the Institute of Medicine reports of the past two years (13,26). This approach also requires that one accept that scientific proof of the efficacy of many interventions and procedures will be difficult or impossible to obtain. Risk-reduction strategies offer the best answer to improving safety, and have proven beneficial and effective in industry and other professions such as commercial aviation. In the hospital venue, the JCAHO standards are likely to override other interests in maintaining a stricter view of safe and

prudent practice. Continuing refinements of guidelines will tighten the interpretation of language and practice, and systems-based approaches have enormous potential to improve both safety and efficiency. A major factor in implementing safe practice will continue to be the considerable cost associated with independent clinician observers and limited resources in an era of shrinking medical funds and reimbursement. It is clear that the JCAHO mandates will provide the rubric under which most, if not all, hospitals and health care institutions will need to operate. The AAP guidelines, supplemented by those promulgated by the ASA, appear to offer the most effective approach to compliance with accreditation standards, together with the goal of promoting safe systems for the sedation care of infants and children. The ongoing identification of lowest-risk practices and continuing assessment will be ongoing projects for the future.

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