

# The Newest Threat to Emergency Department Procedural Sedation



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Guidelines for procedural sedation first appeared in 1985—a National Institutes of Health guideline for dentists<sup>1</sup> and an American Academy of Pediatrics guideline for children.<sup>2</sup> Because procedural sedation is a multidisciplinary field, a wide array of specialty societies, including the American College of Emergency Physicians (ACEP), subsequently crafted and periodically update their own sedation guidelines. These documents are not mandated by regulatory bodies such as The Joint Commission or the Centers for Medicare & Medicaid Services (CMS), but are instead initiated by the specialty societies on behalf of their members. These guidelines begin with accepted core sedation principles<sup>3,4</sup> and include customized elements to address specialty-specific needs, challenges, and patient populations.

The American Society of Anesthesiologists (ASA) is one of the many specialty societies to issue sedation guidelines. However, ASA guidelines have been fundamentally different because they have not been crafted for their own members, but instead were unilaterally written to apply to all other sedation providers. It is inexplicable why sedation practice by anesthesiologists would be excluded from guidelines designed to ensure patient safety. Their first practice guidelines for sedation and analgesia by nonanesthesiologists were released in 1996 and updated in 2002.<sup>5,6</sup> The term “nonanesthesiologists” is imprecise and antiquated, given that the diversity of other specialties practicing sedation is far from homogenous and demonstrates a broad continuum of sedation skills.<sup>7-9</sup> Rather than endorsing the ASA guidelines, major specialty societies, including ACEP and the American Academy of Pediatrics, have chosen to continue updating and applying their own established guidelines. Despite minor differences, these specialty-specific guidelines have been widely implemented with a high level of safety, and are specifically endorsed by the CMS: “A hospital could use

multiple guidelines, for example, ACEP for sedation in the ED [emergency department] and ASA for anesthesia/sedation in surgical services, etc.”<sup>10</sup>

Now the ASA has released updated sedation guidelines that again assert a scope beyond the practice of anesthesiologists, stating that their guidelines “are intended for use by all providers...in any inpatient or outpatient setting.”<sup>11</sup> These new guidelines contain vague, confusing, and misleading statements that run contrary to the existing scientific evidence and threaten the well-established sedation practices of emergency physicians and other specialists. Procedural sedation has long been a core competency in emergency medicine and critical care medicine, and our patients depend on us to provide effective sedation and analgesia for procedures that are often extremely painful (eg, cardioversion, abscess incision and drainage, fracture and dislocation reduction) or unduly frightening (eg, facial laceration repair, neuroimaging in a child). These revised ASA guidelines restrict the use of propofol and ketamine—our 2 most commonly administered sedative agents<sup>12-17</sup>—and any adoption or enforcement of these directives would restrict emergency physician access to these drugs, resulting in widespread use of alternative agents that are less safe and provide much less effective sedation and analgesia.

Despite these concerns, there are some positive aspects to this update. First, this is the first ASA guideline to drop the patronizing and divisive<sup>7-9</sup> “nonanesthesiologists” nomenclature.<sup>5,6,18-20</sup> Second, they now concur with the ACEP recommendations in regard to fasting,<sup>13-15</sup> stating: “In urgent or emergent situations where complete gastric emptying is not possible, do not delay moderate procedural sedation based on fasting time alone.”<sup>11</sup> Additionally, this is the first ASA guideline to invite selected outside specialty organizations to comment during its drafting. Five of these societies have chosen to endorse these guidelines: the American Association of Oral and Maxillofacial Surgeons, the American College of Radiology, the American Dental Association, the American Society of Dentist Anesthesiologists, and the Society of Interventional

Radiology. ACEP chose not to endorse the guideline when their key suggestions were not incorporated. The American College of Cardiology and the American Society for Gastrointestinal Endoscopy also declined to endorse the document. (Of note, these latter 3 societies have been omitted from the final document with their dissent unacknowledged.) Despite the disproportionate need for sedation in children, the ASA did not invite the American Academy of Pediatrics or the Society for Pediatric Sedation to provide guideline input. Similarly, no critical care specialists were included despite their common provision of sedation and their frequent management of hospital sedation services.<sup>21,22</sup>

Most evident in this ASA guideline is a detailed itemization of now-routine sedation precautions that have been reiterated in many such guidelines from multiple specialty organizations during the past 33 years. Of concern, however, are other guideline elements that are imprecise, overly broad, or omitting important context or detail. We describe the most concerning of these as follows:

#### WHAT HAPPENED TO DEEP SEDATION?

In a confusing omission, the new guideline inexplicably excludes deep sedation. Essentially all previous sedation guidelines address both moderate and deep sedation, as did the ASA's previous version of this document.<sup>6</sup> This is particularly perplexing in that deep sedation is just as common as moderate sedation worldwide (if not more so), particularly for children and for the painful procedures performed routinely in ED practice. By retiring the 2002 guideline that included deep sedation and replacing it with this new guideline that does not, the ASA has intentionally placed deep sedation into an indeterminate state.

The ASA promises a deep sedation specific guideline at some future date. A hint as to what it might contain is provided by the following sentence from an earlier draft of the current guideline: "The Guidelines do not apply to patients receiving deep sedation...whose care should be provided, medically directed, or supervised by a physician anesthesiologist...or another licensed physician with specific training in...anesthesia."<sup>23</sup> There was no additional language to specify what "training in anesthesia" specifically meant. In accordance with past precedent,<sup>9,16,24,25</sup> one can imagine that hospital anesthesia chiefs might readily interpret it as formal training in anesthesiology or nurse anesthesia. The ASA has long repeated the claim that deep sedation lies solely within their purview,<sup>9,16,18,24,25-27</sup> contrary to the reality that deep sedation is widely, safely, and routinely performed by emergency physicians and other specialists.<sup>9,13-17,21,22,24,25,28,29</sup> The ASA recently

reiterated this posture in a *New York Times* interview: "Both deep sedation or [*sic*] general anesthesia using an IV should be administered only by qualified anesthesia providers...."<sup>27</sup>

#### AN ANESTHESIOLOGIST GUIDELINE TO GOVERN ALL SPECIALTIES?

As previously noted, the ASA asserts that their guidelines "are intended for use by all providers...in any inpatient or outpatient setting."<sup>11</sup> The vision thus communicated is that the ASA regards their document as a universal replacement for the others. (If such is not their design, the guideline contains no contrary or otherwise clarifying language.)

Should one specialty attempt to dictate patient care for another setting in which they have no experience? Imagine the response if ACEP wrote a set of resuscitation guidelines and specified that they should apply to operating room care by anesthesiologists. Emergency physicians have long-standing, proven sedation skills and a track record as research leaders in this multidisciplinary field.<sup>3,4,12-17,24,25,28,30</sup> The CMS has specifically acknowledged the special situation and training of emergency medicine: "The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality."<sup>10</sup> They continue: "...emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is [*sic*] necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation...."<sup>10</sup>

Some might argue that the ASA is a reasonable choice to write "one guideline to rule them all"; however, the management of procedural sedation is different from that of general anesthesia, and the ASA is hardly in a position to be regarded as neutral and impartial. As noted earlier, the ASA has voiced long-standing<sup>18,26</sup> and current<sup>27</sup> opposition to deep sedation by other specialists, a position at odds with the enormity of the scientific evidence.<sup>9,13-17,21,22,24,25,28,29</sup> The ASA has characterized such sedation providers as "poachers,"<sup>31</sup> demonstrating financial motivations<sup>32,33</sup> driving their disapproval. Anesthesiologists have long objected to gastroenterologist deep sedation,<sup>34,35</sup> fueling an interspecialty competition for revenue because the endoscopy and colonoscopy suite processes a stream of well-insured, healthy individuals needing straightforward sedation during scheduled business hours, amounting to a multibillion-dollar annual business.<sup>34,35</sup>

In additional language from the new guideline that affects sedation finances, the ASA omits credentialing or privileging considerations altogether, stating that "...these guidelines do not address education, training or certification requirements for practitioners..." The previous ASA guidelines<sup>5,6</sup> and those of essentially all other specialties purposefully detail the minimum skill sets required for safe sedation. How can a sedation guideline be helpful if it does not address sedation skills required to safely and effectively perform sedation? This conspicuous omission goes unexplained, leaving readers to speculate on intent. Although the following are unmentioned and unreferenced in this guideline, individuals familiar with previous ASA publications will note the apparent missing puzzle piece: the society's earlier, largely ignored policy statements that declare that anesthesiologists should credential all sedation practitioners and that to keep and maintain such privileges other specialists must undergo anesthesiologist-supervised formal training programs, written tests on ASA policies, and supervised clinical experience.<sup>19,36</sup> (A detailed critique of this concept is found elsewhere.<sup>16</sup>) A new ASA course (costing \$3,399 per person, excluding "hotel, airfare, and other expenses") offers their own proprietary "deep sedation education...based on ASA guidelines for non-anesthesiologist physicians seeking privileges for deep sedation..."<sup>20</sup> Not just for the inexperienced, it is "[d]esigned for beginners and experts alike."<sup>20</sup> With this course offering, ASA would seem to imply that all "nonanesthesiologists"<sup>20</sup> need take this course to be considered eligible for deep sedation privileges, irrespective of preexisting core competency from specialty training. Should the ASA be permitted to implement and oversee such a highly complex regulatory system (with or without required ASA proprietary training), they would effectively control the financial purse strings for all procedural sedation.

### **PROPOFOL AND KETAMINE: "MEDICATIONS INTENDED FOR GENERAL ANESTHESIA"**

A surprising paradox in a guideline ostensibly dealing only with moderate sedation is how much discussion is given to propofol and ketamine, drugs essentially never used for moderate sedation. The guideline puts forth a novel binary categorization of sedation drugs, labeling benzodiazepines, opioids, dexmedetomidine, and a few others as "not intended for general anesthesia" and classifying propofol, ketamine, and etomidate as "intended for general anesthesia." Sedation agents cannot be so readily dichotomized because many of the "not intended for" drugs are actually Food and Drug Administration approved for general anesthesia: midazolam, alfentanil, and remifentanil are approved for "induction of general anesthesia" and fentanyl and nalbuphine are approved as an adjunct and

supplement to general anesthesia. In reality, drugs used for sedation are often safely used for anesthesia, and drugs used for anesthesia are often safely used for sedation.

There is no evidentiary or pharmacologic basis for the "intended for general anesthesia" nomenclature. This concept has no precedent in 33 years of sedation guidelines, which have all focused on the depth of sedation achieved rather than on any specific speculation in regard to what the laboratory chemists who created them originally intended. This odd schema is at best a misguided opinion and at worst an intentional mechanism to erect new semantic barriers against the existing widespread use of propofol and ketamine by multidisciplinary providers. The guideline states that "[w]hen moderate procedural sedation with sedative/analgesic medications intended for general anesthesia by any route is intended, provide care consistent with that required for general anesthesia." No details are provided about what care "consistent" with general anesthesia might actually mean, but one can readily imagine it argued as an operating room with an anesthesiologist or nurse anesthetist. Thus, should this ASA guideline update be widely accepted as authoritative, then the ability to provide patients effective sedation with propofol and ketamine could simply disappear or be left to the political whims of local anesthesia chiefs.

Furthermore, the guideline is inconsistent and confusing in regard to ketamine. The ASA states that "...if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, consult with a physician anesthesiologist."<sup>11</sup> Despite its remarkable safety profile, the ketamine dissociative state by definition entails unresponsiveness, so compliance with this new directive would require anesthesiology consultation before every ketamine sedation. Despite that the unique dissociative state is inconsistent with accepted definitions for moderate sedation, deep sedation, or general anesthesia,<sup>3,12-15,30,37</sup> the ASA overlooks the simple, evidence-based, and commonly applied solution of specifying "dissociative sedation" as a separate category.<sup>3,12-15,30,37</sup>

### **CONCLUSION**

In summary, the ASA guideline update contains numerous confusing statements on critical issues relating to ED sedation practice and misleading characterizations in regard to deep sedation, ketamine, and propofol that are contrary to the existing scientific evidence. Key issues such as deep sedation, guideline relationships, skill sets, and specific drugs lack sufficient clarity for meaningful understanding or consistent interpretation. Given the critical need for emergency physicians to advocate on behalf of their patients, and given that each of the vague or

omitted areas favors previously asserted adverse ASA positions, we believe that emergency physicians must assume the document to be politically motivated until proven otherwise.

Emergency physicians are fully qualified by their training to administer all levels of sedation, and emergency medicine has long been at the forefront of sedation research and safe sedation practice. Non-evidence-based efforts by another specialty to dictate our scope of practice must be vigorously opposed.

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