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COMMENTARY

New sedation and general anesthesia guidelines

Why the changes?

Jason H. Goodchild, DMD; Mark Donaldson, BSP, ACPR, PharmD, FACHE

***Editor's note:** In Dionne's commentary ("Raise the Bar for Safe Sedation, Not Barriers for Access to Care," on page 133) and in this commentary, the authors discuss the latest guidelines for using and teaching sedation and general anesthesia by dentists. Although the authors of both commentaries approach the subject of sedation and general anesthesia from different points of view, their main arguments focus on the concern for patient safety. Hopefully, providing both of these perspectives will afford JADA readers a better and more comprehensive understanding of the very serious issues involved and the challenges ahead.*

During the October 2016 American Dental Association (ADA) annual meeting, the House of Delegates voted to approve Resolution 37 and update guidelines for the teaching and use of sedation and general anesthesia by oral health care professionals (OHCPs).^{1,2} The changes to these documents primarily update educational requirements and clinical guidelines for the use of minimal and moderate sedation. First developed in 1971, this update to the ADA's sedation and general anesthesia guidelines is the latest evolution of a document that has been revised 10 times (most recently in 2012) and further attempts to bring clarity and direction for OHCPs wishing to use these modalities.³

WHAT ARE THE MAJOR CHANGES?

Minimal sedation. For minimal sedation via the enteral route, the dosing of medication is now limited to a single dose or multiple doses in which the cumulative amount does not exceed the US Food and Drug Administration's (FDA) maximum recommended dose (MRD) for unmonitored home use. Supplemental dosing, as described in 2012 in which the total aggregate dose must not exceed 1.5 times the MRD on the day of treatment, is now prohibited and replaced by statements indicating that if cumulative doses exceed the MRD, or if multiple enteral medications are used, that guidelines for moderate sedation must apply. The revisions, including the use of the MRD as a limit, are meant to "guide dosing for minimal sedation" and are "intended to create [a] margin of safety."¹

Also, for minimal sedation, the use of nitrous oxide and oxygen analgesia, specifically permitted by the 2012 guidelines when used in combination with a single enteral drug, has changed. Although still allowed, the original language is replaced by a statement advising that nitrous oxide and oxygen analgesia when

used in combination with a sedative agent may produce minimal, moderate, deep sedation, or general anesthesia.

Moderate sedation. For moderate sedation, the educational requirements have been revised to recommend a didactic course consisting of 60 hours of instruction and administration of sedation to at least 20 individually managed patients with no distinction made as to the route of medication administration. In other words, in 2012 moderate enteral sedation course duration was separate and different from parenteral, but the 2016 revision outlines training and clinical guidelines based on intended level of sedation, not route of medication administration.

Moderate sedation, deep sedation, and general anesthesia. In addition, for moderate sedation, deep sedation, and general anesthesia, the monitoring of ventilation

guidelines is to improve procedural safety and efficacy.³ These guidelines are then disseminated to the state boards and can be incorporated into regulations to help fulfill the mandate of every dental board: to protect the public. Tragic outcomes after dental sedation procedures continue to occur, and these outcomes can prompt scrutiny of guidelines and regulations, and ultimately necessitate changes and updates.⁵⁻¹¹ It is therefore essential that documents outlining education and best practices stay up-to-date and reflect not only the evolution of medications and monitoring, but also incorporate knowledge gained after review of adverse events.¹²⁻¹⁸

In addition, previous guidelines do not and cannot continuously account for the 1 variable that is always changing—our patients. In the last 4 years and beyond, the most important changes clinical

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must now be assisted by capnography and monitoring of end-tidal carbon dioxide (CO₂). In the previous document, end-tidal CO₂ monitoring was only required for intubated patients and was only suggested for nonintubated patients. Finally, patient evaluation for these 3 deepest levels of sedation and anesthesia should include body mass index and the consideration of patients with obstructive sleep apnea as part of the preoperative risk assessment.

Pediatric sedation. Pediatric sedation is now covered by the 2016 update detailed in the “Guidelines for Monitoring and Management on Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016.”¹⁴

WHY ARE THESE CHANGES NEEDED?

The intent of the ADA’s revised sedation and general anesthesia

OHCPs have faced include providing safe and effective sedation and anesthesia services to a population that is older, sicker, and taking more medications (both licit and illicit). Poor patient selection, even coupled with properly educated OHCPs, safe drugs, and up-to-date monitoring equipment, can still result in unintended and catastrophic outcomes.⁵⁻¹¹

In medical practice, there is the common idiom of “matching the right drug, at the right dose and the right time, for the right patient and the right procedure.”¹⁹⁻²⁰ The ADA has historically enhanced this approach by further considering the right setting, the right education, and even the right equipment. Regardless, with all the excellent intentions and iterations of the guidelines for the teaching and use of sedation and general anesthesia by OHCPs, picking the right patients can still be our Achilles’ heel.

WHAT MAKES OUR PATIENTS SO CHALLENGING?

Epidemiologic data continue to demonstrate that we are an aging population.²¹ The authors of this same report further predict that the United States’s 65-and-over population is projected to nearly double over the next 3 decades, from 48 million to 88 million by 2050. Moreover, this older population is retaining their dentition and requiring the expertise of OHCPs much later in life than has been experienced in the past.²²⁻²⁴ Unfortunately, although people are living longer, that does not necessarily mean that they are living healthier. Early studies had estimated that 30% of patients visiting a dental office suffer from at least 1 medical condition.^{25,26} The Centers for Disease Control and Prevention has reported that, “As of 2012, about half of all adults—117 million people—had 1 or more chronic health conditions. And 1 of 4 adults had 2 or more chronic health conditions.”²⁷ Further complicating the medical status of patients is that polypharmacology is becoming the norm as patients get into their sixth, seventh, and eighth decades of life, requiring more medications to treat their different concurrent chronic diseases.^{28,29} It is therefore essential that OHCPs undertake a comprehensive review of every patient’s medical as well as pharmacologic history before any procedure.

This written and verbal review needs to include an emphasis on both licit and illicit medication use as well as any complementary and alternative medications. Among adults 65 years or older, 40% take 5 to 9 medications regularly and 18% take 10 or more medications.³⁰⁻³² Furthermore, considering that nearly 70% of these people do not discuss their computer-aided manufacturing use with their primary care providers, OHCPs should ask all patients about their medication use, particularly when prescribing medications and when

considering the patients' overall sedative or anesthetic plan.³³ Finally, older adults are 7 times more likely than younger adults to experience adverse drug events that require hospitalization, underscoring the importance for all prescribers to carefully consider potential drug interactions and use available resources to mitigate risk (for example, Lexicomp, Micromedex, Clinical Pharmacology).³⁴

Evaluating the medical stability and appropriateness for sedation and anesthesia services for patients as described above may create a confusing milieu of disease states, medications, and potential drug interactions. In these situations, the OHCP must consider several factors: the preoperative fitness of the patient together with the planned sedative or anesthesia protocol, the setting where treatment will be performed, the availability of monitoring equipment, the potential for adverse events, and the ability to rescue the patient should an adverse event occur.³⁵ It is not enough to simply select inherently safe medications and expect a wide therapeutic margin to mitigate procedural risk. The ADA has addressed this in the revised clinical guidelines by stressing the evaluation of preoperative medical status, including implementation of the American Society of Anesthesiologists Physical Status Classification,³⁶ and consideration of the patient's body mass index and the other airway-associated risk factors such as obstructive sleep apnea.

Because the definition of both minimal and moderate sedation involves a patient who can maintain a patent airway without assistance, consideration of airway-associated risk factors is prudent and warranted. Respiratory depression and interruptions in breathing are the most likely sedation and anesthetic mishap, and the prudent OHCP should be vigilant in airway maintenance, both through patient selection and the use of appropriate monitoring.³⁷ To this

end, capnography and end-tidal CO₂ monitoring should add additional safety for moderate sedation.

USING THE MAXIMUM RECOMMENDED DOSE FOR MINIMAL SEDATION?

In most cases in which minimal or moderate sedation techniques are used, the use of benzodiazepines as first-line medications continues to be recommended given their long history of efficacy and safety.^{38,39} From a historical perspective, it is important to understand that the term *maximum recommended dose* is established as a part of the FDA approval process onto the US Pharmacopeia. It serves as a maximum dose, either given singly or as a cumulative amount for unmonitored home use, and continues to be part of the sedation and anesthesia guidelines. Although not expressly noted, the mention of MRD in the minimal sedation guidelines relates primarily to triazolam. When triazolam was approved in 1982, the indication was for the treatment of short-term insomnia (it has never received formal approval by the FDA for the indication of procedural sedation in dentistry). For the indication of insomnia and through subsequent FDA reviews, the MRD was established at 0.5 milligrams.^{40,41} How then should an MRD established for insomnia be interpreted to serve as the maximum dose for minimal dental sedation? The FDA's Web site indicates that per dose maximums for diazepam and lorazepam are 10 mg and 2 mg, respectively.^{42,43} The equivalent dose of triazolam to 10 mg diazepam and 2 mg lorazepam is 0.5 mg, which may provide some empiric guidance and predict an anticipated level of central nervous system (CNS) depression for dental sedation.^{41,44}

There have been theoretical attempts to define minimal and moderate enteral sedation dosing, and clinical reports detailing the CNS depression of triazolam on dental

patients.^{15,45-48} Although the available research is insufficient to clearly delineate the appropriateness of the MRD for minimal sedation, it should be considered suitable for 2 important reasons. First, for OHCPs with the smallest amount of sedation training, it creates a definitive maximum dose that when patient factors and potential drug interactions are accounted for, should provide a reasonable safety margin. Second, because drug effect and psychomotor impairment do not cease at the conclusion of dental treatment but wane over time, the MRD as an intended maximum dose for unmonitored home use can create additional safety for patients who have been dismissed and are no longer directly supervised by the dental team.

NO MORE DIFFERENTIATION BETWEEN ENTERAL AND PARENTERAL MODERATE SEDATION?

The other significant change with the approval of Resolution 37 relates specifically to moderate sedation where the route of administration is no longer a differentiating factor. Although the oral administration of medications is inherently the safest route given the first-pass effect, enterohepatic circulation, and even the presence of the P-glycoprotein pump throughout the intestinal epithelium, it does have its limitations in regard to predictability both in onset of effect and profundity of response. Drug latency allows for blunted responses, which may give the OHCP time to recognize and manage adverse outcomes, but interpatient variability still makes predictability of response a challenge. The intravenous administration of sedative medications, though much more predictable and titratable, is also more immediate in onset, forcing the OHCP to recognize and manage adverse outcomes immediately should they occur.

There may be OHCPs who will disagree with additional training and

expense to deliver the same level of sedation they have always provided,⁴⁹ but this guideline change speaks specifically to the philosophy of “[a]ll dental personnel involved in patient management should be adept in monitoring vital signs and in recognizing and managing life-threatening emergencies, including the ability to rescue the patient from an unintended lapse into a deeper level of CNS depression.”⁵⁰ The inherent differences between enteral and parenteral aside, once patients achieve a level of moderate sedation then the same level of caution to prevent unintended deepening of sedation or compromise in airway patency must apply, regardless of route of drug administration. Patients sedated to a moderate level either via oral triazolam or an intravenous benzodiazepine are equally at risk of experiencing airway-associated morbidity, so the training required to provide this level of sedation to an increasingly compromised patient population should be the same.

The approval of Resolution 37 and the recently updated guidelines for the teaching and use of sedation and general anesthesia by OHCPs will not be the last iteration for this evolving document. Sedation and general anesthesia services in the dental office are essential for the treatment of dental patients, and our profession should never stop striving for improved efficacy and safety (Box). To that end, the ADA should be commended for continuous and timely updates to the guidelines for the teaching and use of sedation and general anesthesia by dentists.

CONCLUSIONS

The new ADA guidelines for the teaching and use of sedation and general anesthesia by OHCPs outline 3 levels of sedation and general anesthesia and encourage OHCPs to embrace education, monitoring, and patient assessment as principal means of ensuring

BOX

Key takeaways

- The most important determinant for safety of dental sedation and general anesthesia is appropriate patient selection and deselection (referral).
- The maximum recommended dose for unmonitored home use is the best surrogate for these same medications in procedural sedation. However, these maximum dosages should serve as the ultimate guardrail and should not be considered target doses; rather, do not exceed doses.
- More educational opportunities, both didactic and clinical, must be made available for oral health care providers to achieve and maintain competency in providing sedation and anesthesia.
- For moderate sedation, the educational requirements should be based on the intended level of sedation and appropriate selection and management of these patients and should not be specifically focused on the route of medication administration.

patient safety. For minimal sedation, the maximum recommended dose for unmonitored home use is the correct surrogate as the ultimate guardrail for these same medications in procedural sedation, but they should not be considered target doses, rather, do not exceed doses. Educational requirements for moderate sedation should be based on the intended level of sedation, and appropriate selection and management of these patients, and not simply the route of medication administration. No single drug is truly safe and no single level of sedation or anesthesia is appropriate for all patients, therefore OHCPs must understand and appreciate limitations based on patient, drug, and procedural factors and the appropriateness of referral. ■

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Dr. Goodchild is an associate professor and the chairman, Department of Diagnostic Sciences, Room 210A, School of Dentistry, Creighton University, 2802 Webster St., Omaha, NE 68131, e-mail JasonGoodchild@creighton.edu. Address correspondence to Dr. Goodchild.

Dr. Donaldson is the senior executive director, Vizient Pharmacy Advisory Solutions, Irving, TX; a clinical professor, School of Pharmacy, University of Montana, Missoula, MT; and a clinical assistant professor, School of Dentistry, Oregon Health & Sciences University, Portland, OR.

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