

Concerns Regarding the Single Operator Model of Sedation in Young Children

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In July 2016, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) released their joint updated “Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures.”¹ The purpose of this update, as stated by the authors and supported by the AAP and AAPD, was to “unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities...; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes.” They described the substantial differences between sedation for children and adults, and emphasized the subtlety and rapidity with which young children can pass from 1 level of sedation to another unintended level. The need to have practitioners that can quickly recognize the signs of deeper levels of sedation and have the skills, equipment, and support personnel to rescue the child from potential adverse responses to these unintended levels of sedation is critical.

CALEB’S STORY BY ANNA KAPLAN, MD, CALEB’S AUNT

My nephew Caleb was a strong, healthy, 6-and-a-half year old when he died. Caleb was scheduled to have a mesiodens tooth extracted, a supernumerary tooth between the 2 central incisors. His oral surgeon had

recommended general anesthesia. Caleb’s parents did not consent lightly to this method of anesthesia. They talked through the options with their doctors, family, and friends. They knew of the minimal but serious risks of anesthesia. However, our family had no idea or reason to know that dentists and oral surgeons provide anesthesia significantly differently than the medical model.

Caleb’s surgery occurred in a private office with an oral surgeon and 2 dental assistants. There was no dedicated separate anesthesia provider, not even a nurse present. The oral surgeon administered fentanyl, midazolam, propofol, and ketamine intravenously, then went to work on Caleb’s teeth. No one noticed that Caleb had stopped breathing until the pulse oximeter read 69%.

Rescue efforts appeared to be woefully inadequate. According to the available records, no one attempted bag and/or mask ventilation. The oral surgeon attempted intubation (knocking out a number of teeth) and was unsuccessful; he attempted cricothyroidotomy and was also unsuccessful. There was no attempt to insert a nasal trumpet, oral airway, or laryngeal mask airway. More importantly, despite having an IV in place, there was no attempt to reverse the fentanyl or midazolam. When the paramedics arrived, no one was doing cardiopulmonary resuscitation. Caleb’s electrocardiogram showed pulseless electrical activity. He had been without oxygen for at least 20 minutes. In

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All authors contributed to the conceptualization of the manuscript after the adoption of the American Academy of Pediatrics Annual Leadership Forum: Resolution 42, “Not One More Child Shall Die in a Dental Chair: Remembering Caleb”; Dr Kaplan is the author of California’s Caleb’s Law and AB 224; Drs Agarwal, Coté, and Kaplan did considerable research on sedation safety and complications; Dr Brown reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DOI: <https://doi.org/10.1542/peds.2017-2344>

Accepted for publication Nov 9, 2017

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

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To cite: Agarwal R, Kaplan A, Brown R, et al. Concerns Regarding the Single Operator Model of Sedation in Young Children. *Pediatrics*. 2018; 141(4):e20172344

the emergency department, he was immediately and successfully intubated, but it was too late. For the next 48 hours, our family stood by Caleb in the PICU as his medical condition deteriorated, until finally, a neurologist told us he had passed. Caleb's parents held him as he was removed from the ventilator.

Over the next months, our family provided support as best we could for Caleb's devastated parents. This profound personal loss spurred our family to educate ourselves further regarding dental practice models and procedures. Looking beyond Caleb's case, it was surprising to learn that this was a common model in dental practice. Our family discovered that Caleb's death was not an isolated incident, but no one was doing anything to change it. We set out to shine a light on this issue and hopefully prevent other families from suffering similar unimaginable losses. Caleb's Law began when our family (Caleb's mother and father, my husband, and myself) met with our California State Assembly member Tony Thurmond. We described what had happened to Caleb and proposed a bill to make dental anesthesia safer. I worked closely with Mr Thurmond to both draft a bill and present it to the State Assembly.

The first version of the bill proposal drafted by our family required that there be a dedicated qualified anesthesia provider to monitor pediatric patients undergoing deep sedation or general anesthesia. This version of the bill hit major opposition from the California Dental Association and the California Association of Oral and Maxillofacial Surgeons. The American Academy of Pediatrics, California (AAP-CA), a 501(c)4 separately incorporated from the national AAP, stepped in as the sponsor of the legislation. The AAP-CA provided clout and credibility. They helped us muster lobbying resources, physicians eager to testify for children's safety, and

had deep experience with child health advocacy. Two authors (C.J.C., R.A.) provided background and testimony as witnesses for hearings and meetings with legislators and broadened the coalition of academics that were now advocating for change. The California Society of Anesthesiologists and the California Society of Dentist Anesthesiologists also joined us with support of the bill. Together this coalition, which included our family, worked to shepherd the bill through the legislature and to the governor for signature. This became known as Caleb's Law Part 1.

Caleb's Law Part 1 (www.calebslaw.org) passed in 2016 and accomplished 3 important changes: (1) it mandated improved data collection by the Dental Board of California by requiring them to collect specified epidemiologic information for each adverse event and encouraged the dental board to contract with a nonprofit anesthesia registry to begin real-time data collection for sedation encounters in the dental office; (2) mandated that the dental board perform a study of sedation safety; and (3) specified the contents of a disclosure form for parents concerning anesthesia-related risks in a dental setting.

The California Dental Board completed their study in December 2016. Our family and Assemblyman Thurmond, together with the AAP-CA, have now sponsored a new 2-year bill to codify these recommendations, which include among several others that there should be a separate anesthesia provider for young children undergoing deep sedation and general anesthesia. This bill, AB 224,² is known as Caleb's Law Part 2. However, the dental lobby continues to challenge the recommended changes, arguing that there are insufficient data to justify change and that a separate anesthesia provider would increase costs to patients and decrease access to care. This point is

especially suspect, given that dentists and oral surgeons usually bill their patients separately for surgery and anesthesia. Caleb's oral surgeon, for example, billed \$670 for the procedure and \$755 for the general anesthesia.

Caleb was a completely healthy child. He did not have an allergic reaction or a latent heart defect. His death was completely preventable. Had a medically skilled independent clinician as recommended by the AAP/AAPD guidelines been used, Caleb would likely not have died. Instead, 2 medically unskilled and inadequately trained dental assistants were unable to assist, chaos ruled, and a tragedy occurred.

DISCUSSION

Younger children are recognized to be at increased risk for side effects and complications with sedation and/or anesthesia. The medical community routinely follows the AAP/AAPD and the American Society of Anesthesiologists (ASA) guidelines regarding procedural sedation. The AAP/AAPD guidelines state:

"During deep sedation, there must be 1 person whose only responsibility is to constantly observe the patient's vital signs, airway patency, and adequacy of ventilation and to either administer drugs or direct their administration. This individual must, at a minimum, be trained in PALS [Pediatric Advanced Life Support] and capable of assisting with any emergency event. At least 1 individual must be present who is trained in and capable of providing advanced pediatric life support and who is skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction."¹

In hospitals, clinics, offices, and most places where moderate or deep sedation is practiced in young children, the person monitoring the patients and administering the medications is at least a qualified nurse, and most often a physician. Most institutions require significant additional training or education for all clinicians involved in sedation

TABLE 1 Level of Education Required in Dental Paraprofessional Positions

Level of Education	Basic	Advanced
Dental assistant	High school	On-the-job, certificate course
Dental anesthesia assistant	High school, 12 mo practice	Online education (36 h), national examination
Dental sedation assistant (CA)	High school, 12 mo practice	On-site, hands on, and online education (110 h); state examination
Dental hygienist	2–4 y dental hygienist	Associate or (less commonly) bachelor's degree, national certifying examination

Adapted from Boynes SG. *Dental Anesthesiology: A Guide to the Rules and Regulations of the United States of America*. 5th ed. Chicago, IL: No-No Orchard Publishing; 2011; Dental Anesthesia Assistant National Certification Examination. Available at: www.aaoms.org/continuing-education/certification-program-daance. Accessed June 2017; and Dental Board of California. How to become a dental sedation assistant permit holder. Available at: www.dbc.ca.gov/verification/index.shtml. Accessed May 15, 2017. CA, California.

services. Sedation modules, courses, and hands-on workshops are taught locally and nationally and include airway management workshops. Both the Food and Drug Administration and the ASA specifically state “propofol used for sedation or anesthesia should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.”³

In contrast to physicians’ offices and clinics, the dentists and oral surgeons often use the single operator model. The single operator model allows for 1 anesthesia permit holder (as defined by the state in which the dentist or oral surgeon is practicing) to administer both the sedatives and/or anesthetics and perform the dental work. Each individual state determines the requirements for licensing and scope of practice. Many of these practitioners will have a dental assistant help monitor the patient. The American Association of Oral and Maxillofacial Surgeons had published guidelines approving oral surgeons to administer anesthesia with only 2 dental assistants for support. They justify this practice by claiming that 1 dental assistant’s only job is to monitor the patient while the other assists the dentist. The oral surgeon in this model is the only one trained in anesthesia, sedation, resuscitation, and medical care. State dental boards do little to track adverse outcomes in dental offices despite the authors of several medical articles reporting disproportionate rates of injury

and death from anesthesia in dental offices as compared with medical settings.^{4,5} The requirements for the education and training of dental assistants vary considerably from state to state.⁶ They often have no more than a high school education, with many having only on-the-job training (Table 1). A dental assistant in most states is not licensed to draw up or administer medications, cannot perform airway rescue maneuvers, and in all likelihood does not have the education or training to recognize changing levels of sedation. There is a Dental Assistant Anesthesia National Certification Examination that requires 36 hours of online education and the successful passage of an online examination.⁷ This certification is required in a few states (WA, OR) for a dental assistant (or in some cases dental hygienists) to be allowed to monitor and assist with sedation of children. The Dental Assistant Anesthesia National Certification Examination still does not qualify participants to draw up or independently administer medications. California has a Dental Sedation Assistant Certification that requires 110 hours of in-office education and training.⁸ Advanced cardiac life support and PALS training are not required, although Caleb’s Law Part 2 (AB 224), which is currently being reviewed in the California State Assembly, would require PALS training. The only person capable of administering medications and assisting with airway emergencies is the dentist or oral surgeon performing the procedure. Thus, the only backup for rapidly summoning additional skilled

help is by calling 911, which may take many minutes and may have emergency medical technicians who lack skills to manage a child’s airway. The dental office is in fact a high-risk venue, which makes adequate skilled staffing even more important. With the single operator model, the dentist or oral surgeon would have to simultaneously manage the airway, draw up and/or administer rescue medications, recognize and run the code, and manage cardiopulmonary resuscitation. This is an impossible task for even the most skilled clinician.

In medicine, adverse events are routinely reported to the institution’s quality improvement or risk management offices. Additionally, multiple national agencies (Joint Commission, Food and Drug Administration, Centers for Disease Control and Prevention, etc) and societies have developed databases to collect as much information on these events as possible, with the intent to understand faulty processes and improve outcomes. The same data collection does not occur in dentistry. The state dental boards are the sole recipient of these data. Before the passage of Caleb’s Law in California and the simultaneous review of dental sedation practices in Texas, not 1 dental board in all 50 states was systematically tracking these data. This year, Texas and California will be the first 2 states to start tracking data on adverse events.

When Caleb’s family evaluated their anesthesia options, they calculated the risks on the basis of the dominant medical model. They had no reason

to consider that their oral surgeon would administer anesthesia and conduct the procedure simultaneously. Dentists and oral surgeons have been able to provide anesthesia services on the basis of the reputation of safety created by the medical community, without disclosing to the patients that they fail to follow the same standards. Those who argue for the continuation of the single operator model cite a lack of data to prove that this practice is any less safe than having a separate qualified anesthesia provider. This argument is disingenuous. Over 15 years ago, Coté et al^{4,5} reported 29 deaths or permanent neurologic injury in dental offices, with failure to rescue a nonbreathing child contributing to 80% of adverse outcomes. The Anesthesia Patient Safety Foundation, the Anesthesia Incident Reporting System, and other databases that collect information on anesthesia or sedation complications have had minimal submissions for dental sedation and/or anesthesia, so the true incidence is unknown.

The authors of a 2015 article in the *Journal of the American Dental Association* examined the incidence of death or brain injury in patients undergoing deep sedation or general anesthesia by an oral surgeon who is also doing the procedure (single operator model).⁹ They used the Oral and Maxillofacial Surgery National Insurance Company anesthesia closed-claims database from 2000 to 2013; this company insures ~80% of practicing oral and maxillofacial surgeons. They determined that ~39 million anesthetics were performed in adults and children, and 113 deaths or brain injuries occurred. They estimated that 1 case of death or brain injury occurs for every 348 602 anesthetics, and at least 1 instance or more occurred nationally every month. These complications are occurring in presumably healthy patients of all ages, undergoing minor noninvasive procedures. These

findings can be compared with the Wake Up Safe initiative (sponsored by the Society for Pediatric Anesthesia), which gathers data on the risk and incidence of complications in pediatric anesthesia.^{10,11} Wake Up Safe is an organization of 32 pediatric anesthesia departments designed to reduce the risk and incidence of complications in pediatric anesthesia by gathering, interpreting, and taking action on data collected from these departments. Hospitals and institutions voluntarily share their deidentified morbidity and/or mortality information as well as their total numbers of cases and demographics. There have been no anesthesia-related deaths or neurologic injuries in almost 2 million healthy children (D. Tyler, MD, personal communication, <http://wakeupsafe.org>, 2017). Another database, the Pediatric Sedation Research Consortium,¹¹ is a collaborative, multi-institutional, multidisciplinary group dedicated to making pediatric sedation safer and more effective.¹²⁻¹⁴ All sedations performed in participating institutions, offices, and clinics regardless of specialty are reported, including data from a few dental providers. There are currently 48 participating institutions. There have been no deaths or significant complications in over 500 000 reported cases to date (J. Cravero, MD, personal communication, Past President and Co-Founder of the Pediatric Sedation Research Consortium, 2017). Although there have been adverse events, each was managed successfully.¹⁵ Thus, the morbidity and mortality of healthy children ranking as a I or II on the ASA scale who are undergoing either general anesthesia or procedural sedation reported by these initiatives (0 of 500 000 to 0 of 2 000 000) appear to be well below that reported from the dental community in healthy children and adults (1 of 348 602), likely because of the ready availability

of skilled personnel to successfully rescue the child.

CONCLUSIONS

The AAP has made a commitment to improving care for children undergoing dental sedation, encouraging all practitioners to follow the AAP/AAPD guidelines. The Annual Leadership Forum included a resolution on preventing deaths in dentists' and oral surgeons' offices as 1 of their Top 10 Resolutions.¹⁶ Some states make the single operator model of sedation and/or anesthesia more difficult to practice, and the Alberta and British Columbia Dental Association have permanently suspended the single operator model.¹⁷ As advocates for the safety of all children, we must persevere until the same rules and guidelines apply to all children undergoing deep sedation or general anesthesia in all locations, in all states, and in all types of practices. Physicians can advocate for these changes by contacting their local AAP chapters and districts or state senators and/or assembly members and offer to help craft legislation similar to what is being done in California. It is unacceptable that healthy children continue to die or sustain permanent neurologic injury because a single provider was unable to rescue the child from an evolving adverse event. Pediatricians can educate parents about the risks of sedation, and encourage them to ask questions (HealthyChildren.org).

ABBREVIATIONS

AAP: American Academy of Pediatrics

AAPD: American Academy of Pediatric Dentistry

AAP-CA: American Academy of Pediatrics, California

ASA: American Society of Anesthesiologists

PALS: pediatric advanced life support

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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Pediatrics 2018;141;

DOI: 10.1542/peds.2017-2344 originally published online March 2, 2018;

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DOI: 10.1542/peds.2017-2344 originally published online March 2, 2018;

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