Fact Check Finds Serious Flaws in ADA Report Concerning Sedation Dentistry

The American Dental Association and its Council on Dental Education and Licensure issued a report – "*Frequently Asked Questions – Resolution 37*" – designed to inform ADA members and delegates of the facts pertaining to Resolution 37, a proposed revision to the ADA's Sedation and Anesthesia Guidelines.

What follows is a summary of a 7,000-word Fact Check of the FAQ prepared by a group of scientists, academics, and dentists – all ADA members – who are independent of CDEL.

To view the full Fact Check, visit: www.GetTheScience.com.

Q.1. What was the Council's response to the directives of the 2015 House of Delegates?

CDEL's CLAIMS:

- The Council relied on a detailed report, titled "*Report on the Risks and Benefits of Using Capnography in Dental Patients Undergoing Moderate Sedation*," prepared at its request by the ADA's Council on Scientific Affairs (CSA).

- The Council "also considered comments received…"

  CONCLUSION: **There is substantial evidence that CDEL and CSA did not fulfill the 2015 House of Delegates mandate.**

Q.2. Why does the proposed guideline not outline training by route of administration?

CDEL's CLAIMS:

- The Council carefully studied this matter and maintains that "moderately sedated patients via either route require the same attentiveness and monitoring; there should be no difference in the training requirements related to routes of administration."

- A review of CE courses was conducted: at least 11 providers currently meet or exceed 60 hours of instruction and 20 patient experiences.

  [For More, See Question #7 and the related FACT CHECK.]

  CONCLUSION: **The recommendations of CDEL do not comport with the ADA's Policy on Evidence-Based Dentistry, lacking peer-reviewed, science-backed substantiation, or clear clinical evidence.**

  Should CDEL's recommendations be adopted by the ADA 2016 HOD, there will not be nearly enough courses to meet the demand of dentists who will need to be certified as competent to administer moderate enteral sedation.

  See: http://GetTheScience.com to review just some of the published, peer-reviewed articles on this topic.

Q.3. Why is the concomitant administration of two different oral medications considered moderate sedation?

CDEL's CLAIMS:

- The Council states that potentiation creates a net effect that is greater than the MRD of each drug alone. It cites the 2012 *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*, which state that giving enteral drugs above the MRD is considered moderate sedation. "Therefore, exceeding the MRD is already considered to be moderate sedation."

  CDEL says it could find only three published papers related to potentiation and oral sedation: from 1986, 2007, and 2009. Two of the three paper's offer indirect support for its position.

  CONCLUSION: **Adopting Resolution 37 and its restrictions on the administration of two different oral medications without extensive additional training, violates the ADA's policy to act in accordance with the "patient's treatment needs and preferences." The scientific justification for making it much harder for dentists to use potentiation – currently a widespread practice – is skimpy at best.**

Q.4. How do the 2016 proposed Guidelines differ from the version considered by the 2015 ADA House of Delegates?

CDEL's CLAIMS:

- The Council states that 2015's Resolution 77 and 2016's Resolution 36 are virtually identical. The main exception is that the 2016 proposed revisions eliminate references to sedation and anesthesia for children.

  CDEL and the ADA defer exclusively to the guidelines set by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (AAPD).

  CONCLUSION: **Like the explanation for virtually every component of Resolution 37, political posturing – *not science* – appears to be the sole motivation for CDEL's decision to allow the AAPD to set all guidelines for pediatric sedation.**

  CDEL does not even feign a science, evidence-based, or clinical rationale for allowing dentists flexibility when it comes to their choice of methods for monitoring sedated children (capnography or prechordial auscultation), but not adults.

Q.5. In what ways were the dental anesthesiology communities notified that the Guidelines were under revision? Was there an opportunity to comment on the proposal?

CDEL's CLAIMS:

- The Council notes that it held a teleconference offering in-person and phoned opportunities to testify on April 21, 2016. It also provided two written comment periods. The teleconference and comment opportunities were promoted via multiple channels, including direct email notification.

  CDEL lists 18 dental anesthesiology communities of interest as those that were contacted and invited to participate.

  A total of 33 written and oral comments were received and "systematically reviewed by the Council."

CONCLUSION: **Cosmetically, CDEL made an effort to solicit the comments and testimony of experts on the topic. But some of its "experts" were far less informed on the topic – and represented far less clinical experience with sedation dentistry – than others.**

Importantly, CDEL repeated its 2015 posture in totally excluding patients from its communities of interest and failing to make even a cosmetic attempt to study the practical and financial impact that Resolution 37, if approved, will have on patients and their access to care.

Q.6. Many dentists hold sedation permits issued by a state dental board. Are dentists' sedation permits in jeopardy if the proposed revised ADA Guidelines are adopted?

CDEL's CLAIMS:

- The Council maintains that the state legislatures and dental boards alone have the authority to establish permit/license requirements by which dentists with anesthesia permits or licenses must abide.

  "The state boards determine the requirements for dentists who administer sedation, not the ADA."

CONCLUSION: **While the ADA, technically, does not set state standards for those who administer sedation and anesthesia, its guidelines, as adopted by the HOD, do become law in a majority of states. Many thousands of dental permits will be in jeopardy if Resolution 37 is approved.**

Q.7. What CE opportunities are available to meet his new guideline?

CDEL's CLAIMS:

- The Council says it is "aware" of at least 11 CE courses with a hands-on component that "may" offer the course content and duration as proposed in Resolution 37.

CDEL adds that it is "confident" that providers of CE on the subject of sedation and anesthesia will enrich their educational offerings to comply with the new guidelines, should Resolution 37 be approved by the 2016 HOD.

CDEL goes on to list the 11 course providers, including non-profit and for-profit educators.

CONCLUSION: **There are not and will not be sufficient courses (for decades to come) to meet the needs of the dental profession, should Resolution 37 and its stricter sedation permit requirements be approved.**

CDEL's "confidence" is not based on a thorough investigation of the capabilities of CE providers.

For more information, see the transcript of the National Dental Town Hall held on October 10, 2016, featuring a panel of four dental luminaries. The transcript is available at: http://tinyurl.com/Dionne-Transcript.)

Q.8. I provided comment to CDEL; why was my advice overlooked?

CDEL's CLAIMS:

- The Council answers that while it "did not agree with all points made," all input was systematically reviewed and considered.

  In response to the feedback it received, the Council acknowledges that "the majority of evidence" it relied on came in the form of expert opinion.

  It further explains that "not one controlled clinical study has ever been performed to demonstrate the optimal training time for dentists who provide moderate sedation," adding that such a study "may be nearly impossible to fund or conduct or to be cleared by an institutional review board."

  CDEL points to its own council members' "expertise in contemporary educational principles," adding, "We rely on our Anesthesiology Committee experts…to evaluate anesthesiology information and provide CDEL with the best recommendations."

  CONCLUSION: **CDEL's reliance on its own members, members appointed to its Anesthesiology Committee, and hand-selected outside experts raises**

important questions of bias. Why did CDEL give the recommendations of certain individuals and groups legitimacy to the total or partial exclusion of other clearly qualified experts and organizations?

CDEL offers no specifics whatsoever about what its "systematic" evidentiary review process consisted of, nor does it provide a detailed list of published citations to support is conclusions and recommendations.

The lack of transparency in CDEL's process – especially after inviting public comment and testimony – undermines the Council's credibility, and calls into serious question the scientific, evidence-based validity of Resolution 37.

See: http://GetTheScience.com to review just some of the published, peer-reviewed articles on this topic.

Q.9. Why is the new definition of operating dentist proposed?

CDEL's CLAIMS:

- The Council says that changing the definition to "operating dentist" from "qualified dentist" – as proposed in Resolution 37 – is intended to bring clarity in the face of some state legislatures and regulators who have set specific definitions pertaining to the clinical operative dentist who works with an anesthesia provider.

  CONCLUSION: **This is a change that appears benign and unlikely to impact ADA members or their patients. If the redefinition was proposed separately from the other provisions of Resolution 37, it is unlikely the new terminology would face meaningful opposition.**

Q.10. How many states currently require dentists to monitor expired CO_2 via capnography during moderate sedation?

CDEL's CLAIMS:

- The Council notes that at least 15 states "mention" capnography in their laws or in dental board policy for moderate sedation, "either as a requirement, a monitoring option, or as a proposed regulation."

CONCLUSION: **Thirty-five states do <u>NOT</u> currently even *mention* capnography as a monitoring option. Moreover, CDEL fails to inform ADA members which state or states absolutely require it.**

CDEL's lack of full disclosure on this matter smacks more of a panel of biased advocates than an impartial council of experts trying to present unbiased facts to the 2016 HOA and other ADA members so that they can make an informed decision.

Q.11. What is the approximate cost of a capnography?
Q. 12. Will these new guidelines increase the cost of dental care or decrease access to care for some patients?

CDEL's CLAIMS:

- The Council states, "in general, a capnograph can range in price from $800-$3,000." [*Question 11*]

  CDEL then cites its own estimate to conclude, "The equipment needed to monitor end-tidal CO2 should not appreciably increase the cost of delivering moderate sedation or decrease its availability to patients." [*Question 12*]

  CDEL labels the $800-$3,000 equipment cost as "a reasonable investment to identify more respiratory complications and support risk management and patient safety."

- CDEL states unequivocally, "There is no evidence* demonstrating that the cost of care will increase, that patient access to sedation will decrease or that the number of sedation permits will decrease" should the 2016 HOD approve Resolution 37.

CONCLUSION: **CDEL's focus on the cost of capnography equipment in these two FAQ questions is a form of misdirection. It is the training costs, lost production, and related travel expenses that need concern dentists, not only for their own economic well-being but also for the financial well-being of their patients.**

CDEL's contention that "there is no evidence" demonstrating the economic impact on dentists and their patients ignores a three-month independent analysis undertaken by a former Wall Street Journal reporter and a patients' rights group. In 2015 and 2016, CDEL, itself, made no effort whatsoever to conduct a study to gauge the likely impact of Resolution 37 on patients.

Q.13. When and why were the Sedation and Anesthesia Guidelines developed?

CDEL's CLAIMS:

- The Council states that the Guidelines, which have been revised ten times since they were first established in 1971, are intended to "assist dentists in the delivery of safe and effective sedation and anesthesia. The revisions "reflect emerging practice and scientific principles."

CONCLUSION: **CDEL's charter is to update the ADA's use and teaching guidelines for sedation as needed. In Resolution 37, CDEL has proposed broad unneeded, unjustified, and scientifically unsound changes to the existing ADA 2007 Guidelines that have proven – above and beyond dispute – to protect patients when dentists administer moderate enteral sedation in accordance with the existing Guidelines.**

Q.14. What is the process for proposing revisions to the House of Delegates?

CDEL's CLAIMS:

- The Council notes that in keeping with a directive from the House of Delegates, it reviews the ADA's sedation and anesthesia guidelines every five years. It cites "changes in practice and science" to explain the reasons the guidelines have recently been updated more frequently.

  CDEL notes that along with its Anesthesiology Committee, its seeks input from the "anesthesia communities of interest." It further explains that its Anesthesiology Committee, which carefully studies the issues and provides technical and scientific input to CDEL, includes "representatives from":

- American Academy of Periodontology
- American Association of Oral and Maxillofacial Surgeons
- American Dental Society of Anesthesiology
- American Society of Dentist Anesthesiologists
- American Society of Anesthesiologists
- American Academy of Pediatric Dentistry

This year, CDEL adds, a member of the ADA's Council on Scientific Affairs also participated in committee meetings.

CDEL writes that it "considers the Committee's recommendations and circulates proposed revisions to its dental anesthesiology communities of interest."

CONCLUSION: **CDEL does not appear to be acting in the best interests of all dentists and their patients as its only priority. CDEL's arbitrary inclusion of some experts and evidence, and exclusion of others, taints its recommendations and conclusions.**

The most serious issue facing professional dentistry and public safety surrounds deep sedation/general anesthesia – not moderate enteral sedation.

The very credibility of the ADA as a champion of evidence-based science and public health is threatened by CDEL's action and the duplicity of Resolution 37.

Q.15. What information was used to develop the proposed revised Guidelines?

CDEL's CLAIMS:

- The Council responds that its Committee on Anesthesiology "relied on current standards of care, guidelines of other medical and dental organizations, the scientific literature, current state regulations for sedation, and the expertise of practitioners, academicians and state dental board members…"

CONCLUSION: **CDEL failed to weigh or place sufficient weight on the vast clinical experiences of the tens of thousands of dedicated dentists who regularly use moderate enteral sedation in their practices. Instead, the Council turned to "textbook" experts who seem compelled to recommend the changes**

proposed in Resolution 37 for change sake alone. There is no public health crisis in enteral sedation dentistry and no compelling need for Resolution 37.

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