This PDF document includes written comments and correspondence received by the Council during March and April 2016 regarding 2015 proposed revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.
The American Association of Oral and Maxillofacial Surgeons (AAOMS)
9700 West Bryn Mawr Avenue
Rosemont, IL 60018-5701
847/678-6200

Testimony to the Council on Dental Education and Licensure
In Response to Proposed Revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists
Presented by Louis K. Rafetto, DMD, President

The American Association of Oral and Maxillofacial Surgeons appreciates the opportunity to provide testimony to the Council on Dental Education and Licensure regarding the Proposed Revisions to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists.

Dr. Phillip O. Bridenbaugh, recipient of the American Dental Society of Anesthesiology’s 2005 Heidbrink Award, advised his audience, “It’s all about the patient. Our social, political, and professional energies should be directed toward protecting our rights to give up-to-date safe patient care. We must remember that quality of care requires up-do-date physical resources and the knowledge to give our patients our best. Patient safety is an increasing part of that care.”

We at the AAOMS believe that the ability to provide dental sedation in an ambulatory or office setting is both a privilege and a profound responsibility. The recent deaths and adverse events resulting from anesthesia-related procedures in the dental office have generated national media attention and shaken the public’s confidence in the degree of safety they have come to expect from their dental professional. Moreover, a number of state legislatures and regulatory boards are considering language that could severely limit the way in which dentists provide sedation in the office setting. This unpredictable environment underscores the importance of these guidelines and their possible consequence for patient safety and the future of dental sedation.

The AAOMS would like to address two key areas in the Guidelines:

Section 2. Pre-Operative Preparation, lines 317-319, state that a “focused physical evaluation must be performed as deemed appropriate, including recording the patient’s body weight and BMI.” The AAOMS strongly endorses this section, and commends the ADA for recognizing that a patient’s BMI is essential to calculating and administering the appropriate dosage and level of anesthesia. As stated in the Journal of Clinical Anesthesia, “Patients with high BMI have a greater prevalence of comorbid conditions, require alterations in anesthetic and oocyte retrieval management, and more often experience intraoperative and postoperative events.”

Section 2. Equipment, lines 332-336, calls for the immediate availability of a “positive-pressure oxygen delivery system” when anesthesia is administered during dental procedures. The AAOMS strongly supports Section 2. Equipment, and believes the use of capnography in all office-based procedures requiring moderate, deep or general anesthesia aids the provider and offers an important measure of safety for the patient.

The use of such capnography monitoring equipment for office-based anesthesia-related procedures has been shown to provide real benefits for the provider and a safer experience for patients. Capnography, long the standard of care in the hospital OR, has been greatly improved and is quickly becoming an important asset in the ambulatory surgical setting as well.

The American Society of Anesthesiologists, in their Statement On Granting Privileges For Administration Of Moderate Sedation To Practitioners Who Are Not Anesthesia Professionals, state that “During
moderate sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment.iii

Following the lead of the American Society of Anesthesiologists (ASA), the American Heart Association and other organizations that develop parameters of care and practice guidelines for their dental and medical surgical specialists, the AAOMS revised its Parameters of Care in 2014, to require oral and maxillofacial surgery practices to utilize capnography equipment for all procedures requiring moderate sedation, deep sedation and general anesthesia. iv

Conclusion

Moderate and general sedation in the dental office are becoming widely available for patients who are considering lengthy procedures or who have a high level of anxiety. Its growing acceptance and availability, however, requires that we, as leaders of the profession, assure that those practitioners who administer sedation in their office are:

1. Trained to administer the anesthetic and committed to ongoing continuing education to assure they are aware of the latest equipment, drugs and techniques;
2. Knowledgeable about the importance of the physical evaluation and the relationship between the patients’ health and the type, level and dosage of the anesthetic they receive; and
3. Equipped with the appropriate monitoring and rescue equipment, including a positive-pressure oxygen delivery system, that the assisting staff knows how and when to use.

Providing patients with a safe and effective experience is every dental professional’s primary concern. It is vital that our practice guidelines assist them achieving this objective.

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iii Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who are Not Anesthesia Professionals, American society of Anesthesiologists, Approved by the ASA House of Delegates on October 25, 2005, and last amended on October 19, 2011.
1. American Society of Anesthesiologists, STANDARDS FOR BASIC ANESTHETIC MONITORING, Committee of Origin: Standards and Practice Parameters (Approved by the ASA House of Delegates on October 21, 1986, and last amended on October 20, 2010 with an effective date of July 1, 2011)
5. ADSA Pulse: Establishing a Culture of Safety, Fall 2015
6. ADSA Pulse: Why Capnography, Summer 2014
April 20, 2016

Council on Dental Education and Licensure
American Dental Association
211 East Chicago Avenue
Chicago, IL 60611

Dear Sirs/Madam:

As a member of the community of interest, the American Dental Society of Anesthesiology (ADSA) appreciates the opportunity to comment at the ADA Members’ Hearing on the proposed revisions (Resolution 77H) adopted by the 2015 ADA House of Delegates to the ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists and the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students.

1. Elimination of the mandate for monitoring end tidal CO₂ for moderate sedation to allow for the choice of options such as: continuous use of a precordial or pretacheal stethoscope, continuous monitoring of end tidal carbon dioxide, and continual verbal communication with the patient. [Lines 445-448, 472-477, 585-589, and 603-607]

The ADSA supports the position that the dentist must observe clinical signs of ventilation continually and must monitor ventilation via end-tidal CO₂. This should be augmented by auscultation of breath sounds.

2. Reconsideration of the section “Moderate Sedation Course Duration” (hours and content), as proposed by level of sedation, or a possible option of separate course requirements for enteral and parenteral routes of sedation. [Lines 1386-1415 and 1402-1407]

The ADSA believes that moderate sedation is moderate sedation regardless of the route of administration and that the training to manage a patient under that modality must be consistent whether the drug is given orally, rectally, intranasally, intramuscularly, intravenously or by any other route.

The ADA and ASA definition of moderate sedation is a clinical definition. It describes the clinical presentation of the patient. It makes no reference as to how the patient arrived at that state. Any reputable pharmacological textbook will detail the interaction between a drug and a specific receptor in the brain which, depending on the dose and the patient’s individual tolerance, will have a particular effect. That particular effect, in this case moderate sedation, is what the dentist is taught to manage through the training course. The management of the patient is the same no matter how the drug gets to the receptor.
In conclusion, the ADSA believes that dentists providing moderate sedation should be trained to the same standard regardless of the route of administration of the sedative agents.

3. Making patient evaluation provisions consistent throughout the document, including but not limited to, rationale and guidelines for the use of Body Mass Index (BMI) and the timing of medical review. [Lines 314-319, 334-336, 403-408, 417-422, 438-440, 530-550, and 575-576]

As the ADSA opined last year, we strongly believe that consistency and clarity help ensure safety. For this reason, we believe the sections discussing patient evaluations for the various levels of sedation and/or anesthesia should read the same for consistency. In addition, we can find no literature supporting a pre-operative evaluation "within the previous 30 days". Our suggestion is to simply require an immediate pre-operative review prior to the administration of sedation and/or anesthesia. The Body Mass Index (BMI) has become a standard measure of body mass for medicine in general and anesthesiology specifically. Weight alone is insufficient to judge body mass and anesthetic risk. ADSA feels these sections should be rewritten to include Body Mass Index (BMI). An example of such language might be: "A focused physical evaluation must be performed and recorded and must include the patient's Body Mass Index (BMI)."

The ADSA is grateful for the opportunity to comment and recommend possible changes to the ADA's Anesthesia Guidelines documents and would be happy to discuss any questions with the Council at their convenience.

Sincerely,

Kenneth L. Reed, DMD
Kenneth L. Reed, DMD
President, ADSA
TESTIMONY ON BEHALF OF THE ACADEMY OF GENERAL DENTISTRY (AGD)

April 20, 2016

Thank you for this opportunity to speak to CEDL on the topic of Resolution 77. My name is Dr. Linda Edgar, general dentist, Academy of General Dentistry (AGD) Past President, and ADA Delegate for the past 15 years. In my practice, I have provided oral moderate sedation for 23 years without incident. I was involved in accepted amendments to the 2007 ADA guidelines and I am also a member of the District XI, 8 person (5 state) committee on Resolution 77.

Today, I am speaking on behalf of the AGD to share our concerns regarding two of the three areas identified for comment by CDEL.

First, I will address our comments on the proposed combination of enteral and parenteral moderate sedation training requirements, specifically lines 1386 through 1415, and lines 1402 through 1407.

Second, I will address the addition of the end tidal CO2 (capnography) requirement, specifically lines 445-448, 472-477, 585-589, and 603-607.

Please note that, on both of these issues, the positions of the AGD are aligned with the testimony of ADA District XI presented by District Chair, Dr. Mark Walker by phone today.

1. Combining Enteral and Parenteral Routes for Training in Moderate Sedation

The proposed combination of oral and IV moderate sedation training requirements is of concern to the AGD for two reasons.

First, it increases didactic hours by 250% and cases by 100% (live cases by 667%) including IV administration, for the practice of oral sedation, without presenting any evidence that the exponential increase in training will correlate to improved safety. It is also likely, in the very rare case that moderate oral sedation goes to deep, that a sublingual injection of reversal agent be done.

An advocate for this change might argue that IV sedation offers the ability to better control titration, reducing the risk of the patient becoming deeply sedated. However, IV administration requires a greater skillset than giving a pill. The 2006 JADA noted a significant decrease in
adverse events from enteral sedation over the last 20 years with the shift away from opioids.\(^1\)

The enteral administration of benzodiazepines has shown no evidence of lack of safety.

Second, by allowing for the 20 live cases to be “by any route,” “including intravenous administration,” you could have anywhere from one IV case and 19 enteral cases, to all 20 IV cases. The current training requirement for IV is that all 20 cases must be IV cases. So, this change inadvertently reduces the IV practitioner’s live-patient training requirement by as much as 95% (from 20 cases down to 1 case).

Just as there was no evidence presented to correlate the exponential increase in training for oral sedation with increased safety, there has been no evidence presented to justify up to a 95% decrease in live IV patient training for practitioners of IV sedation.

Finally, in that Supplemental Report, CDEL also noted that a reason for the proposed change is that the Course Objective and Course Content sections already included IV for all routes of moderate sedation. Course Objective 5 on line 1339 of Appendix 1, and Course Content 15 on line 1379 of Appendix 1, include IV. The fix for this is easy; add “for moderate parenteral sedation courses” after each of these items.

Conclusions:

IV administration and oral administration are far too distinct to combine simply for the sake of having a singular set of moderate sedation training requirements. We recommend staying with the current guideline recommendations of 24 hours for oral and 60 hours for IV. We would hate to see fewer patients receive dental care because fewer dentists chose to get trained in oral sedation since over 50% of the population is very fearful and is being helped.

*II. End-tidal CO2 Mandate for Moderate Sedation (except when “precluded or invalidated by the nature of the patient, procedure or equipment”)*

The science has shown that capnography may work well in complex airway systems, but it may create false-positives in an open airway system.

In January 2015, ADSA told CDEL unequivocally that visual changes in an end tidal CO2 waveform (or capnograph) might escape detection in the absence of an individual dedicated to continuously observing the monitors. ADSA informed CDEL that a precordial or pre-tracheal stethoscope is an acceptable option for moderate sedation and that it may be more practical.\(^2\)

Studies have found that capnographs produce inaccurate data in an open airway system where the atmospheric air dilutes the expired CO2, or when the patient is a mouth-breather.\(^3\) A 2010 study also found that measurement of oxygen saturation with a pulse oximeter detects respiratory events in adults quicker than a capnography.\(^4\)

After looking at the make-up of the anesthesia committee it appeared that no members were general practicing dentists that do moderate oral sedation. Neither ASA nor AAOMS are societies dedicated exclusively to dental pain and anxiety management. It is also important to note that the American Heart Association (AHA), which preceded ASA and AAOMS in requiring capnography, only required a capnograph in complex airway systems, during
placement of an endotracheal tube and to improve CPR quality; these are not applicable to an open airway system in moderate sedation in dentistry.⁵

The current science and practice indicate that, in an open airway system for dental moderate sedation, relying upon a capnograph could be an inaccurate proposition, and that pulse oximeters and precordial or pretracheal stethoscopes are often better solutions.

Accordingly, the AGD supports the *choice of options* such as: continuous use of a precordial or pretracheal stethoscope, continuous monitoring of end tidal carbon dioxide, and continual verbal communication with the patient.

Thank you again for this opportunity to provide testimony and for all your hard work on these guidelines.

**Sources:**

ADA Members Hearing
Sedation and Anesthesia Guidelines
Resolution 77H-2015

Raymond Dionne, DDS, PhD
Department of Pharmacology,
Brody School of Medicine
Department of Foundational Sciences,
School of Dental Medicine

¹ No conflicts of interest, the opinions expressed do not represent ECU or any professional organization
Respiratory depression causes most serious M&M

- **Opioids** produce dose-related decrease in respiration at therapeutic doses
- **General anesthetics** produce respiratory depression at therapeutic doses
- **Local anesthetics** produce respiratory depression at very high doses
- **Additive respiratory depression** can occur when combinations of drugs are given at individual maximal doses
- **Loss of consciousness** may result in airway obstruction
- **Benzodiazepines do not** produce respiratory depression at therapeutic doses when administered as the sole anxiolytic drug

Lines 445-448, ‘...end tidal CO$_2$ must be monitored…’
Lines 472-476: ‘...the dentist must monitor ventilation and/or breathing by monitoring end tidal CO$_2$...’
Patients’ Evaluation of Efficacy

Surgeons’ Evaluation of Efficacy
Benzodiazepine but not an opioid decreases self-reported pain during oral surgery using LA

Dionne RA, J Dent Res 1984
Evidence – Based Implications

- Benzodiazepines not likely to cause respiratory depression
- Respiration rate and $O_2$ saturation are sensitive to changes in ventilation
- Monitoring expired $CO_2$ should be reserved for drugs that predictably cause respiratory depression
- Adjunctive administration of opioids does not reduce pain if patient has been adequately anesthetized
- Differentiating monitoring requirements between anxiolytic drugs that do not produce respiratory depression and sedative drugs that depress respiration without anxiolytic benefit encourages safety
Line 1402, Moderate Sedation course: ‘…60 hours of didactic instruction plus…’

One page = 3 minutes. 400 pages in book, 60 hours = reading this book 3X
Medical pharmacology course ~ 120 hours
EMT training (NC) ~ 200 hours
Parenteral routes of administration most likely to result in serious morbidity and mortality – why encourage its use?


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<thead>
<tr>
<th>Route</th>
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<td>IM</td>
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<td>Inhalation</td>
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Why is Sedation Needed?
Prevalence of Dental Fear and Anxiety in Population

• Well documented by 19 studies
• Common to all cultures
• *Originates in childhood*
• Persists throughout life
• Leads to *avoidance of dental care*
• Has remained stable over the past 50 years

Haas D, Workshop on Enteral Sedation in Dentistry
In Dionne et al, JADA 137:502 - 513, 2006
Basis for Wide Variation in Patient Presentation

Foolish  Fearless  Little or No Anxiety  Anxious  Fearful

Sociocultural Influences, Expectations, Prior Experiences, Idiosyncrasy

Neuroendocrine Functions, Autonomic Function, Stress Response

Physiologic Augmentation & Descending Modulation: Inflammation, Plasticity

Protein Expression & Epigenetic Modification

~ 10 M SNPs in human genome

20-25,000 Protein-Coding Genes (1.5%)
Recommendations for Revising Res. 77H-2015

• Anxiety level **varies widely** across patients

• General dentists and most specialists can **safely** and **effectively** treat anxious patients with an **enteral administration** of a benzodiazepine

• Should **increase access to care** for anxious and fearful patients by improving sedation training and safety based on scientific evidence:
  - End-tidal CO\textsubscript{2} not needed for benzodiazepine sedation
  - Proposed N of didactic hours is excessive
  - Encourage enteral sedation training and clinical use without requiring IV access for continuing education courses
Good afternoon,

Thank you for this opportunity to speak to the Council on Dental Education and Licensure on the topic of resolution 77. I am Dr. Mark Walker; Chair of an 8-member task force organized by Dr. Laura Williams and composed of representatives from each of the 5 states in District XI. I want to address our concerns about the proposed changes to the anesthesiology education guidelines.

In particular there are two areas of great concern that our district would like to address. The first is with regard to increasing the education requirement to 60 hours and eliminating the distinction between enteral and parenteral training thus creating one moderate sedation permit category. For patient safety, we must recognize the distinction between enteral and parental routes of administration, as we currently have with the existing ADA Guidelines.

It is essential to understand that the different route of the administration of a sedative agent is important. The educational guidelines for training should recognize these differences and that the guidelines are commensurate with the level of training indicated for that specific route of administration.

Looking at current state dental practice acts, only eleven states have an educational requirement that does not differentiate between routes of administration of a sedative agent. On the other hand, thirty-nine states recognize the inherent differences that the route of administration, enteral v. parental, make and thus mandate separate training and permit process commensurate and applicable to that route of administration. Of these thirty-nine states that recognize the differences between enteral and parenteral routes of administration, only seven states require the increased educational hours (60 hours) for both modes as proposed by resolution 77. There is little if any data published to suggest that states requiring 60 hours training for enteral sedation results in a lower mortality rate than those requiring 24 hours as current ADA guidelines recommend.

In fact according to Raymond Dionne et al, in a 2006 JADA article titled, “Balancing efficacy and safety in the use of oral sedation in dental patients” their study of dentists trained under the 24 hours guidelines reported that in a 12 month period, and I quote, “A total of 613 dentists administering incremental triazolam reported 85 adverse reactions in 28,881 cases (0.3% incidence). None of the instances resulted in the need for hospitalization, and the administering dentists managed all of the instances in the dental office.” End quote.

An orally administered drug is exposed to metabolic clearance mechanisms in the intestine and liver before it gets into the circulatory system. By comparison, an intravenously administered drug is deposited directly into the circulatory system. Factors such as gastric emptying, GI absorption, GI inactivation, first-pass hepatic metabolism and variability in patient response associated with using fixed doses raises patient safety concerns that can only be addressed by having training specific to the route of administration. The argument that “sedation is sedation” simply doesn’t hold true.

As stated in the aforementioned JADA study, “The oral route is inherently the safest route for drug administration.”
Stanley Malamed, in his book, *Sedation- A Guide to Patient Management*, states "Drug-related side effects are less likely to develop following enteral drug administration (i.e., oral, rectal) than they are following parenteral drug administration. In addition, adverse reactions developing following oral administration are often much less intense than noted following parenteral administration of the same drug.iv

Increasing the educational requirement for enteral sedation would add additional time and expense to our members without sufficient evidence that this would increase patient safety and may adversely impact access to care.

Our second concern is in regards to the use capnography for moderate sedation.

In the proposed new guidelines it states that there should be an end tidal CO2 (capnography) requirement except when "precluded or invalidated by the nature of the patient, procedure or equipment.”

We are opposed to the addition of this requirement for the following reasons:

The current guidelines fail to explain more fully the statement, “except when precluded or invalidated by the nature of the procedure or equipment.” Failure to provide clear direction for this topic leads to inconsistent interpretations by state boards as to what constitutes appropriate justification for use of capnography.

In a report to The Royal College of Physicians and Surgeons of Edinburgh and Glasgow entitled;

“Standards for Conscious Sedation in the Provision of Dental Care Report of the Intercollegiate Advisory Committee for Sedation in Dentistry” states;

“Sampled exhaled gas or transcutaneous capnography may be appropriate for some ‘at risk’ ASA grade III/IV dental patients, particularly those receiving supplemental oxygen, during sedation”, and it goes on to state, "until results of dentistry-specific research are available, its routine use for ASA grade I and II dental patients lacks high level scientific validation and cannot be recommended.”v

Another study done in Canada in 2010 entitled “A comparative evaluation of capnography versus pulse oximetry during procedural sedation and analgesia on room air” by Sivilotti et al, concluded that “During PSA in adults breathing room air desaturation detectable by pulse oximetry usually occurs before overt changes in capnography are identified. Moreover, substantial variation among and within participants in the end-tidal carbon dioxide values at baseline hampers the identification of clinically important changes in capnography.”vi

District XI, the ADA, and its member dentists pride themselves on using accurate data to determine what guidelines are best for their patients’ safety. The general lack of research regarding patient safety in a dental setting in regards to monitoring of end tidal CO2 during moderate sedation makes it difficult to suggest this added requirement of the use of capnography is needed. We do feel that the use of capnography in general anesthesia and deep sedation cases is important. We do recommend that the use of a precordial
stethoscope as well as monitoring equipment that records blood pressure, oxygen saturation and heart rate be used during moderate sedation.

In addition it is our conclusion that there is no evidence to support increasing the continuing education hours to 60 hours for the eternal route of administration of sedative agents. We recommend that the CE hours required stay at the current 24.

The members of District XI respectfully point to the fact that the majority of the Anesthesia Committee practice deep sedation techniques in a closed system and their guideline recommendations are drawn from that perspective. The open system that occurs during a moderate sedation gives rise to the aforementioned variables that do not occur during deep sedation.

\[1\] ADA District XI workgroup own research, April, 2016
\[2\] Raymond A. Dionne, DDS, PhD; John A. Yagiela, DDS, PhD; Charles J. Cote, MD; Mark Donaldson, PharmD; Michael Edwards, DMD; David J. Greenblatt, MD; Daniel Hass, DDS, PhD; Shobha Malviya MD; Peter Milgrom, DDS; Paul A. Moore, DMD, PhD, MPH; Guy Shampaine, DDS; Michael Silverman, DMD; Roger L. Williams, MD; Stephen Wilson, DMD, MA, PhD. Balancing efficacy and safety in the use of oral sedation in dental outpatients. JADA 2006;137:502-513
\[3\] Ibid
\[v\] The Dental Faculties of the Royal Colleges of Surgeons and Royal College of Anaesthetists, Standards for Conscious Sedation in Provision of Dental Care; Report of the Intercollegiate Advisory Committee for Sedation in Dentistry, 2015; (p.28)
\[vi\] Marco L.A. Sivilotti, MD, MSc; David W. Messenger, MD; Janet van Vlymen, MD; Paul E. Dungey, MD; Heather E. Murray, MD, MSc. A comparative evaluation of capnometry versus pulse oximetry during procedural sedation and analgesia on room air. Canadian Journal of Emergency Medicine. 2010;12(5):397-404
To: Council on Dental Education and Licensure (CDEL)  
From: the Idaho State Board of Dentistry (IBOD) and the Idaho State Dental Association (ISDA)  
Re: ADA Resolution 77, Sedation Guidelines

Dear Council Members,

Both the Idaho State Board of Dentistry and the Idaho State Dental Association have significant concerns over the proposed changes to sedation guidelines that CDEL is considering. We consider safeguarding our patients and improving the oral health of all Idahoans as the top imperatives for our organizations and we embrace actions that have a meaningful impact on these goals. In Idaho we believe that Resolution 77 as presented at the ADA 2015 House of Delegates, rather than having a meaningful impact is actually a step backwards.

Resolution 77, by eliminating the separate permit process commensurate with the low risks of enteral sedation, will deter dentists from seeking sedation permits, and likely will result in dentists failing to obtain appropriate education, patient monitoring equipment, and emergency medical training. Since Idaho recognized enteral sedation as distinct from parenteral sedation, seventy-six Idaho dentists have obtained permits (received training, patient monitors, emergency training, and passed office sedation evaluations). During this time, the number of patients suffering adverse effects due to enteral sedation has remained at zero. Clearly, this is an indication that current guidelines adequately protect patient safety when proper procedures are followed.

The current guidelines, while not only maintaining patient safety, have increased the access to care for countless Idahoans. We know that many patients cannot or will not take advantage of dental care without the aid of enteral sedation. Increasing the demands on training for enteral sedation will drastically increase the cost of obtaining a permit, and will therefore reduce the number of dentists with permits. This will in turn decrease the access to care for those who need it, which goes directly against one of the key callings of the dental profession.

It is our understanding that there are 39 states whose dental practice acts regarding sedation are not in compliance with the guidelines as proposed by Resolution 77. If CDEL and the ADA House of Delegates were to adopt Resolution 77, it is likely that a plaintiff’s attorney in a malpractice litigation would raise the question of compliance, even if a dentist is in compliance with their state dental practice act. In short, adopting Resolution 77 would likely put the dentists in these 39 states at a medical-legal risk.

We have not found evidence that suggests adverse effects of sedation are a result of inadequate guidelines and training. In fact, the evidence indicates that adverse effects are the result of a select few not following the existing guidelines. This would indicate the issue is one of compliance, not of education. Increasing educational requirements will not increase compliance, and in fact will likely result in a decrease. When we consider the overwhelming success and increased care provided under the current guidelines, we have to ask why the change is being considered. Unfortunately, our conclusion is that this is the result of a desire to create competitive barriers by a select few in the profession. This action does not benefit the ADA, its members, or the patients of the communities we serve.

On behalf of both the ISDA and the IBOD we ask that you carefully reconsider the impact of adopting Resolution 77, and together we recommend rejecting this resolution.

Respectfully,

Susan Miller  
Executive Director  
Idaho State Board of Dentistry

John E. Hisel Jr., DDS  
President  
Idaho State Dental Association
Dear Dr. Gesek and Committee Members,

Thank you for the opportunity to testify. My comments will be emailed to you today, including my media references.

I am a general dentist that has been in practice for 17 years. My philosophy of dentistry allows me to take time with my patients, getting to know them and striving to meet their individual needs as we work together to improve their oral health. Because of my patient centered approach, I have had many patients with high anxiety come to see me for treatment. For years, I treated them when they would come to see me, but often that was after they had put off their treatment until there was a dental emergency. I would treat them very gently, sometimes using anxiolytic agents such as diazepam or nitrous oxide, both of which had less than satisfactory results in controlling the anxiety of these high fear patients. In 2010, I decided to receive training in moderate enteral sedation. I received education, bought the equipment necessary to safely administer moderate sedation and to treat medical emergencies should they arise, and have been treating patients with high fear with moderate enteral sedation since that time. I am very careful to follow protocols to prevent oversedation and to avoid medical emergencies. I have treated over 50 patients with moderate enteral sedation in that time, with more scheduled this year. I have NEVER once had a medical emergency while administering moderate enteral sedation because I have followed the protocols of careful patient selection and careful sedation administration. Because I have been able to offer this to my patients, I have been able to change the lives of patients who have now been able to receive general dental procedures that they otherwise would not have received. I have been able to prevent financially and emotionally costly dental emergencies by treating dental problems in high fear patients before they have symptoms.
The changes to the educational recommendations that you propose in Resolution 77H-2015 [Lines 1386-1415 and 1402-1407] (i.e. requiring ALL practitioners of moderate sedation, enteral or parenteral, to take a courses involving IV sedation) will result in most practitioners discontinuing the practice of moderate sedation because of cost. The courses for IV sedation are highly expensive and require a large amount of time away from the office. It would require a dramatic increase in cost to the patients in order to cover the increased cost that the practitioner would incur through having to take these courses. Many of my high fear patients already have a difficult time with the small fee that I charge to administer enteral sedation because their insurance doesn’t cover that cost. Therefore these new requirements would leave them with no option for general dentistry other than going to a hospital setting to receive their needed fillings, crowns, root canals, etc…. routine general dental care.

I believe that the motivations for changing the educational requirements are because of concerns over patient safety, and I agree that patient safety is of the utmost importance. In fact, I am concerned enough about it that I served the Idaho State Board of Dentistry as an In-Office Evaluator for Oral Sedation, until this year when I was appointed as a member of the Board. In my duties as an evaluator, I performed reviews of the offices and dentists in Idaho that carry Moderate –Enteral Sedation Permits. I reviewed equipment, records, training of dentist and staff, and observed a live sedation case in each office visit. The reviews that I participated in have shown me that oral sedation is largely practiced in a safe and effective manner. Any loss of life or injury to patients is a gravely serious matter, and a tragedy. The committee asked for scientific reference to any comments. However, there are no studies indicating the need for a change in the educational requirements proposed. We are therefore left to observe the cases that have been reported in the media and review what the outcomes of those cases are. My own personal review of the cases making the news shows that most of these cases have been pediatric deaths, although adult deaths have certainly occurred. These deaths have occurred at the hands of general dentists, pediatric dentists, and oral surgeons. I found 29 reported deaths in recent news. Of those deaths, the outstanding majority occurred with IV sedation or general anesthesia. Of the practitioners involved 3 were general dentists, 4 were general dentists operating with an anesthetist present, 21 were specialists (oral surgeons, pediatric dentists, endodontists, anesthesiologists, with 1 practitioner whose specialty I could not find listed. These specialists would have received training in IV parenteral sedation. In ALL of the cases that I read, the deaths did not occur because of the sedation protocol. They occurred because the practitioners were NOT following protocol. Changing educational requirements which already teach a safe and effective protocol will NOT change the fact that some practitioners will not follow those safe protocols. It will only make it harder for those who do follow the protocols to practice safe and effective dentistry for their anxious patients.

In summary,

I do not agree with or support the proposed change in educational requirements because they do not address patient safety, but instead create more barriers to practitioners practicing already safe protocols. This in turn will create more barriers to high fear patients receiving the care that they need, and will induce practitioners to avoid getting the training that they need due to cost. This will make the safe treatment of patients seeking sedation less available.
Respectfully submitted,

Spencer J. Lloyd DMD, MAGD, FICOI
Pearl Dentistry
4012 Brian Ave.
Caldwell, ID 83605
yodadmd@gmail.com


Salomon Barahona Junior – Pediatric Dentist – oral sedation
Raven Maria Blanco – Pediatric Dentist – oral sedation
4 developmental disabled deaths in 2005 – oral surgeons (deaths at home after likely IV sedation)
2 deaths – developmental disabled 2013 – oral surgeons (deaths at home after likely IV sedation)
Rose Tecumseh – pediatric dentist w/ anesthetist – oral sedation
Rena Suba – Oral Surgeon – IV sedation
Kimberly Ortiz – Oral Surgeon – IV sedation
Billy Lee Hatcher – Oral Surgeon – IV sedation
Patrick Clare – General Dentist – oral sedation

Three Deaths - Oral surgeon – Protopappas – sedation type unknown – likely IV


One death in Texas – Oral Surgeon/Periodontist – James Michael Davis – sedation type unknown – likely IV


Marcus Gressett – Endodontist w/ Anesthesiologist present – IV sedation

Diamond Brownridge – Pediatric Dentist - IV sedation

Darren Denholm – General Dentist w/ Anesthetist - General Anesthesia

Karla Selley – General Dentist w/ Anesthetist - General Anesthesia

Katie Dougal – General Dentist w/ Anesthetist - General Anesthesia

Bradley Legge – General Dentist w/ Anesthetist – General Anesthesia

Suzanne Johnson – Hospital Dentist – General Anesthesia

Yair Lupolianski – Pediatric Dentist – oral sedation

Dasia Washington – General Dentist – nitrous oxide

AZ death – Dr. Glen Doyon – Endodontist - IV sedation

29 deaths – 3 General Dentists – 4 General Dentists w/ anesthetist – 5 pediatric dentists – 13 oral surgeons – 1 Endodontist – 1 Endodontist w/ Anesthesiologist – 1 Hospital Dentist General Anesthesia - 1 unknown dentist

29 deaths – 1 nitrous oxide, 5 oral sedation, 1 “likely” oral sedation, 6 IV sedation, 10 “likely” IV sedation, 5 General Anesthesia, 1 sedation type unknown

• “likely” – inferred by type of dentist performing the procedure. Oral surgeons are most likely to use IV sedation. General dentists are most likely to use oral sedation.
04/19/2016

To: Dr. Daniel Gesek, CDEL Chair
    Dr. David Sarrett, CDEL Anesthesiology Committee Chair

Via: Jasekj@ada.org

Re: Resolution 77H-2015 and the following:
    ADA Policy Statement: The Use of Sedation and General Anesthesia by Dentists (2007)
    Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students (2012)
    Guidelines for the Use of Sedation and General Anesthesia by Dentists (2012)
    ADA Sample (Filled-in) Sedation - Anesthesia Record (PDF)

To Whom It May Concern:

I am writing you to express my individual sincere concerns in how this debate over sedation has somehow lost its way over time in a very disconcerting way.

The ADA Clinical Practice Guidelines Handbook - 2013, page 5, Section 1.1 clearly states:

“1.1 Purpose of ADA Clinical Practice Guidelines (page 5)

The ADA Clinical Practice Guidelines provide clinicians with tools to help them implement evidence-based interventions. The American Dental Association defines Evidence-Based Dentistry as “an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating to the patient's oral and medical condition and history, with the dentist's clinical judgment and the patient's treatment needs and preferences.” This definition acknowledges that treatment recommendations should be individualized for each patient by his or her dentist, and that the clinician’s judgment and patient preferences should be considered while planning treatment. Evidence-based clinical practice guidelines are intended to provide guidance and should be integrated with a practitioner’s professional judgment and a patient’s needs and preferences. They are not standards of care, requirements, or regulations. They represent the best judgment of a team of experienced clinicians, researchers and methodologists interpreting the scientific evidence on a particular topic.”

As you can see from the above, key words and terms are noted such as tools, help, evidence-based, judicious integration, the patient’s oral and medical condition and history, dentist clinical judgement, patient’s treatment needs and preferences, individualized, clinician’s judgement, patient preferences, and practitioner’s professional judgement. These thoughts are then further emphasized in the end with the phrases like “not standards of care, requirements, or regulations ……… best judgement of a team of experienced clinicians, researchers, and methodologists interpreting the scientific evidence on a particular topic.”
As I review the 2007 and the 2012 documents noted above, every single thing the ADA states that it stands for in its EBD Clinical Practice Guidelines and recommendations is overridden or completely ignored with numerous elementary and arbitrary statements.

Evidence based tools and help are now arbitrary statements and subsequent mandates that totally ignore the patient’s individualized oral and medical conditions and history, the clinician’s professional judgement, and the preferences of the patient.

Without ever seeing the patient, while classifying any and all sedative medications as having the same level of sedative effect on a patient, the guidelines state you are intending to do a level of sedation you are not and classifying a patient to be in a given sedative state, without consideration of the real-time physiologic monitoring of the patient by a trained professional. For example, classifying nitrous plus any one oral drug as minimal sedation, and while classifying nitrous plus any two or more drugs as moderate sedation, without any consideration for the specific drug, dosage level, or projected response of the patient based on their tolerance levels, anxiety levels, and/or extent of treatment is very elementary and arbitrary at best.

Likewise, the misuse of the terms like MRD dosage levels and applying them to a professional monitored clinical setting is elementary and arbitrary at best. What physicians call unmonitored at-home in the living room pain control, we are now calling moderate sedation, even without the application of nitrous, if it occurs in a dental office. Nothing could be further from the truth and further shows the world our apparent complete lack of understanding of the subject matter at hand.

MRD levels of a certain drug carry a very wide margin of safety, are set for unmonitored at-home use, and have been misused and misrepresented in the ADA documents. Everyone knows that low dosages of multiple drugs can most times be more predictable, more likely to reach an intended level of sedation, less likely to have an adverse effect on the patient, and/or more easily reversible than high doses of a single medication, especially when these medications are administered at mere fractions of MRD recommendations. Yet, our teaching and clinical guidelines are written to the contrary.

Sedation levels are determined by patient response as monitored by a professional, a doctor, a clinician, not arbitrary caveats as stated in the ADA guidelines. In our guidelines the ADA has historically tried to assign level of sedation by route of administration. Today, the ADA is using arbitrary statements about MRD levels and the number of drugs administered. Again, these are arbitrary and elementary statements at best.

More pertinent to the current considerations at hand, I find it interesting that the clinical use of sealants topical fluorides by dentists, two of the most innocuous procedures ever known in the 9000 plus year history of dentistry have undergone more evidence based scrutiny than the teaching and clinical use of sedation and anesthesia in dentistry has to date, which happens to be the most dangerous, life-threatening procedure of physicians and dentists alike. Why would the ADA ever give more systemic analysis to the evidence for sealants and topical fluoride than it has for sedation and anesthesia? Why would it not give preference to professional judgement and individual patient needs?

I say this because it doesn’t matter how voluminous you make the guidelines, those practitioners who aren’t reading them now, will still not be reading them then. Furthermore, those practitioners who do follow the current guidelines, whether ADA or AAPD, they have not had a problem of any significance with sedation. My main concern here is the demonization of minimal sedation, arbitrarily calling it moderate sedation when it is not, and creating a world where one of the most needed procedures in dentistry is no longer available to the public due to over-reaching and arbitrary regulation. Please note the reports below.

Evidence-based clinical recommendations for the use of pit-and-fissure sealants
A report of the American Dental Association Council on Scientific Affairs - March, 2008
Topical fluoride for caries prevention
Executive summary of the updated clinical recommendations and supporting systematic review - November, 2013

Robert J. Weyant, DMD, DrPH; Sharon L. Tracy, PhD; Theresa (Tracy) Anselmo, MPH, BSDH, RDH; Eugenio D. Beltrán-Aguilar, DMD, MPH, MS, DrPH; Kevin J. Donly, DDS, MS; William A. Frese, MD; Philippe P. Hujoel, MSD, PhD; Timothy Iafolla, DMD, MPH; William Kohn, DDS; Jayanth Kumar, DDS, MPH; Steven M. Levy, DDS, MPH; Norman Tinanoff, DDS, MS; J. Timothy Wright, DDS, MS; Domenick Zero, DDS, MS; Krishna Aravamudhan, BDS, MS; Julie Frantsve-Hawley RDH, PhD; Daniel M. Meyer, DDS; for the American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents

With specific comment to capnography, we all know that in open-airway anesthetic systems this monitor can be highly unreliable giving practitioner’s a false sense of security or via repeatedly unnecessarily interrupting a procedure with false alarms that may have a limited time window for successful completion.

With respect to excessive requirements for patient evaluations in patients undergoing minimal and moderate sedation, they should be eliminated. Likewise, timing of medical history and the use of BMI needs to be given more discretion.

With respect to educational requirements, the 2015 proposal was excessive, yet the language in the document reduced the requirement for conducting IV moderate sedations from several to a minimum of one. More reasonable consideration needs to be given to that language, including a return to the previous IV moderate sedation requirements.

Having sat as a liaison on the topical fluoride panel a few years back, I do not envy the task you have at hand. However, I think it is important to remember what you do here should not have an adverse impact on the availability of minimal sedation to the public in any way. Millions of patients avoid dental care annually due to their perceived fear of pain. Minimal sedation should not be demonized or over-regulated in any way. Rather, its availability to the public, especially children, should be noted as one of the greatest advances in the delivery of dentistry to the public achieved in the 21st century.

I sincerely appreciate all you do and the time you donate to our profession.

And, thanks again from ........

Where it's an access day every day we're open!
More than $644,617 of free and uncompensated care in 2015 alone!!

Talk with you later,

Until then......................

DOCERE ! - DOCTOR !! - TEACH !!!

Rocky

Rocky L. Napier, DMD, FACD, FICD, FPFA, and Staff
Pediatric Dentist
143 Trafalgar Street, SW
Aiken, SC 29801-3760
803-641-1000 (office)
803-643-3902 (fax)
803-270-0653 (cell)
drocky@aol.com

Member - American Academy of Pediatric Dentistry
National Spokesperson - American Academy of Pediatric Dentistry, 2007 - Present
Member - American Academy of Pediatrics - Section on Oral Health
Associate Member - American Academy of Pediatrics
President Elect - South Carolina Dental Association (SCDA), 2016
Liaison to the SCDA - South Carolina Society of Pediatric Dentistry, 2010 - Present
16th District Alternate Delegate - American Dental Association (ADA), 2014 - Present
Region 19 Delegate - Academy of General Dentistry (AGD), 2014 - Present
Region 19 Representative - AGD, Dental Practice Council, 2011 - Present
Chair Elect - SC DHEC Oral Health Advisory Board and Coalition, 2015 - Present
16th District Representative - ADA, Council on Access, Prevention, and Interprofessional Relations, 2010-2014

Confidentiality Note

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If you have received this in error, please notify me immediately and destroy the related message.
Dear Sirs and Madams,

In reference to the ADA Resolution 77H-2015 in the Feb. 12 issue of ADA News p. 13. The present definition of Minimal sedation and Moderate sedation are identical with the exception of the words normally vs. purposefully from the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students 2012.

Functionally there is no difference in the two definitions. (see below) The problem is some states have requirements for moderate sedation that require doing 20 live cases and 18 hour of lecture. For minimal sedation most states require a 21 hour course. This would make a course to do moderate sedation, the patient is conscious a 13 day course with a price tag of $5,000 to $7,000.

There have been multiple incidents of State Boards and Provincial Colleges deciding a practice was doing moderate sedation when patients were lightly sedated, completely conscious, in control of all their protective vital reflexes and they fit the definition of minimal sedation. The confusion exists because there is no difference in the definitions as published in the ADA guidelines for Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students 2012.

If I could be so bold as to make a suggestion, if you define minimal sedation as responding normally to verbal command (stimulation) without tactile stimulation and keeping the present definition of moderate sedation - respond purposefully to verbal commands accompanied by light tactile stimulation. By these definitions there is a distinct difference between minimal and moderate sedation. Moderate sedation would be a deeper level of sedation and could require more training.

Why do I feel qualified to make such suggestions. I have taught 253 nitrous oxide oxygen sedation courses and 117 oral conscious sedation courses with or without nitrous oxide oxygen sedation. I have published over 50 papers on sedation and written chapters in 3 books on fear and pain control. I have attached my resume to better introduce myself.

Please feel free to call if I can be of any assistance.

Fred

Fred Quarnstrom, DDS
FASDA, FAGD, FICD, FACD, CDC
Fellow Am. Society of Dental Anes.
Fellow Academy of General Dentistry
Fellow International College of Dent.
Fellow American College of Dentistry
Certified Dental Consultant
Diplomate, American Board of Dental Anesthesiology
Diplomate, National Board of Dental Anesthesiology

5767 S. Oaklawn Pl., Seattle WA 98118
Phone 206-313-0496
Recommendations Concerning Sedation and Anesthesia Guidelines

ADA Sedation and Anesthesia 4.20.2016

I. Capnography should be mandatory for monitoring of moderate sedation. Other options (use of pretracheal stethoscope and continuous verbal monitoring) are just not sufficient and are not in agreement with other national professional anesthesia organizations. Support is provided below.

II. Moderate sedation course duration hours should be 60 hours with both for both IV and nonparenteral routes with a minimum of 20 cases. Emphasis should be placed on interpretation of physiologic monitoring and airway management techniques.

III. Patient evaluation (i.e. history and physical examination) should be consistently employed for all sedation modalities. Provisions should include use of body mass index (BMI) and timing of medical history review. With the increased awareness of sleep apnea and BMI as markers for airway compromise, this portion of the patient evaluation should be included.
Introduction, History

Beginning with the introduction of nitrous oxide and continuing with the development of outpatient anesthesia techniques, dentistry, and the American Dental Association (ADA) has historically always been a vital force in anesthesia. Although various groups and organizations attempt to delineate physiologic distinctions between anxiolysis, procedural sedation, conscious sedation, moderate sedation, twilight sleep, deep sedation, and general anesthesia, the distinctions between various levels of sedation and anesthesia are oftentimes blurred making a determination of a defined level of sedation or anesthesia not always possible. For the purposes of the discussion to follow, moderate sedation is defined as: a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.¹

Sedation levels and the definitions that surround them, are dynamic, not static, and may change in an instant due to drug administration, absorption of oral medications, ventilation, and other medical conditions. This makes sedation a continuum, not a staircase, of effects. This continuum philosophy is supported by the fact that up to 68% of patients planned for a moderate sedation, may temporarily enter a deep sedation state in which ventilatory function is impaired.²³ Patients may be asleep, yet sleep may mimic deep sedation. Patients may become apneic, yet be easily arousable. Patients may be awake, yet hypoxic. All of these factors may be due to a patient’s sensitivity to anesthesia medications and their pharmacologic response, their age, the medications patients take on a daily basis, their recreational drug habits, and their medical problems (especially undiagnosed sleep apnea); some more challenging than others. The current training dogma is that anesthesia providers should be able to “rescue” (usually via airway maneuvers) any patient that progresses to the next level of anesthesia. This usually means maintaining the airway, blood pressure, and cardiovascular function. The truth is that a
patient’s level of sedation is: 1) impossible to accurately determine using physical examination, 2) not continually measurable, 3) is difficult to determine when a patient transitions from one level of sedation to another, and 4) bears no relationship to the method of monitoring. Monitoring should be a universal modality to insure safety for all levels of sedation and anesthesia.4

**Why Pulse Oximetry is Not Sufficient!**

Pulse oximetry was developed to measure blood oxygenation using infrared sensors. It is believed that if a pulse oximeter measurement is elevated that patients must: 1) be ventilating properly, 2) have sufficient oxygenation in their blood to be maintain cardiovascular function, and 3) can tolerate additional sedative medications if necessary. Pulse oximetry does not directly measure ventilation or apnea. However, when patients develop hypoventilation or apnea, the oxygenation can continue to remain within the normal range for some time. The pulse oximeter does not reveal downward trends in PaO2 at levels greater than 100 mm Hg.5,6 In patients receiving supplemental oxygen, where the PAO2 can be elevated to 600 mm Hg, this lag can be even longer.7 Contrary to popular belief, adding supplement oxygen can doesn’t prevent apnea, but masks it’s detection by artificially increasing the pulse oximetry readings. Without some way to measure breathing and ventilation, the patient’s may be evaluated, as under-sedated and apneic episodes may not be detected. If a patient is evaluated and found to have an elevated pulse oximeter reading, sedative medications may inadvertently be administered to deep the anesthesia contributing to continued apnea8

**Capnography Use During Sedation**

Because there exists a spectrum between conscious sedation and general anesthesia, loss of consciousness and respiratory depression can occur in any patient and at any time regardless of age, medical problem, and doses of drugs used. Recognition of these events and maneuvers to eliminate them is vital to preventing untoward anesthetic events. The current technology to continually monitor sedation is pulse oximetry. Most providers will interpret an elevated pulse oximeter reading as a direct minute-to-minute measure of adequate ventilation. However, pulse oximetry measures oxygenation and supplemental oxygen via nasal mask or cannula can mask hypoventilation and apnea. However, the newest technology used to measure of ventilation is capnography.
Capnography is the most recent advance in sedation monitoring standards, but has been used in the operating room for more than 35 years. Monitors currently available use infrared spectrography technology to measure carbon dioxide in respired gases, then give a numerical reading (capnometry) and a waveform (capnography). The capnogram provides information about respiratory rate and effectiveness, and end-tidal carbon dioxide values. It has been mandated for use in moderate sedation by: the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, the American Association of Oral and Maxillofacial Surgeons, the Society of Interventional Radiology, the Canadian Anesthesiologists Society, and the Association of Anaesthetists of Great Britain and Ireland. Most recently, the Oregon Board of Dentistry mandated capnography for moderate sedation effective 1 Jan. 2016. It is also used in cardiac resuscitation as an indicator of return of spontaneous circulation (ROSC). It is anticipated that the Centers for Medicare and Medicaid Services (CMS) will mandate a capnography requirement for moderate sedation in the near future.

Capnography involves the monitoring of CO₂ in a patient’s expired gases. The end-tidal CO₂ (ETCO₂) is roughly equivalent to a patient’s arterial blood CO₂ and has been validated as a method to monitor a patient’s hypoventilation and apnea; events which can precede hypoxia by being an early detector of ETCO₂ and downward pulse oximetry changes. Hand-held and integrated vital signs monitors are available for in-office use, have been available for several years, and are quite economical. Capnography can also be used to detect disordered breathing 30-90 sec. earlier than pulse oximetry. Apnea or downward trends in ETCO₂ suggest that airway maneuvers (chin lift, jaw thrusts, airway devices, laryngeal mask airways or endotracheal intubation, etc.) can then be used to improve and optimize ventilation in a timely fashion.

The Value Capnography in Sedation

There are oftentimes pros and cons during the introduction of any new monitoring method in anesthesia. However, several studies have validated the importance of capnography during moderate sedation. The fact that ETCO₂ monitoring of ventilation during sedation has several studies supporting its use underlies its importance in providing safe sedation and anesthesia. Early detection of respiratory changes by capnography was improved in children having GI procedures with moderate sedation. In a meta-analysis of studies conducted during procedural sedation, respiratory depression was 17.6 times more likely to be detected in cases using capnography. Hart et al. showed that when using drugs commonly used for conscious
sedation, a high incidence of subclinical depression was produced. ETCO₂ monitoring provided an earlier indicator of respiratory depression and pulse oximetry and respiratory rate alone. Waugh, Khodneva, and Epps concluded in a meta-analysis that during procedural analgesia and anesthesia, respiratory depression was 28 times more likely to be detected using capnography than by traditional methods. A randomized, controlled study of 132 patients receiving procedural sedation in an emergency department, showed that adding capnography resulted in identifying all hypoxic events before onset. In 247 patients having elective endoscopic retrograde cholangiopancreatography and endoscopic ultrasonography with moderate sedation, capnography reduced the frequency and severity of hypoxemia and apnea.

**Other Methods to Monitor Ventilation**

There also exist other alternative methods for monitoring ventilation. These include: 1) patient communication, 2) visual assessment of chest wall motion, 3) use of an earpiece precordial stethoscope for auscultation of breath sounds, or 4) use of a wireless precordial stethoscope for amplified auscultation. Patient communication is oftentimes not a measure of ventilation as patients can speak or babble continuously, but then immediately drift off into sleep where they may become apneic. Given the current technology for patient monitoring, visual methods can also have major shortcomings. Observation of chest wall motion does not measure gas exchange or depth of inspiration and expiration, only the movement of the chest wall. During any procedure, patient drapes, throat packs, nasal masks or cannulas, dental equipment, and instruments trays placed anywhere around a patient’s face or chest, can obscure visual observation of the patient. Relying on clinical observation to recognize gas exchange, ventilation, and hypoxemia is not optimal as changes which detect disordered or apnea do not occur in relation to oxygenation.

Pre-cordial stethoscopes use tubing or amplification of lung sounds to monitor ventilation. These devices can give varying and unreliable results depending on the size of the bell, length of the tubing, and ambient room noise. Sound amplification of breath sounds can be monitored using an earpiece or amplified sound via a speaker or ear piece; usually by only one provider, the anesthetist. In a study of 520 anesthesics, anesthesia providers were listening via an anesthesia stethoscope in only 28% of cases. Additionally, earpieces are detrimental to communication in the treatment room, and are subject to amplification of ambient sounds in their vicinity as they are placed in the pre-tracheal region. Background sounds including staff
communication, suctioning, high-speed handpieces, monitoring devices, monitor alarms, and instruments placement may camouflage monitoring of breathing. The newer precordial stethoscopes utilize wireless earpieces, are usually connected to a single dedicated channel in the stethoscope and have to be re-synchronized if moving to a different room on a different channel. There are few studies comparing traditional monitoring using visual assessment and auscultation of breath sounds versus electronic monitoring using capnography and pulse oximetry. This study evaluated 39 pediatric dental sedations using an oral narcotic, hydroxyzine, chloral hydrate combination. The results showed 10 confirmed episodes of respiratory compromise which were identified electronically by capnography; none were detected by pulse oximetry.24

**Enthusiasm of Capnography Monitoring For All Sedation**

In summary, capnography has been mandated for use in moderate sedation by numerous professional organizations as a monitoring modality for improving patient safety. The value of capnography for detecting apnea and ventilation is well documented. Since dentistry has made significant contributions to anesthesia, the time has come for the ADA to mandate capnography as a monitoring requirement for moderate sedation and anesthesia. Even in the best of circumstances, sedation may cause untoward events. In Texas, there have been anesthetic deaths in the last several months, even when dental anesthesiologists managed the patients. These events likely get reported to state legislators who then mandate requirements to the state dental board. Many times the fallout includes unreasonable and financial requirements (e.g. continuing education requirements) to individual practitioners. It behooves the ADA that dentists are practicing at or above the standard of care for out-of-hospital anesthesia. Capnography is now that standard of care. Failure of the ADA to support capnography for moderate sedation will leave ADA members in a difficult position should anesthesia complications occur. If these events proceed to lawsuits, expert witnesses will likely be anesthesiologists who will ask why capnography was not used as this is the standard of care in anesthesiology.

**REFERENCES**

1. American Society of Anesthesiologists Standards, Guidelines, Statements and Other Documents - Standards for Basic Anesthetic Monitoring. .
   2012.


There are profound questions facing the dental profession and the American Dental Association.

The stakes are high. Very high.

The core issue is much bigger than Resolution 77 and which guidelines the ADA sets for sedation dentistry.

The ultimate question is whether we will be a profession guided by science or by emotion and/or politics.

The answer is not nearly as obvious as you might think.

Caleb Sears, six years old, was a first grader in Northern California who loved climbing trees, singing, and playing with his little sister. In March 2015, his parents took Caleb to an oral surgeon to have a tooth extracted. The little boy never returned home.

Caleb's tragic death – resulting from massive anesthesia-related injuries – is a black mark on our profession, as is the injury of every single patient – young or old – who visits an oral surgeon or pediatric or general dentist for care, and leaves in an ambulance or a hearse.

What are we, as dedicated dentists, to do about Caleb Sears and the handful of other widely publicized cases such as his that arise each year?

To do nothing is inhuman. It’s not right, and it doesn’t feel right.

In California, the response to Caleb’s death was Caleb’s Law, a legislative proposal that its supporters hope will improve patient safety in dental offices.

One provision of the proposed legislation would require dentists to inform the parents and guardians of child patients of the increased risk that occurs when general anesthesia or deep sedation is provided without a separate anesthesia provider, or without specific monitoring equipment.

As the backers of Caleb’s law point out, general medicine surgeons must rely on a separate anesthesia provider, so isn’t it logical that oral surgeons, at the very least, ought to inform parents of the heightened risk of extracting a tooth without having a separate anesthesia provider in the room?
Who would argue against that provision of Caleb's Law? Legislators and regulators in other states, undoubtedly, are asking themselves the same question: Why not?

Indeed. Why not require all oral surgeons, nationally, to either use a separate anesthesia provider or, at least, inform their patients of the heightened risk of proceeding without a separate provider?

Perhaps this year the ADA should revise its guidelines as they pertain to anesthesia and oral surgery to endorse Caleb's Law?

It certainly seems logical. Having the ADA endorse Caleb's Law would be an appropriate tribute to Caleb Sears and the others who've died or been injured by an oral surgeon. And it would clearly demonstrate to the public, legislators, and the media that the ADA really, truly, cares.

Or would it?

As a professional organization that first endorsed Evidence-Based Dentistry in 2000 and established its own Center for Evidence-Based Dentistry in 2007, should we base our guidelines for dentistry on emotion – Caleb's Law, or on scientific evidence?

Where is the science that justifies Caleb's Law?

Does the fact that general medical surgeons use a separate anesthesia provider make it proven science that oral surgeons are putting their patients at greater risk if they don't rely on a separate provider? Where is the science? Where is the empirical data that Evidence-Based Dentistry is supposed to be built upon?

There are untold numbers of victims of bad public health policy and misguided ADA guidelines that rarely make news headlines.

We don't see the uncounted children who die each year, or have their oral and general health severely compromised, because they don't visit an oral surgeon or a pediatric or general dentist.

If oral surgeons were required to have a separate anesthesia provider present when they administer general anesthesia or deep sedation, is there science to show that it would actually be safer than current guidelines? Would there still be oral surgeons, even in the company of a separate provider, who screw up and injure their patients?

Would the added cost of having a second health professional in the room raise the cost of treatment so high that many patients would be priced out of the market – and suffer the health consequences?
How do we, and the ADA, decide such questions? Based on emotion? Based on news coverage? Based on “best intentions?”

If there is a means, through guidelines and regulations, to prevent all tragic and senseless deaths at the dentist office, who would vote against it?

There is, of course, one obvious way. Outlaw all dentistry. If we do that, at least no one will suffer tragically because some oral surgeon or pediatric or general dentist fails to follow protocols.

Just how far will we let emotion and fear carry us before reason and science prevail?

When we set our guidelines based, not on science or empirical data, but on emotion and fear, we open a Pandora’s box of consequences.

Today we are talking about guidelines for general dentists who use oral sedation in their practices. In the foreground, is a growing movement to change the way that oral surgeons treat and inform their patients. In both instances, there is a glaring, overwhelming, lack of science to support the proposed changes.

Will we be seduced into abandoning our long commitment to Evidence-Based Dentistry in exchange for the false comfort that “at least we’re taking action?”

Will Caleb Sears’s death be a motivation for our profession to actually improve patient safety, or will it cause us to act precipitously – mistakenly – to soothe our broken hearts?

If there is evidence – scientific evidence, that clearly demonstrates the changes proposed in Resolution 77 will make our patients safer, then show it to us. We are an evidence-based organization. Where is the evidence?

If dentistry need not do its own studies and due diligence, relying instead on the way physicians and general medical surgeons practice, then produce the evidence that convincingly demonstrates that what is right for general medicine is always right for dentistry, too.

I haven’t seen any such evidence – and believe me, I’ve looked.

The ADA Center for Evidence-Based Dentistry currently includes 89 critical summaries and systematic reviews in its evidence database pertaining to Anesthesia, Oral Sedation, and Pain Control. None of the articles offer a scintilla of evidence to support the changes embodied in Resolution 77. Not a one of them.

By contrast, there are dozens – perhaps hundreds, of peer-reviewed Journal articles and studies that reinforce the need and efficacy of oral sedation in treating fearful
and anxious patients, and the safety of oral sedation when administered in accordance with the existing ADA guidelines and state regulations. A sampling of these studies can be found at www.GetTheScience.com.

The true question facing the ADA and its members is NOT simply to approve or kill Resolution 77. That is only a skirmish in a much larger, more profound battle. The real question is whether the ADA and its members will abandon Evidence-Based Dentistry and, in its place, pass guidelines that make us feel like we’re preventing tragedies, when in fact, we have nothing to base such changes on other than wishful thinking.

In summary: If the ADA reintroduces Resolution 77 – without the evidence-based dentistry such changes demand – it will be endorsing a Pandora’s box of uncontrolled emotion that will ultimately consume all of professional dentistry.

The future of every dentist in this country, and all of our patients, is at stake.

7:24 seconds