Anesthesiology 2003; 98:1261–8

The American Society of Anesthesiologist's Efforts in Developing Guidelines for Sedation and Analgesia for Nonanesthesiologists

The 40th Rovenstine Lecture

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I am honored to have been selected to deliver the 40th Annual Emery A. Rovenstine Memorial Lecture. At previous Rovenstine lectures, I learned about his pioneering efforts as the Director of the Anesthesia Service at Bellevue Hospital (New York City, New York) where he served from 1935 to 1960; his Presidency of the American Society of Anesthesiologists (ASA), 1943–1944; and as the recipient of the ASA's Distinguished Service Award in 1957. In the past year, however, two outstanding articles have been written that present material I was unaware of.

Lucien Morris, M.D. (Professor Emeritus, Medical College of Ohio, Toledo, Ohio) authored the fascinating article "Ralph M. Waters' Legacy: The Establishment of Academic Anesthesia Centers by the 'Aqualumni'."[1] The 'aqualumni,' is defined as Waters' own trainees. The article was written to commemorate the 75th Anniversary of Waters accepting an academic appointment to the medical faculty of the University of Wisconsin (Madison, Wisconsin).

I found particularly interesting the section describing Professor Waters' concern that when Dr. Rovenstine, one of his aqualumni, went to Bellevue Hospital, New York University (NYU, New York City, New York), he might not have sufficient staff to establish a new academic training center for anesthesia. As a result, Waters split his Wisconsin group, sending both staff and residents to New York City to ensure the success of Dr. Rovenstine at NYU. Waters had enough confidence in Dr. Rovenstine to predict that he would succeed. He would not disappoint Dr. Waters.

David Waisel, M.D. (Department of Anesthesia, Children's Hospital, Boston, Massachusetts) provided a comprehensive review of "The Role of World War II and The European Theater of Operations in the Development of Anesthesiology as a Physician Specialty in the USA."[2] In 1942, Waters and Rovenstine and others teamed up to train "90-day wonders" in 12-week courses "to prepare medical officers to take charge of the anesthesia sections of the various types of hospitals of the U.S. Army." Courses were given at several institutions, including Bellevue, and were developed by the Subcommittee on Anesthesia of the National Research Council. The latter was chaired by Dr. Waters. Dr. Rovenstine was the Secretary. Many future anesthesiologists were attracted to the specialty as a result of their initial exposure to the field in World War II and the influence of role models such as Dr. Rovenstine.

Although I did not know Dr. Rovenstine personally, I was trained by another aqualumnus of Dr. Waters, Robert D. Dripps, M.D. (Professor and Chair, Department of Anesthesiology, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania). Dr. Dripps was interested in attracting medical students into the field of Anesthesiology. One of his efforts led to the establishment of the ASA Preceptorship Program and the Committee on which I first served the ASA.

In the 36 yr in which I have been involved in the activities of the ASA, 20 yr have been spent on developing guidelines for sedation for nonanesthesiologists. It has been the most challenging, frustrating, and contentious issue I have had to address.

Even though ASA's efforts have been exemplary, the results have been misunderstood by not only the groups we have attempted to educate but also by our own members. I have decided to set the record straight by discussing the history of "ASA's Efforts in Developing Guidelines for Sedation and Analgesia for Nonanesthesiologists." Some of the comments that follow are my own thoughts and interpretations; however, most of the statements are documented in the literature or are part of my own collection of documents. The latter will be donated to the Wood Library Museum (Park Ridge, Illinois) together with the script of this lecture.

The formal process of ASA's evidence-based guideline development for members did not begin until 1990, and for nonanesthesiologists, in 1993. Other specialty groups began setting guidelines earlier and their efforts must be acknowledged before proceeding with ASA's efforts. It is not intended to provide a comprehensive or complete review of these accomplishments but rather to attempt

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Submitted for publication June 12, 2002. Accepted for publication December 16, 2002. Presented at the Annual Meeting of the American Society of Anesthesiologists, October 14, 2002, Orlando, Florida. 40th Annual Emery A. Rovenstine Memorial Lecture.

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to chronicle the background from which ASA developed some of its interest.

Dentistry

Driscoll[3] describes one of the anesthetic eras, "conscious and unconscious sedation," as beginning in 1970. He notes that, previously, the use of diazepam along with local analgesia was relatively uncomplicated. However, soon meperidine, atropine, fentanyl, methohexital, and a host of other drugs were also added. Polypharmacy posed a potential problem.

In 1972, "Guidelines for Teaching the Comprehensive Control of Pain and Anxiety in Dentistry" were published.[4] These guidelines established a standard for training all dental personnel in this area of patient management.[5] Apparently the dental profession continued to strive for a balance between minimizing fear and anxiety and maximizing safety. To resolve some of the issues, The National Institutes of Health (NIH), The Food and Drug Administration, and The NIH Office of Medical Applications of Research (Bethesda, Maryland) convened a Consensus Development Conference on Anesthesia and Sedation in the Dental Office.[6]

A host of experts, including anesthesiologists, agreed on developing answers to frequently asked questions. Although the principles and definitions described in the document are not necessarily original (but undoubtedly originated in the dental literature), they do represent important features, which continue to be emphasized, and must not be ignored. Several of these are as follows:

1. Drugs that depress the central nervous system produce a progressive dose-related continuum of effects.
2. "Conscious Sedation": The patient retains the ability present before sedation to independently maintain an airway and respond appropriately to verbal command—protective reflexes are normal or minimally altered.
3. The use of central nervous system depressants for conscious sedation, especially when used in combinations, requires careful titration and close monitoring to avoid unanticipated deep sedation or general anesthesia.

From time to time, other Dental groups, such as The American Dental Association (Chicago, Illinois) and American Association of Oral and Maxillofacial Surgeons (Rosemont, Illinois), have issued comprehensive guidelines for sedation and anesthesia; however their design and content are beyond the scope of this discussion.

The American Academy of Pediatrics

My involvement with the formulation of guidelines related to sedation began in 1983 as a member of the Committee of the Section on Anesthesiology, American Academy of Pediatrics (AAP) (Elk Grove Village, Illinois). Sedation guidelines were developed by the AAP primarily because of the reporting of a number of deaths in dental offices.[7] In 1985, The Committee on Drugs, Section on Anesthesiology, AAP, in conjunction with The American Academy of Pediatric Dentistry (Chicago, Illinois), published Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Patients.[8] In this document, the three states were defined as were the requirements for selection of patients, personnel, monitoring procedures, facility, equipment, and recovery care. The definition of conscious sedation included the patient's ability to maintain a patent airway and that this be retained independently and "continuously." It also noted that "the drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely."

Although a number of anesthesiologists, including myself, were members of one of the committees drafting the Guidelines, the ASA was not officially involved. As a matter of fact, in its 1985 Annual Report, the ASA Committee on Pediatric Anesthesia stated "members of the committee, as well as others within the ASA, were interested and concerned with (these) guidelines . . ."* As a result, the 1985 ASA House of Delegates instructed the ASA Committee on Standards of Care to review the Guidelines and report back to the March Board of Directors. At the time of the referral, I was the Chair of this Committee. An official reply was drafted and specifically addressed items of concern, such as the requirement for the use of intravenous (IV) injections in patients undergoing Deep Sedation and General Anesthesia.† This was subsequently "clarified" by the AAP making it permissible for personnel expert in securing IV access in infants and children to be immediately available. Both the Committee on Pediatric Anesthesia and Standards of Care agreed that many portions of the AAP Guidelines were well designed but believed that it was "essential—that future undertakings of this type and importance have official input from the ASA."

In 1992, the AAP published a revision of the 1985 Guidelines.[9] In this document, it was noted that "regardless of the intended level of sedation or route of administration, the sedation of a patient represents a continuum—and a patient may move easily from a light level of sedation to obtundation." It also added that "the practitioner should be prepared to increase the level of vigilance corresponding to that necessary—" if the patient becomes more deeply sedated. Use of pulse oximetry was required for both conscious and deep sedation.

* Committee on Pediatric Anesthesia, ASA, Annual Report, September 1985, 620-1, p 1.

† Committee on Standards of Care, Interim Report to the Board of Directors, March 1986, 433-1, p 2.

(Note: I have not attempted to describe this important document in its entirety.) The 1992 Guidelines were reviewed and suggestions made by the ASA's Committees on Pediatric Anesthesia and Standards of Care before the document was published. Their contributions were acknowledged by the AAP.

Several articles have been written that describe the evolution of the development of the AAP's Guidelines.[10,11] Of particular interest to me are several references to the reason that ASA "renewed" its interest in the revised (1992) Guidelines. Striker and Coté[11] state, "at the time of revision, the Committee on Drugs felt it important to once again work with the ASA, since during the intervening years from the original guidelines, The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (Oakbrook Terrace, Illinois) took the torch of responsibility." Further, "with renewed interest (in part because of the JCAHO), the ASA Committee on Standards reviewed each iteration of the revised pediatric guidelines."

These statements clearly imply that ASA was complacent until JCAHO provided the impetus for ASA to get moving. Nothing could be further from the truth. To the contrary, ASA had taken a different path in generating guidelines for sedation and, as early as 1985 through our liaison activities with JCAHO, we were able to convince them to incorporate the concept of sedation into their accreditation standards. ASA's initial concern and involvement related to deaths outside the operating room when nonanesthesiologists sedated adult patients with a new drug, midazolam (VERSED®, Hoffman–La Roche Laboratories, Nutley, NJ).

In 1985, the Food and Drug Administration approved the use of midazolam, and in 1986, it was marketed in the United States. Midazolam was reported to be twice as potent as diazepam.[12] There were warnings from abroad that the comparative potency with diazepam was underestimated.[13] Midazolam had certain advantages over diazepam—water solubility, less venous irritation, potent amnesia, and "short" duration of action. As a result, its use was embraced by a variety of types of practitioners who administered sedation.

Bailey *et al.*[14] demonstrated in human volunteers that the combination of midazolam with fentanyl in reasonable doses produced hypoxemia. Subsequently, they cited data from the Department of Health and Human Services, Office of Epidemiology and Biostatistics, Center for Drug Evaluation and Research, Data Retrieval Unit, in which 86 deaths were collected in the United States after the use of midazolam.[15] All but 3 occurred outside the operating room "in clinical situations where patients are typically unattended by anesthesia personnel." Seventy-eight percent of these deaths were associated with oxygenation or ventilation difficulties, and in 57% of these respiratory deaths, various opioids were used.

Bailey *et al.*[15] also noted that endoscopists were beginning to document the risk of hypoxemia in their environment. Further, most of these midazolam-associated adverse drug reaction reports involved care outside the operating room, where standards for the assessment of ventilation and oxygenation had not been defined and therefore were variable.

In 1986, the ASA published its first standards for its members—Standards for Basic Intraoperative Monitoring. These applied not only to the states of general and regional anesthesia but also to "Monitored Anesthesia Care" or "MAC." The latter term was also introduced in 1986 and applies to the service provided by the anesthesia care team in which the same level of care is provided with sedation/analgesia as with general or regional anesthesia. In the 1986 Standards, the use of pulse oximetry was encouraged.

In 1988, the package insert for midazolam HCl (VERSED®) was modified to state the "clinical experience has shown VERSED® to be 3–4 times as potent per mg. as diazepam. Because serious and life-threatening cardiorespiratory adverse events have been reported, provision for monitoring, detection, and correction of these reactions must be made for every patient to whom VERSED® injection is administered, regardless of age or health status" (injection, package insert, Hoffmann–La Roche, Nutley, NJ).

ASA and the JCAH (Early Efforts)

In the early 1980s, the section in the JCAH manual titled "Anesthesia Services" focused primarily on organization; staffing; safety (electrical and explosion hazards); delivery of care (*e.g.*, written guidelines for use of all general anesthetics); and quality and appropriateness of care. In 1982, the ASA developed a liaison with the JCAH (no "O" at that time). Representation was established in the Hospital Professional and Technical Advisory Committee (HPTAC), and in the Ambulatory Health Care Professional and Technical Advisory Committee (AHCPTAC).[16]

ASA's representatives, Eli Brown, M.D. (then, Professor and Chair, Department of Anesthesiology, Wayne State University, Detroit, Michigan) and Harry Wong, M.D. (then, Medical Director and President of the Medical Staff, Salt Lake Surgical Center, Salt Lake City, Utah) brought to the JCAH their concerns with the deaths occurring outside the operating room when potent sedatives with or without narcotics were administered by the "operating practitioner" to patients who were not adequately monitored. Largely due to their influential efforts, in 1985 the JCAH drafted proposed Standards for Surgery and Anesthesia services that addressed the surgical and anesthesia care of patients wherever they receive care in a hospital and to reflect current practices in the delivery of surgery and anesthesia care.

In 1986, a draft was sent for "field review" to 1951 organizations and individuals. This led to the landmark language of the 1988 Standards for Surgical and Anesthesia Services (SA).

"The standards in this chapter apply to services for all patients who (1) receive general, spinal, or other major regional anesthesia or (2) undergo surgery or other invasive procedures when receiving general, spinal, or other major regional anesthesia and/or intravenous, intramuscular, or inhalation sedation/analgesia that, in the manner used in the hospital, may result in the loss of the patient's protective reflexes. Invasive procedures include, but are not necessarily limited to, percutaneous aspirations and biopsies, cardiac and vascular catheterizations, and endoscopies."‡

The Director of Anesthesia's clinical and administrative responsibilities included "assuring" the effective monitoring and evaluation of the quality of appropriateness of anesthesia care provided by individuals in any department/service of the hospital, including— dental, emergency, *etc.* Requirements for assuring the availability of continuing medical education programs, monitoring the quality and appropriateness of anesthesia services, and other key items were included. The Standards required that "patients with the same health status and condition receive a comparable level of quality of surgery and anesthesia care throughout the hospital." Obviously, the standard applied to adults and children and was promulgated by an accrediting organization that required conformance or else "deemed status" might not be attained.

The endoscopists, in particular, were very alarmed by this development and considered the whole issue to be a turf battle between them and the anesthesiologists. They objected to being placed under the category of "surgical and anesthesia services." In 1988, I replaced Eli Brown, M.D. (then, Professor and Chair, Department of Anesthesiology, Wayne State University, Detroit, Michigan) as ASA's liaison with the JCAH HPTAC. At the request of Jim Roberts, M.D. (Vice President, JCAH), I met with him and a representative of the endoscopy community, David Fleisher, M.D. (Division of Gastroenterology, Georgetown University Hospital, Washington, DC). After a lengthy discussion, Dr. Roberts confirmed that the language in the JCAH Standards for Surgery and Anesthesia Services was intended to promote safety and uniformity in the quality of care and that, indeed, the requirements applied to endoscopists using sedation that "in the manner used—may result in the loss of protective reflexes."

One of the results of this meeting was the establishment of a dialogue between the endoscopists and anesthesiologists at a national level. In 1989 and 1992, I was invited to address the conventions of the American Society of Gastrointestinal Endoscopists (ASGE) (May, 1989, Washington, DC, and May, 1992, San Francisco, California). In 1989, The Society of Ambulatory Anesthesiologists (SAMBA invited the Chair of the Standard's Committee, ASGE, to SAMBA's annual meeting; April, 1989, San Antonio, Texas). Anesthesiologists and endoscopists began a dialogue but disagreed on several key issues: (1) the level of sedation for which the JCAH Standards applied, and (2) the use of the pulse oximeter. Fleisher[17] wrote "the proper role of pulse oximetry and continuous electrocardiographic monitoring during endoscopic procedures is controversial and unsettled." The ASGE's position was that the intensity of monitoring should be proportional to the patient's perceived risk factors, degree of sedation, and the type and duration of the procedure.

In 1990, the JCAHO added to the Standard for Anesthesia the requirement for the Director of Anesthesia Services to *participate* "either directly or through a designee(s) with representatives of other departments/services that provide anesthesia services in the formulation of mechanisms and material that help to provide uniform quality of anesthesia services throughout the hospital." Previous language including approaches to effectively monitor and evaluate the quality and appropriateness of anesthesia care . . . in any department/service in the hospital . . ."was retained.

The requirement to "participate" was interpreted by many anesthesiologists as an obligation to develop policies and procedures and to be responsible for the activities of practitioners who functioned outside their department without having the authority to oversee their practice. To add to the confusion, Directors of Departments of Anesthesia were also scurrying around to collect official ASA materials to incorporate into their facilities' policies and procedures for sedation. In an attempt to clarify this issue and to reassure our members, I authored an article for the ASA Newsletter: "JCAHO Update: Anesthesia Services in other Hospital Departments."[18] In this article, I emphasized that the applicable JCAHO standards only required that the Director of Anesthesia be responsible for the actions of the members of his/her department compared to practitioners not affiliated with the department. ASA documents that could be used as the basis for designing policies and procedures such as Standards for Basic Intraoperative Monitoring were noted.

Although many other significant events occurred in the redrafting of the language of the JCAHO Standards between 1990 and 2001, suffice it to say that confusion and conflict reigned within ASA and between our organization and other specialties. In 1993, one "revision" by JCAHO of the definition of anesthesia care was especially upsetting and unsettling. It redefined the circumstances under which the sedation standards applied including "sedation (with or without analgesia) for which there is

‡ Accreditation Manual for Hospitals, Joint Commission on Accreditation, 1988, p 287.

a reasonable expectation that in the manner used, the sedation/analgesia will result in the loss of protective reflexes for a significant percentage of a group of patients." In other words, if the drugs, doses, and techniques used were not expected to produce a loss of consciousness for a significant percentage of a group of patients, sedation as used in the above manner would not require the practitioners' compliance with the Standards for Anesthesia Care.§ The endoscopists were elated. The ASGE Governing Board concluded that during conventional IV conscious sedation employed by most endoscopists, protective reflexes are not lost in a significant percentage of patients. JCAHO appeared to confirm what the ACGE continued to contend, *e.g.*, that in most cases, endoscopic procedures are safe and that cardiorespiratory complications are rare.[19]

In response to this JCAHO revision, an irate ASA member wrote to the President of the ASA "most distressing is the lack of comment by the ASA. I am ashamed and embarrassed to be a member of a professional society, which did not assume the role of patient's advocate. . . *etc.* The ASA was silent."

As I pointed out in "Update on 1993 Accreditation Manual for Hospitals,"[20] the new language was adopted by the ultimate authority of the JCAHO, the Board of Commissioners, without the knowledge, input, or consent of the PTAC and without the traditional field review. Representatives to JCAHO from ASA and The Society for Ambulatory Anesthesia (SAMBA) were blindsided. This illustrates that, even if there had been objections from our representatives at the PTAC level, their recommendations might have been accepted, rejected, or modified by the two levels above them; *e.g.*, Standards and Survey Procedure Committee (SSP) and The Board of Commissioners.

Between 1985 and 1993, we learned many lessons from Guidelines and Standards generated by other organizations and received valuable input from our members about what they needed to fulfill their departmental and institutional commitments related to the development of policies and procedures for the practice of nonanesthesiologists who provided sedation outside the operating room. Thus began ASA's efforts to establish its own Guidelines for this purpose.

Guideline Development by ASA

Public Law 101-239, The Omnibus Budget Reconciliation Act of 1989, created The Agency for Health Care Policy and Research. In 1990, Richard Stein, M.D., President of the ASA, was advised by the Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research (AHCPR), Department of Health and Human Services (Rockville, Maryland), of new legislation to develop, review, and update clinical guidelines. The products (guidelines) were expected to be derived from science-based analysis of the literature, expert opinion, and perspective of health care providers. In 1991, ASA established the Ad Hoc Committee on Practice Parameters under the chairmanship of James Arens, M.D. (then, Vice President for Clinical Affairs, University of Texas Medical Branch, Galveston, Texas).

Although the process that ASA adopted for guideline development is highly relevant, the details are beyond the scope of this lecture. Suffice it to say, the original members of the Ad Hoc Committee and the Chairs of the two initial task forces (Pulmonary Artery Monitoring and Management of the Difficult Airway) were briefed on the "Methodologic Steps in Guideline Development." The consultant who conducted the briefing was Steven H. Woolf, M.D., M.P.H., Office of the Assistant Secretary for Health, Department of Health and Human Services. The Guidelines were to be "evidence based."

In 1992, there was much discussion in favor of the development of an ASA Guideline to be titled "MAC" or "Conscious Sedation" for nonanesthesiologists. Ellison (Jeep) Pierce, M.D., President, Anesthesia Patient Safety Foundation (APSF) (Park Ridge, Illinois), emphasized that the development of Standards, Guidelines, and/or Practice Parameters should be the "exclusive property of the ASA," not APSF. He also noted prophetically, "if anybody in anesthesia does MAC, it will be considered self-serving by the other specialty societies involved. Therefore, by far the best approach is to have it carried out at the level of the Agency for Health Care Policy and Research" (personal Communication, Ellison C. Pierce, Jr., M.D., President, APSF, to Bernard W. Wetchler, M.D., First Vice President, ASA, November 23, 1992).

James Arens took Jeep's advice and recommended to AHCPR that they develop the Guideline. If they refused, ASA would proceed. AHCPR was not interested. In 1993, ASA selected members of a task force and appointed as its Chair, Jeffrey B. Gross, M.D. (Professor of Anesthesiology and Pharmacology, University of Connecticut School of Medicine, Farmington, Connecticut). Dr. Gross and I described the format of the process in an article "ASA Commissions Task Forces on Analgesia and Sedation by Non-Anesthesiologists."[21] In this article are several highly relevant comments:

1) Among the more challenging problems facing the task force is one of terminology. Although the term "conscious sedation" is used frequently, it is poorly defined, spanning the gamut from modest preprocedure sedation to minimal responsiveness during painful stimulation. Therefore. . . the task force concluded "sedation and analgesia" more accurately

§ Official Interpretation, JCAHO, Accreditation Manual for Hospitals, 95-000, February 2, 1995.

described the condition for which the guidelines are intended.

2) The task force intended to address scientifically whether or not the use of advanced monitoring techniques (*e.g.*, pulse oximetry, exhaled carbon dioxide detection) reduced the risk of adverse outcome. This was to be done by separating the issues into 2 serial linkages:
   a. Does appropriate monitoring reduce the risk of intermediate outcomes (hypoxemia, hypotension, dysrhythmias)? and
   b. Does detection of these intermediate outcomes reduce the likelihood of an overall bad result (such as cardiac arrest or cerebral anoxia)?

Prior to its final publication, the task force solicited opinions on the guidelines from selected experts (consultants) in the field of anesthesiology and from other specialties in which sedation and analgesia is commonly administered. The draft Guideline was also presented to anesthesiologists and invited representatives of specialty groups of nonanesthesiologists at several "open forums." In addition, the task force included as a member, Gregory Zuccaro, Jr., M.D. (Department of Gastroenterology, Cleveland Clinic, Cleveland, Ohio), an endoscopist who was officially recommended by ASGE.

In 1995, The Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists was approved by the ASA House of Delegates and in 1996 was published in the journal ANESTHESIOLOGY.[22] The Guidelines were also unanimously endorsed by the ASGE with the "intent to distribute the document to our entire membership for their reference in their practice" (personal communication, Emmet B. Keefe, M.D., President, ASGE to Glenn Johnson, Executive Director, ASA, December 14, 1995). After 7 yr of dialogue and obvious disagreements on the approach to the sedated patient, ASA and ASGE had finally reached consensus.

The Guidelines were welcomed by the ASA membership. Complimentary educational material was sponsored by Roche Pharmaceutical (Nutley, NJ) and Glaxo Wellcome (Research Triangle Park, NC) and the distribution was coordinated by APSF. Included in this material was a video, which was part of the ASA Patient Safety Series under the auspices of the Committee on Patient Safety and Risk Management. On the surface, it appeared that ASA had produced an evidence-based guideline, which would be embraced by all nonanesthesiologist practitioners. Unfortunately this was not the case.

The ASA's initial effort did not address the state of "deep sedation." In its "Definition of Terms," it is stated that "patients whose ONLY response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by 'sedation/analgesia'." The focus was on the state "that allows patients to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation."

Several prominent pediatric anesthesiologists pointed out that "since most pediatric patients, especially younger children, require a level of deep sedation, the new AAP (1992) sedation guidelines will still supersede the ASA task force recommendations."[11]

Maxwell and Yaster[23] noted that less personnel and less stringent monitoring and recovery facilities are usually associated with the state of "conscious sedation." "Not surprisingly, in current practice, nearly all sedation is called conscious sedation, regardless of the depth of sedation produced. Can painful procedures or nonpainful procedures requiring complete immobility (*e.g.*, diagnostic imaging or radiation therapy) be realistically performed in a child who is consciously sedated? We believe the answer is no. The myth of the achievability of a state of conscious sedation in which pediatric patients are simultaneously responsive to voice stimulus while immobile in the face of pain is just that—a myth."

Other criticisms were that the ASA was developing guidelines for nonanesthesiologists in order to retain their turf and that, in the end, the "evidence-based process" turned out to be a "consensus-based" document. Selection of "consultants" by the task force without the advice of specialty groups was also questioned.

Meanwhile, JCAHO was still collecting examples of adverse events associated with the use of sedation by nonanesthesiologists outside the operating room environment. Presumably, much of the recurring problems related to practitioners underestimating the degree of sedation provided and not instituting the monitoring and resuscitative efforts required.

A Breakthrough

ASA's liaison representatives to the JCAHO are members of the ASA Committee on Quality Management and Departmental Administration (QMDA).¶ The representatives notified the Chair, John Zerwas, M.D. (Staff Anesthesiologist, Memorial Hermann Healthcare System, Houston, Texas), of JCAHO's dilemma. In order to assist JCAHO staff in redrafting the Standards, Dr. Zerwas formed a working group.

Fortuitously, unable to address a report of the ASA Committee on Standards of Care relating to monitoring the adequacy of ventilation, the 1998 House of Delegates recommended referral of the definition of "general anesthesia" to a committee of the Presidents' choice. President John Neeld referred the definition to the "QI" Committee. Dr. Neeld was asked, and he agreed, to allow the Committee to expand its charge in order to define other states in addition to that of general anesthesia.

¶ Previously known as the Committee on Peer Review (until 1994); Quality Improvement and Practice Management (1994–1999); Quality Improvement (1999–2000); QMDA (2000–present).-

Early in 1999, the QI Committee met together with Jeff Gross, Chair, ASA Task Force on Sedation and Analgesia for Non-Anesthesiologists. It was noted that the only state previously defined by ASA was "sedation and analgesia" (conscious sedation), "Clinical" definitions were then established for 4 states:

1. Minimal Sedation (anxiolysis)
2. Moderate Sedation/Analgesia ("Conscious Sedation")
3. Deep Sedation/Analgesia
4. General Anesthesia

The proposed definitions were incorporated into a document titled "Continuum of Depth of Sedation." In the document, it was specifically recognized that by nature of being 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."

A representative of the Department of Standards of the JCAHO requested a draft of the document before it was to be officially presented to the ASA House of Delegates. She was thoroughly impressed. In 1999, the ASA House of Delegates gave its approval. It should be noted that early in 2000, the JCAHO representative attended the winter meeting of the "QMDA" Committee. Proposed, revised JCAHO Standards were presented, which leaned heavily on ASA's definitions. A dialogue ensued and alterations were recommended. A "final" document was presented at JCAHO's "PTAC" meetings, was enthusiastically received, and the new Standards were formally adopted, effective date, January 2001.

Importantly, the new JCAHO Standards for "Sedation and Anesthesia Care" apply when patients receive moderate (conscious) or deep sedation or general anesthesia. The continuum of sedation is recognized as is the requirement for the individual administering moderate or deep sedation and anesthesia to be qualified and have the appropriate credentials to "manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally."[24]

Coincidentally, following the ASA 5-yr review process, the ASA Task Force on Sedation and Analgesia for Non-anesthesiologists was required to review its original 1995 Guidelines. The Task Force also benefited from the ASA's definitions. An "updated" Guideline was approved by the 2001 ASA House of Delegates. It incorporated recommendations for management of a patient in whom deep sedation is produced. The Guidelines were officially endorsed not only by the ASGE but also by the American College of Radiology (Reston, Virginia) and The American Association of Oral and Maxillofacial Surgeons. Gross has provided a summary of the review process.[25] The complete version of the Guidelines was published in the journal, ANESTHESIOLOGY.[26]

Where Are We and Where Are We Going?

After many years of continuing efforts to educate other practitioners and specialty groups about the hazards of and safeguards for administering sedation and analgesia, the skeptics remain unconvinced about ASA's motives, the methodology, interpretation of the data, and the conclusions/recommendations. Some of this criticism could have been anticipated.

A perception remains that ASA's Guidelines are self-serving. Some believe that the recommendations for safe practice imply that anesthesia personnel should be involved when moderate or deep sedation is administered. This misinterpretation has surfaced more recently because of the close resemblance between the ASA's Updated Guidelines and The 2001 JCAHO Standards. In order to conform to the latter, some hospital officials have demanded the presence of a member of the anesthesiology department when sedation is administered in the magnetic resonance imaging or endoscopy suite.[27] Turf issues will continue until other physicians understand our motives and realize that the shortage of anesthesiologists exceeds our capacity to administer all sedation in hospitals, free-standing ambulatory care facilities, and offices.

The methodology used by ASA is even more stringent than that advocated by AHCPR and, in my opinion, is not a major issue. Employing an evidence-based model implies, however, that the meta-analytic findings supporting a specific linkage are present in a sufficient number of well-designed studies to be "supportive" of the recommendations. In general, this is not true.

For example, consider pulse oximetry. The "published data suggests that oximetry effectively detects oxygen desaturation and hypoxemia . . ." The term "suggests" was used rather than "supports" because there were too few randomized comparative studies or nonrandomized case control studies" (personal communication, Richard T. Connis, Ph.D., Methodologist, ASA Task Force on Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists to Burton S. Epstein, M.D., May 31, 2002). As is the case in many areas of medicine in which guidelines are intended to direct decisions, what is intended to be an evidence-based document ultimately ends up as one which is based largely on the consensus of experts.

In "Why Don't Physicians Follow Clinical Practice Guidelines?"[28] the authors describe multiple "barriers" to physician adherence in relation to behavior change. Two of these are 1) lack of agreement with specific guidelines—interpretation of evidence, and 2) lack of agreement with guidelines in general—biased synthesis. The doubters have even extended their skepticism to the issue of whether or not administration of sedation even requires the presence of a physician. In a Commentary, expressed in 2001,[29] Freeman states, "But is a qualified

and credentialed individual needed to manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. Perhaps the EEG technicians (Note: described in accompanying article) could be trained to respond to the monitor's beep. One would feel more comfortable if the current costly recommendations (JCAHO Standards) were developed by a group with less potential conflict of interest than anesthesiologists, and validated with empirical data." Freeman took aim particularly at an article by Coté *et al.*[30] analyzing adverse events in pediatrics. Freeman stated, "there has been no denominator in these critical incident analyses, and no evidence that the Guidelines produce safer sedation."[31]

In an editorial,[32] Lema warns a surgical colleague about the potential hazards of allowing nonphysician providers to take charge of administration of sedation. He notes "many low-incident, high risk procedures appear routine, as we perform hundreds of these procedures annually . . . when everything is all right, does this mean that nothing ever goes wrong? There's a cost for maintaining safe practice. It's called knowledge and experience." Bailey[33] notes that "anesthesiologists need to help educate and train their colleagues (we should stop calling them nonanesthesiologists) so that they too can administer safe and effective sedation." Yet there exists an ongoing debate within ASA whether or not to educate surgeons so that they may fulfill their responsibilities in supervising administration of sedation. Even those who agree with the concept are uncertain about the extent to which we should direct the educational endeavor. A continuing medical education course, for example, cannot simulate a formal residency in anesthesia.

To me, the pivotal issue, which remains, is how to convince a variety of practitioners about the actual hazards of administering sedation. If we are to negate the criticism concerning our Guidelines and our efforts to educate, anesthesiologists and other physicians administering sedation must make a greater effort to conduct well-designed prospective studies that quantify the risks. Until and unless recommendations are based on indisputable facts, our efforts to promulgate uniform safe practices and "vigilance" will be challenged. We will continue to be left with recommendations based on qualitative yardsticks and will remain vulnerable to valid criticism from within and outside the field. ASA and its affiliated foundations must take the lead in assisting anesthesiologists in designing definitive evidence-based research, which will lead to the optimum care of the sedated patient.

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