Sedation disasters in pediatrics and concerns for office based practice

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THE American Academy of Pediatrics (AAP) became interested in sedation disasters in 1983 when three children died in a single dental office in California. In response to these disasters, the AAP asked that the Section on Anesthesiology help develop guidelines for monitoring children under sedation by non-anesthesiologists and, hence, the first guidelines of the AAP were published in 1985.¹ Subsequently, the Academy, as well as the Committee on Drugs of the AAP and the Section on Anesthesiology of the AAP, recognized that the guidelines, because they contained the word "anesthesiology" in the title, were basically ignored by general pediatric practitioners, particularly those in the emergency room, radiology, and other areas where sedation is widely used. Therefore, the guidelines were revised in 1992 with an emphasis placed on "systems issues" such as presedation evaluation, appropriate monitoring during and following the procedure (pulse oximetry for all sedated children), appropriate fasting guidelines, a time based anesthesia type record for sedation, and appropriate recovery and discharge criteria.² The caveat that "sedation is a continuum such that a patient may progress from a light level of sedation to general anesthesia" was described. It was also stressed that the practitioner must have the skills to manage reasonably foreseeable emergencies as well as the ability to increase the degree of vigilance consistent with the depth of sedation. This implied that the practitioner had to have advanced airway management skills.

One of the confusion areas was the definition of "conscious sedation", which was defined as "*a purposeful response to either a painful stimulus or a verbal command.*" However, some practitioners have chosen to interpret a reflex withdrawal to pain as being consistent with conscious sedation and this, therefore, has led to a number of sedation accidents. This term, I believe, is contradictory to what really happens to the child and in fact is misleading.³ I believe that the phrase conscious sedation is an oxymoron!

Some practitioners still prescribe "light sedatives" at home prior to scheduled dental or radiologic procedure.⁴ These are serious deviations from the recommendations of the AAP and this practice has resulted in much debate between pediatricians, anesthesiologists, pediatric dentists, and pediatric cardiologists.

As part of an FDA panel in 1994 during the initial hearings for the approval of the fentanyl Oralet®, an epidemiologist from the FDA presented a review of the adverse drug reports submitted to the FDA for a list of medications that I suggested. I was able to obtain this database through the Freedom of Information Act and in addition conducted a survey of pediatric anesthesiologists, pediatric intensive care medical specialists, as well as emergency medicine physicians (all members of their respective Sections within the AAP). We collected a total of 95 cases where all four reviewers agreed to the contributory causes. The results are quite interesting in terms of outcome regarding the differences between hospital based and non-hospital based health care facilities. As one might expect, approximately 80% of cases presented with some form of respiratory depression; however, nearly three times as many children sedated in non-hospital based venues suffered cardiac arrest despite the fact that they were older and healthier (lower ASA status; see figures).⁵ In addition there was no relationship between adverse outcomes (death/neurologic injury) and route of drug administration (*iv*, nasal, rectal, *im*, *po*, inhalation [nitrous oxide plus other sedatives]) or drug class (opioids, benzodiazepines, barbiturates, sedatives, chloral hydrate).⁶ Failure to, "rescue" the patient and inadequate CPR skills were the major contributory factors. This was evident from the fact that despite most patients presenting with some evidence of respiratory depression, nearly three times more progressed to cardiac arrest indicating that efforts at ventilation and oxygenation were not effective. Other contributory causes included drug overdose, drug-drug interactions, inadequate monitoring, inadequate recov-

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ery, prescription/transcription errors, drug administration without medical supervision, drug administration by a technician, inadequate equipment, and premature discharge from recovery or inadequate recovery procedures. These "systems" issues are basically the same as those found in perioperative misadventures.⁷⁻¹¹ A report from the Institute of Medicine has commended the specialty of anesthesiology as providing leadership in developing safe practices thereby reducing anesthesia related mortality and morbidity;¹² a similar reduction is needed for sedation related injuries.

A concern for any procedure performed in a non-hospital venue is the immediate availability of additional skilled help when an adverse event occurs. In an office it may take three to ten minutes or longer for the emergency medical technicians to arrive whereas in a hospital help literally comes from throughout the institution to assist with an emergency. In our database it was clear that monitoring with pulse oximetry was an important safety feature. All 15 in-hospital patients monitored with pulse oximetry who suffered an adverse sedation related event

were rescued without harm whereas four out of five non-hospital based patients who suffered an event and who were monitored with pulse oximetry were not successfully rescued. This observation emphasizes the importance of airway skills and CPR skills in recognition that an event is occurring and then successfully intervening. Without question pulse oximetry is far more reliable in recognition of a developing event than simple clinical observation.^{13,14} The concept of rescue is an important one because that is what is key. Any patient can get in trouble at any time since a drug will have the same effects upon the patient regardless of who administers the drug or in what venue the drug is administered, however, as long as the problem is recognized and intervention initiated on a timely basis, then the outcome should be that the patient is rescued. If however there is delayed recognition, intervention is delayed, or if the practitioner lacks the skills to intervene successfully, then a disaster results. There were two children who died on the way to a facility who had received sedating medications at home administered by a parent. Both received drugs in doses

FIGURE 1 The sequence of presenting medical events revealed that a respiratory event was most common as the presenting event, however, in nonhospital-based facilities the incidence of cardiac arrest as the second or third event was significantly higher ($*P < .001$). These data suggest that either there was a delay in recognition of the severity of the event or that the practitioners lacked appropriate skills in airway management and/or in cardiopulmonary resuscitation and failed to rescue the patient. Reproduced with permission from *Coté et al.*, *Pediatrics* 2000; 105: 805-14.

FIGURE 2 Outcome of adverse sedation-related events in children sedated in hospital-based compared with nonhospital-based facilities. Note that the outcome of death or permanent neurologic injury were significantly greater in nonhospital-based facilities. ($*P < .001$). Reproduced with permission from *Coté et al.*, *Pediatrics* 2000; 105: 805-14.

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Continuum of depth of sedation

	<i>Minimal sedation</i> (“ <i>anxiolysis</i> ”)	<i>Moderate sedation/analgesia</i> (“ <i>conscious sedation</i> ”)	<i>Deep sedation</i> <i>analgesia</i>	<i>General anesthesia</i>
Responsiveness	normal response to verbal stimulation	purposeful** response to verbal or tactile stimulation	purposeful** response following repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be adequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate sedation/analgesia (“conscious sedation”) is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep sedation/analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate sedation/analgesia (“conscious sedation”) should be able to rescue patients who enter a state of Deep sedation/analgesia, while those administering Deep sedation/analgesia should be able to rescue patients who enter a state of general anesthesia.

* Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”

**Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

considered safe (chloral hydrate 60 mg·kg⁻¹ or midazolam 0.5 mg·kg⁻¹). Likely what happened was that the child was placed in a car seat and then fell asleep and was unable to unobstruct the airway when the head fell forward. Eight other children suffered adverse events after discharge; all had received long acting drugs such as chloral hydrate (half-life ~ ten hours), *im* pentobarbital (half-life ~ 25 hr), *im* Demerol, Phenergan, Thorazine (DPT) (half-life 7–12 hr).

Our data suggest that the entire United States health care profession needs to reexamine the push for office-based anesthesia and, in particular, for office-based procedures without the benefit of skilled anesthesiology care. Most pediatric patients in the United States do not have dental insurance that pays for anes-

esthesiology services. A major need is for the insurance industry to recognize that dental care should be treated just like any other pediatric disease such as inguinal hernia or otitis media. I would add parenthetically that at least one of these office-based accidents resulting in death occurred with a nurse anesthetist who was not supervised by an anesthesiologist. A recent ASA newsletter outlined preliminary data for adults in the closed claims database. These data suggest a similar high failure to rescue in the office based setting even at the hands of anesthesiologists.

In 2001 the American Society of Anesthesiologists developed new terminology that has been adopted by the Joint Commission of Accreditation of Healthcare Organizations.^{15,16} These definitions are an attempt to

provide uniform guidance across all specialties and for adults and children. The JCAHO regulations went into effect January 1, 2001. The AAP guidelines are also being modified to include these same definitions but await formal approval by the executive board of the AAP. Eventually we hope that all organizations adopt the same language, delete the phrase "conscious sedation" and provide uniform care in the office as well as in the hospital.¹⁷

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