mm **Review Article**

A history of sedation guidelines: where we are headed in the future

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The development and implementation of guide lines probably elicits more controversy and emotional fury than any other activity professional organizations undertake. Sedation guidelines, both among and within professional organizations, are a prime example. Yet, guidelines offer a sense of accountability, direction, and integrity that would seem both demanded and appreciated by most elements ofsociety.

The purpose of this article is to 1) describe the background and development of sedation guidelines of the American Academy of Pediatric Dentistry (AAPD), 2) address specific issues in current AAPD guidelines that may be too broadly interpreted and confusing to individuals within and outside of the organization, and 3) offer for consideration a proposed sedation guideline plan that may be more clinically congruent with private practice than the current guidelines. In so doing, it is the authors' intent to provide the readers with information that may be useful for decisions on acceptability of future guidelines and to offer an alternative concept of sedation guidelines more representative of clinical practice.

History of Academy's guidelines

The first guidelines on sedation, published in 1985, were a joint effort of the American Academy of Pediatrics (AAP) and the AAPD.[1] This joint project was the result of several coincidental events.

In September 1980, the Roche Laboratories Division of Hoffman-LaRoche Pharmaceutical Corporation - as a result of reported severe adverse reactions to their sedative agent Nisentil®, a brand of alphaprodine - recalled the agent and ceased production. The major concern was the potential litigation based on misuse by uninformed practitioners. The Food and Drug Administration (FDA) was also becoming increasingly concerned over efficacy and safety.

Realizing that a considerable number of pediatric dentists had been sedating patients with Nisentil®, a narcotic, and that there were no available alternative agents having the desirable characteristics of the sedative agent, the AAPD began a dialogue with Roche Laboratories with the intention of reversing their decision.

A joint retrospective study involving more than 7,000 sedations performed was undertaken. Severe adverse reactions were reported only eight times among this large number of sedative experiences. While anecdotal in design, the evidence seemed to indicate that the agent was probably not the basis of the problem. Discussion now began to focus on how procedures were being done through a thorough analysis of the collection of cases of severe outcomes being reported by practitioners and the media. A proposal was made for a combined effort to educate practitioners using sedation and to publish guidelines for the use of sedative agents in the pediatric dental population.

In the early months of 1982, an ad hoc committee met to begin the process of creating sedation guidelines. Members of this committee came from the AAPD, the American Society of Dentistry for Children, and the Medical Research Division of Roche Laboratories. The committee learned that the AAP had charged their Committee on Drugs with the task of writing guidelines for sedating children. The pediatrician members, many of whom were doing presedation physical examinations and were being asked by parents about the safety of sedation, were concerned. Much later in the cascade of events, they were to change the focus to both dental and medical practitioners utilizing sedation procedures. Rather than produce two possibly different sets of guidelines, the pediatricians accepted an invitation to join in a combined effort. The Council on Dental Education of the American Dental Association (ADA) also was considering this emerging issue as it was at that time revising the guidelines for teaching pain and anxiety control.

By March 1984, guidelines had been developed that included input from many organizations and individuals from both dentistry and pediatric medicine. At this time, the FDA convened a workshop on the "Anesthetic

Management of the Pediatric Patient." Final approval of the guidelines, having had multiple revisions, was finally accomplished in April 1985. These guidelines were utilized as the position paper of the AAPD for a consensus development convened by the National Institute of Dental Research (NIDR) in April 1985. These guidelines, representing five years of intensive effort and the involvement of many individual practitioners and professional organizations and entitled "Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia," were finally published by AAPD and AAP in their respective journals in July 1985.

Historical impact of guidelines

No comprehensive measure has been available indicating practitioner acceptability and incorporation into practice of the 1985 guidelines. But suggestions that the guidelines initially had a bearing on practice have been published.[3] Factors such as the rapid development, modifications, and cost of monitoring equipment, litigious societal inclinations, changes in education standards and training in accredited programs, and continuing education involving sedation, practitioner fears resulting from lack of compliance with guidelines, and the unknown were and continue to be limiting factors. Thus, consequences of the guidelines in terms of practitioner compliance, changes in patient selection, and preferred modalities of pharmacologic behavior management (e.g., increased utilization of general anesthesia) over a longer assessment period are not fully understood, but cognizance of their existence by clinicians seems universal.

The guidelines established a format for focusing attention to details, which would theoretically act to protect and promote the welfare of children who because of their dental, behavioral, and financial needs required sedation. From the patient's or consumer's perspective, it is not clear if the guidelines adversely altered the appropriate delivery of care to children who had significant dental and behavioral needs. For example, have fewer children received comprehensive and emergent care under more stressful clinical situations (i.e., wrapping an unsedated 2-year-old child in a Papoose Board™ and providing care under local anesthesia alone when the cost of general anesthesia, as an alternative, is too prohibitive) since the implementation of the guidelines?

From the practitioner's viewpoint, the guidelines had requirements that may have been perceived as mediating major change in practice. For instance, maintaining time-based records of sedations may be misconstrued as a significant logistical problem for the private practitioner. Who in the operatory will be responsible for and trained to record the physiological parameters? What should be on the form? When is it really necessary? What guidance do present guidelines offer in interpreting these and other relevant questions?

Likewise, and possibly more relevant, the cost of doing sedations under the conditions of the guidelines may be a significant factor. Consideration of cost-related items must include malpractice insurance, third-party payments, trained personnel, special equipment and supplies, and time.

We may never understand the impact that the issuance of the guidelines had on dental practice, sedation safety and efficacy, and children's needs. As new techniques are introduced, the guidelines will continue to evolve, changing the contents and implications of current guidelines.

Recently, the AAPD had the foresight to recognize the need to modify the 1985 sedation guidelines. Some issues associated with the perceived need for change included new information on monitoring, a lack of clarity in the original guidelines leading to a broad interpretation of the 1985 guidelines, and a sense of exigency to remain contemporary with our medical brethren in the AAP.

Current guidelines

The subcommittee on sedation of the AAPD clinical affairs committee was convened in 1992 to evaluate and recommend action on the 1985 guidelines in light of knowledge that AAP was in the process of modifying their guidelines. Efforts were made to scrutinize each section of the 1985 guidelines while considering issues outlined above. The result of much discussion was the presentation of proposed revised guidelines before the general assembly at the 1993 AAPD Annual Session. The guidelines were approved as amended and hence, the new guidelines were published in the 1993 July/ August issue of *Pediatric Dentistry.4* Table 1 represents a comparative overview of the major changes of the AAPD guidelines in reference to the 1992 AAP's.[5]

Not all of the changes were viewed positively by the AAP. No doubt, misinterpretation played the spoiler's role in the process and promulgation of unity by the two organizations. The following discussion gives more detail to the justifications underlying some changes found in the 1993 guidelines. Hopefully, it will also provide some clarity of thought that will ameliorate the misinterpretation by the membership of both organizations.

Monitoring

The major emphasis of the guidelines (especially the AAP's) is monitoring. The reason is simple and logical. It is impossible to predict, with a reasonable degree of certainty, the clinical effect most sedative drugs used alone or in combination will have on a child, particularly a very young child. This is true because of individual variation in response regardless of the route of administration and/or dose.

Unconsciousness is a conceivable consequence of administering any sedative agent and hence monitor-

TABLE 1. MAJOR CHANGES IN GUIDELINE CONTENT AND COMPARISON WITH AAP

	AAPD 1985	*AAPD1993*	*AAP 1985 and* 1992
Preamble	None	Yes-Abbreviated history of Guidelines and justification for revision	Yes
New terminology		"Guideline" is defined	None
Goal of sedation	4 goals	5 goals	5 goals
Local anesthesia	Yes	Key terms: "cardiac and CNS depressants;" more emphasis on interactive effects; determine maximum recommended dose and record prior to administration	None
Oxygen analyzer	None	Specifically defined conditions when it is recommended	A must under all conditions
Prescriptions	Present, butvague	Present and specifies "minor tranquilizers" (e.g., diazepam, hydroxyzine, NOT chloral hydrate OR meperidine) that can be given preprocedurally outside treatment facility	Vague
Vital signs	Present	Present, but adds "intermittent quantitative monitoring and recording of oxygen saturation"	Same
Conscious sedation	Present	Added "shall provide appropriate monitoring" and "shall be capable of managing any reasonably foreseeable complication"	Same and more (PALS)
		Added "drugs, other than minor tranquilizers ...shall be prescribed, dispensed, or administered by appropriately licensed individuals"	None
		Also indicated pulse oximeter is minimum monitoring for sedation other than minor tranquilizers and/or nitrous oxide	Special section on nitrous oxide
		Operative monitoring should be "continuously for patient responsiveness and airway patency"	
Deep sedation		Added capnograph as being "desirable"	Capnograph is "encouraged"
Appendices	ASA Classification & Recommended Ernergency Drugs	Recommended discharge criteria, ASA classification, and recommended emergency drugs with choice varying with individual practitioner, patients treated, and facility	The same and more

ing, to some degree, becomes necessary. For the very young child (3 years or younger), drug-induced sleep from which a patient can be aroused often is desired by many medical and dental personnel. The important distinction between this state and deeper states (nonarousable and/or general anesthesia) is that the child can be aroused with a reasonably strong, repeatedly applied stimulus (e.g., pinch of the trapezius muscle). Furthermore, the aroused child should respond in a purposeful fashion to such a stimulus: withdrawal from the noxious stimulus and awakening with crying. Failure to respond in this fashion suggests deeper levels of depression, requiring more intense monitoring criteria. However, it would be clinically inefficient to continually "test" if the child is arousable every 5 min. If appropriate monitoring (pulse oximeter, capnograph [or stethoscope to determine good air exchange], blood pressure cuff, and clinical signs) demonstrates stable physiological parameters, then attempts to arouse the child during procedures seem unnecessary. Given this premise, the best method of preventive management is to provide the best possible opportunity for reflecting the child's physiologic status at any given point during the procedure with appropriate monitoring.

Since respiratory depression and subsequent inadequate tissue oxygenation are potentially major adverse effects of many sedatives, a means of monitoring this

effect is paramount. Pulse oximetry is recognized as the best noninvasive method of determining inadequate tissue oxygenation. It may not be the most "preventive" monitor (viz., a monitor that will allow appropriate intervention [e.g., head-tilt, chin-lift] to prevent inadequate oxygenation). Evidence exists in one dental study that the capnograph has a slight edge as a preventive monitor.[6] Side-stream capnography is easy to use with appropriate nasal probes, but very few practitioners are familiar with the apparatus. Nonetheless, the pulse oximeter has become an easy-to-use monitor familiar to most practitioners as compared with the capnograph. The pre-cordial stethoscope may also be a useful instrument, but no studies have compared its preventive capabilities directly to pulse oximetry and capnography.

Under conditions of deep sedation, a capnograph was added to the 1993 guidelines as being "desirable". By definition deep sedation cannot be measured because definitive clinical tests of a compromised airway do not exist. No monitor can detect such a compromise. Further, no practitioner is willing to administer 5 cc or less of water or blow compressed air into a sedated individual's airway to test if the patient can swallow or continue to breathe unimpeded. Yet every sedation guideline contains the definition wherein a portion alludes to the patient's possibly having "...partial loss of protective reflexes, including the ability to maintain a patent airway independently ...". Presently, the capnograph is the best early monitoring tool to determine such a condition, hence its inclusion as a desirable monitor in the guidelines.

Monitoring is important from a patient management perspective. Specific language was incorporated into the guidelines to encourage a responsible individual to intermittently acknowledge and record information that cannot be obtained solely by visual or auditory assessment (e.g., skin color and airway sounds, respectively). Requiring intermittent checks and recordings significantly increases the likelihood that early compromise of patient status is detected and managed accordingly.

Prescriptions and nitrous oxide

The current guidelines indicate that pulse oximetry is a minimum requirement during sedations except when "minor tranquilizers and/or nitrous oxide" are used. It has become clear that the term "minor tranquilizers" has caused misunderstanding. The terminology of minor tranquilizers [7] was utilized by the subcommittee to include only *anxiolytic* doses of hydroxyzine, Benadryl™, or a benzodiazepine (i.e., diazepam) *administered orally*. It DOES NOT include promethazine, meperidine, or chloral hydrate. Thus, any prescription designated as "minor tranquilizer" would not include the administration of chloral hydrate or meperidine outside of the dental facility by a parent or guardian.

Similarly, nitrous oxide used in dentistry rarely exceeds 50% concentration and, at this level, has not been shown to induce general anesthesia in young children. In dentistry, nitrous oxide is used in an "open" system where the patient can breathe room air, decreasing the effects of nitrous oxide. Rarely, if ever, does it induce a state from which the young child cannot be immediately aroused with or without the cessation of nitrous oxide flow. Practitioners recognize that children will not lose consciousness during appropriately titrated nitrous oxide inhalation *if the practitioner continues to talk with them even if they have had a minor tranquilizer administered as well!* Consequently, pulse oximetry becomes unnecessary under these conditions.

Oxygen analyzers

Oxygen analyzers are not flow meters, but devices that detect the presence of oxygen in a gaseous state. Debate on the cost and efficacy of oxygen analyzers could be eternal. The 1993 guidelines indicate that a newly built facility that has central nitrous oxide delivery systems must have the lines checked for proper gas delivery prior to use. Also, portable nitrous oxide delivery systems should be checked prior to each use. Any system capable of delivering greater that 80% nitrous oxide must have an in-line oxygen analyzer.

Crossed lines, hose brittleness and leakage, dysfunctional fail-safe systems, and tank problems (e.g., improperly coded, over-filled, or mismatch of PIN-indexing system) have occurred more commonly than previously thought. [8] The current guidelines indicate that nitrous oxide equipment be tested on an annual basis. An oxygen analyzer, not a flow meter, is the appropriate monitor that definitively determines oxygen concentration; however, they are rarely installed on nitrous oxide units used in dentistry.

Future directions

Sedation guidelines will require modification on a periodic basis. One of the most perplexing issues of the past, present, and, no doubt, future-both among and between medical and dental specialties-will be the understanding and consensus of definitions of sedation states. Considerable differences of opinion exist on what constitutes "conscious" and "deep" sedation. To wit and anecdotally speaking, one of the authors (SW) recently had the opportunity to discuss with all medical, dental, and nursing staff who routinely use sedation for procedures involving children at Columbus Children's Hospital. At the time, the two guidelines followed by the hospital personnel were the AAP (1992) and AAPD (1993). Clinicians and nursing staff not only disagreed among specialties on the clinical signs associated with these defined states, but more often than not, clinicians within the same specialty could not agree on the definitions. As a result, those definitions and guidelines have been superseded by new ones on which all clinicians and nursing staff could agree.

Importantly, consensus definitions will have to include working knowledge of needs in various clinical settings and the establishment of measurable physiologic and behavioral parameters reflective of the different sedation states. Development of guidelines that possibly impact on other professional practices requires exposure to and consideration of the actual clinical practice of all; otherwise, disagreement and misunderstanding will occur.

Proposed alternative concept of sedation guidelines

Sedation for many children may be the only humane modality for providing dental care because many third-party policies refuse payment for dental treatment under general anesthesia. Unfortunately, access to an operating room has become limited or nonexistent and the impact of managed care is unknown at this time. The authors offer the following sedation guideline plan (summarized in Table 2) as a possible embarking point for future discussions on definitions of sedation states. The plan, although based on the present understanding and need of pediatric dentists who must provide oral care to the very young, precooperative child, has been shown to be flexible and acceptable to every specialty group within one author's (SW) institution.

As a part of this guideline plan, it is proposed that the terms "conscious" and "deep" be removed from all guidelines. These were terms introduced when sedation guidelines were first developed. Because they are impossible to measure with any instrument, semantically and arguably confusing, and since monitoring technology has advanced so dramatically in recent years, the terms are no longer useful.

It has been known for decades that chloral hydrate is the most popular sedative agent used in medical and dental proced u res.[9-13] In therapeutic doses (in dentistry, this is usually 50 mg/kg or less), it has the potential of rendering the child into a sleep-like state. However, with appropriate practitioner training and monitoring, it can be and is used safely every day in the United States.

The induction of a sleep-like state is contrary to most guidelines, which use the term "conscious sedation", although many practitioners would admit that induced sleep is preferred in the efficient treatment of the very young (3 years or younger). Further, it is generally acknowledged that in this type of sleep most children are easily aroused with proper stimuli. Also, pharmacologically induced sleep is not an undesirable state if adequate and appropriate monitoring guides the practitioner's activities. This statement assumes the practitioner is trained to a level of proficiency in the understanding of monitoring techniques and in man-

TABLE 2. SUBCATEGORIZATION SCHEME FOR CURRENT AAPD GUIDELINES ON SEDATION

	Conscious Sedation		*Deep Sedation*
	Interactive	*Noninteractive, Arousable*	*Noninteractive, Difficult to Arouse*
Goals	a. Decrease patient anxiety b. Facilitate patient coping skills c. Maintain patient in drowsy state	a. Decrease or eliminate patient anxiety b. Pharmacologic-induced sleep	a. Eliminate patient anxiety
Characteristics	a. Patient drowsy, but awake b. May have eyes open or temporarily closed (< 1 min) c. Can communicate verbally	a. Eyes closed b. Mimics sleep behaviorally and physiologically c. Arousable with minimal or moderate stimulus (e.g., trapezius pinch resulting in reflex withdrawal and crying)	a. Sleep b. Inseparable behaviorally from general anesthesia c. Nonarousable with moderate to intense stimuli
Personnel	a. Minimum of two b. At least one trained at level required in guidelines c. BLS	a. Minimum of two b. At least one trained at level required in guidelines c. BLS	a. Minimum of three b. At least one trained at level required in guidelines c. PALS or ACLS required
Facilities	a. O_2 at 10 L/min for 60 min b. Emergency kit	a. O_2 at 10 L/min for 60 min b. Emergency kit	a. O_2 at 10 L/min for 60 min b. Oxygen analyzer required c. Emergency kit
Monitors	a. Pulse oximeter b. Precordial stethoscope	a. Pulse oximeter b. Precordial stethoscope c. Capnograph desired, but not required d. Blood pressure cuff	a. Pulse oximeter b. Precordial stethoscope c. Capnograph d. Blood pressure cuff e. Electrocardiograph f. Defibrillator available

aging a patient in this state. The following clinical states are described for consideration by the dental and medical community and form the basis for the proposed sedation guideline plan.

Interactive sedation

The first state, referred to as "interactive", has as goals the reduction of anxiety and the promotion of coping skills in the patient (Table 2). Under these conditions patients would not lose consciousness, that is, they would have their eyes open and communicate verbally. Rarely, they may close their eyes momentarily and if longer, respond immediately to a spoken stimulus (e.g., "open your eyes"). The only monitors suggested would be a pulse oximeter and precordial stethoscope. The need for the pulse oximeter arises because it is not always predictable if patients will maintain open eyes or verbally respond on command. If patients close their eyes, they can be prompted to respond on a frequent basis provided they do not become agitated by the interruption. If they no longer open their eyes upon command, they have transcended into another state that we call "noninteractive, but arousable".

Noninteractive, arousable sedation

The goal of the "noninteractive, but arousable" state is to decrease or eliminate patient anxiety and induce pharmacologic sleep that is physiologically like natural sleep. Characteristically, patients would have their eyes closed and would not respond to spoken stimuli. However, they would respond purposefully to a physical stimulus designed to induce, temporarily, minimal to moderate discomfort such as a pinch of the trapezius muscle. The purposeful response would include withdrawal from the noxious stimulus and ultimately crying, especially when the stimulus is applied repeatedly and rapidly.

In pediatric dentistry, this is a highly desirable state for providing restorative care to the very young child. The minimal monitoring requirements would be a pulse oximeter, precordial stethoscope, and blood pressure cuff. A capnograph is highly desirable, but not required.

The provoking stimulus should be applied in areasonable fashion. It is detrimental to arouse a child from such a state every 5 min, causing them to become agitated and disruptive if otherwise the physiological signs are stable, an open airway is documented, and the movement of air into and out of the lungs occurs. Failure to elicit this type of response would place the patient into state referred to as "noninteractive, nonarousable".

Noninteractive, difficult-to-arouse sedation

The noninteractive, difficult-to-arouse state would be indistinguishable from general anesthesia in that the patient could not be aroused easily with sustained to intense stimuli. There would be a minimum of three individuals present with PALS or ACLS required for at least one of them. The monitors required would include pulse oximeter, precordial stethoscope, capnograph, blood pressure cuff, and an electrocardiograph with a defibrillator available.

Each of these clinical states can be determined by the trained practitioner because they are based on clinically measurable indices as compared to the current guidelines, which use terms such as "conscious" and "deep" sedation that are not measurable with today's monitors. Thus, training and monitoring should be the keys to managing sedation trials, not terminology that is confusing and unmeasurable.

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1. Guidelines for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients. Pediatr Dent 7:334-37, 1985.
2. Anesthesia and Sedation in the Dental Office. National Institutes of Health Consensus Development Conference Statement, Vol. 5, No. 5, 1985.
3. Davis MJ: Conscious sedation practices in pediatric dentistry: a survey of members of the American Board of Pediatric Dentistry College of Diplomates. Pediatr Dent 10:328-29, 1988.
4. Guidelines for the elective use of pharmacologic conscious sedation and deep sedation in pediatric dental patients. Pediatr Dent 15:297-301, 1993.
5. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. Pediatrics 89:1110-15, 1992.
6. Croswell RJ, Dilley DC, Lucas WJ, Vann Jr WF: A comparison of conventional versus electronic monitoring of sedated pediatric dental patients. Pediatr Dent 17:332-39, 1995.
7. Bergman SA, Wynn RL, Roth-Schechter BF, Requa-Clark B, Holroyd SV: The benzodiazepines, sedative-hypnotics, and central muscle relaxants. 4th Ed. In: Clinical Pharmacology Dental Practice, Holroyd SV, Wynn RL, Requa-Clark B, Eds. St Louis: CV Mosby Co, 1988.
8. Wilson S: A survey of the American Academy of Pediatric Dentistry membership: nitrous oxide and sedation. Pediatr Dent, in press.
9. Association of Pedodontic Diplomates: Technique for behavior management- a survey. ASDC J Dent Child 39:368-72, 1972.
10. Davis MJ: Conscious sedation practices in pediatric dentistry: a survey of members of the American Board of Pediatric Dentistry College of Diplomates. Pediatr Dent 10:328-29, 1988.
11. Duncan WK, Ashrafi MH, Pruhs RJ, Post AC: Chloral hydrate and other drugs used in sedating young children: a survey of American Academy of Pedodontic Diplomates. Pediatr Dent 5:252-56, 1983.
12. Keeter S, Benator RM, Weinberg SM, Hartenberg MA: Sedation in pediatric CT: national survey of current practice. Radiology 175:745-52, 1990.[Comments175:611-12, 613-15, 1990]
13. Binder LS, Leake LA: Chloral hydrate for emergent pediatric procedural sedation: a new look at an old drug. Am J Emerg Med 9:530-34, 1991.