THE FUTURE OF ANESTHESIA IN OMFS: THE OUTLOOK

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THE FOLLOWING POTENTIAL CONFLICT OF INTEREST RELATIONSHIPS ARE GERMANE TO MY PRESENTATION.

EQUIPMENT: NONE SPEAKERS BUREAU: NONE STOCK SHAREHOLDER: NONE GRANT/RESEARCH SUPPORT: NONE CONSULTANT: NONE

Status of FDA devices used for the material being presented None

Status of off-label use of devices, drugs or other materials that constitute the subject of this presentation N/A

WHAT'S THE STORY?

- AAOMS has been single operator model for many years
- This has been known to the American Society of Anesthesiologists(ASA) and the American Academy of Pediatrics(AAP)
- For over 24 years AAOMS has reviewed guidelines for office-based anesthesia with ASA and AAP who have been in agreement
- In March 2019, the dental anesthesiologists were recognized as a dental specialty— American Society of Dental Anesthesiologists(ASDA)

WHAT'S THE STORY?

- In June 2019, AAP posted guidelines for pediatric anesthesia
- In July 2019, ASA posted statement regard office based pediatric anesthesia without AAOMS consult
- In August/Dec 2019, AAOMS responded to new guidelines/statements
- In March 2020, ASDA released recommended guidelines with descriptive changes

3 year old Finley Boyle has died after careless sedation by dentist and staff in Hawaii dental office.

NEWS

Like

Receptionist who administered drugs that killed Finley Boyle testifies

Posted: Nov 7, 2018 / 06:30 PM HST / Updated: Nov 7, 2018 / 07:14 PM HST

- Sadly these deaths are more common than you may think. In 2011 there were 8 that were reported, who knows how many were not
- STATE DENTAL BOARDS ARE DOING LITTLE TO PROTECT THE PUBLIC AND EVERYTHING TO MAKE IT EASIER FOR DENTISTS TO INCREASE THEIR INCOME STREAM BY OFFERING SEDATION.

LOCAL // BAY AREA & STATE

4-year-old boy dies after dental procedure in Oakland — state board investigating



Gwendolyn Wu | May 16, 2019 | Updated: May 16, 2019 7:14 p.m.

• HE WAS GIVEN TWO DOSES OF ANESTHESIA AND STOPPED BREATHING DURING THE PROCEDURE, THE FAMILY SAID.

• Over a 21-month period in 2017 and 2018, sedation was involved in two deaths and 23 hospitalizations of patients under 21, according to the Dental Board of California.

COMMENTARY

Dental Sedation Kills 4-Year-Old Who Might Have Been Saved By A Toothbrush

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November 10, 2017 By Paul C. McLean 🔰

- THE DENTIST LEFT THE CHILD IN RECOVERY WITH A DENTAL ASSISTANT.
- THE PEDIATRIC DENTIST PERFORMED SURGERY IN A DENTAL OFFICE, NOT A HOSPITAL OPERATING ROOM.

WEST METRO

Teen's death after oral surgery prompts suspension of Edina dentist's license

Board finds his surgical assistant wasn't certified.

By Paul Walsh Star Tribune | FEBRUARY 23, 2016 - 9:44AM

-ENABLED MEDICAL PERSONNEL (I.E., AN UNLICENSED DENTAL ASSISTANT, LICENSED DENTAL ASSISTANT, AND STUDENT INTERN) TO PERFORM TASKS WHICH EXCEEDED THE LEGAL SCOPE OF PRACTICE."
-ALLOWED A DENTAL ASSISTANT WHO LACKED THE STATE-REQUIRED COURSE WORK AND CERTIFICATION TO MONITOR THE TEEN AS SHE RECEIVED ANESTHESIA.

RELATIONSHIP WITH THE ASA

• IN 1996 THE FIRST SET OF GUIDELINES WERE PUBLISHED:

- "PRACTICE GUIDELINES FOR SEDATION AND ANALGESIA BY NON-ANESTHESIOLOGISTS: A REPORT BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS TASK FORCE ON SEDATION AND ANALGESIA BY NON-ANESTHESIOLOGISTS"
- The findings of the literature analyses were supplemented by the opinions of Task Force members and surveys of the opinions of a panel of consultants drawn from...AAOMS AMONG OTHER GROUPS
- IN 2002, UPDATED GUIDELINES WERE PUBLISHED
 - "PRACTICE GUIDELINES FOR SEDATION AND ANALGESIA BY NON-ANESTHESIOLOGISTS"
 - AGAIN ENDORSED BY AAOMS AMONG OTHERS

RELATIONSHIP WITH THE ASA

• MOST RECENT GUIDELINES WERE FROM 2018:

- "PRACTICE GUIDELINES FOR MODERATE PROCEDURAL SEDATION AND ANALGESIA 2018: A REPORT BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS TASK FORCE ON MODERATE PROCEDURAL SEDATION AND ANALGESIA, THE AMERICAN ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN DENTAL ASSOCIATION, AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS, AND SOCIETY OF INTERVENTIONAL RADIOLOGY"
- HIGHLIGHTS FROM THE DOCUMENT
 - PATIENT MONITORING
 - AN INDIVIDUAL DEDICATED TO PATIENT MONITORING
 - EMERGENCY SUPPORT
 - INDIVIDUAL(S) CAPABLE OF ESTABLISHING A PATENT AIRWAY, POSITIVE PRESSURE VENTILATION AND RESUSCITATION
 - EMERGENCY AND AIRWAY EQUIPMENT
 - An individual to establish intravenous access
 - "The literature is insufficient to assess whether the presence of an individual capable of establishing a patent airway, positive pressure ventilation, and resuscitation will improve outcomes."
 - "IN ADDITION, THE LITERATURE IS INSUFFICIENT TO DETERMINE THE BENEFITS OF KEEPING AN INDIVIDUAL PRESENT TO ESTABLISH INTRAVENOUS ACCESS DURING PROCEDURES WITH MODERATE SEDATION/ANALGESIA."

AMERICAN ACADEMY OF PEDIATRICS-JUNE 2019

- "GUIDELINES FOR MONITORING AND MANAGEMENT OF PEDIATRIC PATIENTS BEFORE, DURING, AND AFTER SEDATION FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES"
 - HIGHLIGHTS FROM THE DOCUMENT
 - The use of moderate sedation shall include the provision of a person, **in addition to the PRACTITIONER**, whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitation measures, if required.
 - This individual should be trained in and capable of providing advanced airway skills
 - IT IS RECOMMENDED THAT AT LEAST 1 PRACTITIONER BE SKILLED IN OBTAINING VASCULAR ACCESS IN CHILDREN.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS -JULY 2019

- WITHOUT DISCUSSION WITH AAOMS, THE ASA PUBLISHED IN JULY 2019:
 - "JOINT STATEMENT FROM THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS, THE SOCIETY FOR PEDIATRIC ANESTHESIA, THE AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS, AND THE SOCIETY FOR PEDIATRIC SEDATION REGARDING THE USE OF DEEP SEDATION/GENERAL ANESTHESIA FOR PEDIATRIC DENTAL PROCEDURES USING THE SINGLE-PROVIDER/OPERATOR MODEL"
 - HIGHLIGHTS FROM THE DOCUMENT
 - THE ORAL SURGERY COMMUNITY HAS PRACTICED... THE SINGLE-PROVIDER/OPERATOR PRACTICE MODEL, WITH...A DENTAL ASSISTANT AS THE MONITORING ENTITY.
 - This person has virtually no hands-on or formal medical training, cannot administer drugs, cannot establish venous access and cannot reliably provide definitive airway assistance.
 - These activities, critical to the safe administration of sedation, are outside the scope of practice of a dental assistant.

JOINT STATEMENT FROM THE ASA JULY 2019

- HIGHLIGHTS FROM THE DOCUMENT
 - HOW SUCH AN INDIVIDUAL WITH NO REAL-LIFE MEDICAL EXPERIENCE AND NO SIGNIFICANT HANDS-ON TRAINING COULD PROVIDE SKILLED HELP WITH A LIFE-THREATENING EVENT SINCE DAANCE DOES NOT EVEN QUALIFY PARTICIPANTS TO DRAW UP OR INDEPENDENTLY ADMINISTER MEDICATIONS.
 - Even if trained to do so, drawing up and administering anesthetic or resuscitative medications runs counter to most state dental regulations where dental assistants cannot even administer intra-oral local anesthesia.
 - WITH THE SINGLE-PROVIDER/OPERATOR PRACTICE MODEL, THE ONLY MEDICALLY SKILLED INDIVIDUAL MAY BE A SINGLE ORAL SURGEON.

AAOMS RESPONSE IN AUGUST 2019

- "AAOMS STATEMENT ON OFFICE-BASED OMS ANESTHESIA"
- HIGHLIGHTS FROM THE DOCUMENT
 - The unique OMS anesthesia team model has consistently been proven as safe, effective and affordable.
 - PRACTICES ARE SUBJECT TO REVIEW BY STATE DENTAL BOARDS AND THE MANDATED OFFICE ANESTHESIA EVALUATION PROGRAM OF THIS ASSOCIATION.
 - THESE REGULATIONS ASSURE THAT PROPER EMERGENCY SAFEGUARDS ARE IN PLACE AND PROPER PATIENT SELECTION PROTOCOLS ARE ADHERED TO.

• AAOMS STATES: PLEASE REMEMBER THAT THE JOINT STATEMENT AND AAP GUIDELINES DO NOT IMPACT YOUR ABILITY TO PRACTICE, WHICH IS DETERMINED BY EACH STATE'S REQUIRED PERMIT OR CERTIFICATE PROCESS.

- "AAOMS RESPONSE TO RECENT CHALLENGES TO OMS OFFICE-BASED ANESTHESIA FOR PEDIATRIC PATIENTS"
- HIGHLIGHTS FROM THE DOCUMENT
 - AAOMS developed the Dental Anesthesia Assistant National Certification Examination (DAANCE) [which] has proven to be psychometrically superior and validates the understanding and competency of those individuals performing a unique set of job skills for which they are being tested.
 - AAOMS members participate in a mandatory Office Anesthesia Evaluation (OAE) program which requires completion of an on-site inspection of OMS facilities. They include ensuring compliance with all state law and permitting requirements and appropriate training of all staff

- NO DEFINITION OF AGE FOR PEDIATRIC PATIENT IN AAP/ASA STATEMENTS
- THE AHA STATES FOR THE PURPOSES OF [THEIR] GUIDELINES, THE TERM "CHILD" REFERS TO THE AGE GROUP FROM 1 YEAR TO 8 YEARS.
- AAOMS \rightarrow a pediatric age of 7 and under is logical for the purposes of anesthesia regulation.
- RETROSPECTIVE AND PROSPECTIVE STUDIES, INDIVIDUAL CASE STUDIES, SURVEYS AND CLOSED CLAIMS REPORTS HAVE SHOWN VERY LOW MORBIDITY AND MORTALITY RATES FOR OMS ANESTHESIA DELIVERY.
- IN A 2003 PROSPECTIVE COHORT STUDY OF MORE THAN 34,000 PATIENTS, PERROTT⁸ ET AL., REPORTED AN OVERALL COMPLICATION RATE OF 1.3% IN THE OMS OFFICE SETTING. MOST WERE MINOR INCIDENTS. THERE WERE NO DEATHS REPORTED IN THIS STUDY.
 - Vomiting, laryngospasm, cardiac arrhythmias, syncope, and seizures, among others

- THE USE OF PROCEDURAL SEDATION IS COMMON IN EMERGENCY MEDICINE AS WELL AS IN GASTROENTEROLOGY AND INTERVENTIONAL RADIOLOGY.
- THE AMERICAN COLLEGE OF EMERGENCY PHYSICIANS (ACEP) GUIDELINES FOR THE CLINICAL PRACTICE OF PROCEDURAL SEDATION DEFINE AN ANESTHESIA TEAM THAT DIFFERS SIGNIFICANTLY FROM THE AAP/AAPD GUIDELINES
- Each medical or surgical specialty should craft its own guidelines as it is ultimately the most knowledgeable of the unique resources and personnel required to provide effective and safe patient care.

- AAOMS CONTENDS THAT ANY NEW RESTRICTIONS WILL DO SIGNIFICANT HARM BY
 - 1) REDUCING ACCESS TO CARE
 - 2) INCREASING COSTS
 - 3) LIMITING CARE AVAILABILITY TO AT-RISK POPULATIONS
 - 4) LIKELY INCREASING THE DEMAND ON ALREADY-OVERBURDENED HOSPITAL EMERGENCY ROOM RESOURCES
- ANY CHANGES SHOULD ONLY BE PROPOSED WHEN THERE IS SUPPORTING SCIENTIFIC EVIDENCE AND ALL OF THESE INTENDED OR UNINTENDED CONSEQUENCES ARE CONSIDERED.

WHAT DOES THIS BREAK DOWN TO?

- TRAINING
- COMPETENCE & QUALITY ASSURANCE
- STAFFING

RESIDENCY REQUIREMENTS FOR SEDATION TAKEN FROM CODA STANDARDS

- **OMS**: MINIMUM OF 5 MONTHS DEDICATED TO ANESTHESIA, 1 OF THESE MONTHS SHOULD BE DEDICATED TO PEDIATRIC ANESTHESIA. THE ORAL SURGERY RESIDENT MUST FUNCTION AS AN ANESTHESIA RESIDENT.
 - A MINIMUM OF 300 CASES
 - 50 patients younger than 13
 - A MINIMUM OF 150 OF THE 300 CASES MUST BE AMBULATORY ANESTHESIA OUTSIDE OF THE OPERATING ROOM.
- **DENTAL ANESTHESIOLOGY**: 24 MONTHS DEDICATED TO CLINICAL TRAINING IN ANESTHESIOLOGY WITH 6 MONTHS IN DENTAL ANESTHESIOLOGY.
 - 800 TOTAL CASES OF DEEP SEDATION/GENERAL ANESTHESIA TO INCLUDE:
 - 300 INTUBATED GENERAL ANESTHETICS
 - 125 CHILDREN AGED 7 AND UNDER
 - 75 PATIENTS WITH SPECIAL NEEDS
- PEDIATRIC: 4 WEEKS DEDICATED TO ANESTHESIA ROTATION
 - 50 PATIENT ENCOUNTERS IN WHICH SEDATIVE AGENTS OTHER THAN NITROUS OXIDE ARE USED. (INCLUDING ORAL SEDATION)
 - Of the 50 patient encounters, each student/resident must act as primary operator in a minimum of 25 sedation cases

QUALITY ASSURANCE

- EACH STATE DIFFERS IN REQUIREMENTS BUT ARE SIMILAR TO FLORIDA
- FLORIDA BOARD OF DENTISTRY, FOR EXAMPLE:
 - GA PERMIT
 - 1 YEAR CODA ACCREDITED DENTAL ANES RESIDENCY
 - CODA ACCREDITED OMS RESIDENCY
 - AN ON-SITE INSPECTION OF THE FACILITY, EQUIPMENT, DRUGS AND PERSONNEL SHALL BE CONDUCTED TO DETERMINE IF THE REQUIREMENTS OF THIS CHAPTER HAVE BEEN MET.
 - CONSCIOUS SEDATION PERMIT
 - FORMAL TRAINING IN THE USE OF CONSCIOUS SEDATION VIA RESIDENCY, ACCREDITED PROGRAM OR TEACHING HOSPITAL
 - CERTIFIED BY TEACHING INSTITUTION
 - COMPETENT TO HANDLE EMERGENCIES
 - 60 HOURS TRAINING, 4 HOURS WITH ADVANCED AIRWAY
 - 20 SUPERVISED CASES
 - AN ON-SITE INSPECTION OF THE FACILITY, EQUIPMENT, DRUGS AND PERSONNEL SHALL BE CONDUCTED TO DETERMINE IF THE REQUIREMENTS OF THIS CHAPTER HAVE BEEN MET

ASDA PROPOSED STATEMENT MARCH 2020 MILD TO MODERATE SEDATION

Patient 9 years and older	Minimum of 2 people	1) Moderate Sedation Permit holder	ACLS training
		2) Second Staff member	BLS with training in managing sedation emergencies approved by the board
Patients 8 years and younger <u>with</u> bidirectional communication	Minimum of 2 people	1) Moderate Sedation Permit holder with Pediatric Endorsement	PALS training
		2) Second staff member	BLS and PEARS training

PEARS means Pediatric Emergency Assessment, Recognitions and Stabilization course approved by the American Heart Association

ASDA PROPOSED STATEMENT MARCH 2020 MILD TO MODERATE SEDATION

Patients 8 years and younger <u>without</u> bidirectional communication	Minimum of 3 people	1) Moderate Sedation Permit holder with Pediatric Endorsement	PALS training
Such as a developmental disability		2) Second staff member	BLS and PEARS training
		3a) An independently licensed provider	ACLS, PALS, & PEARS with board approved additional training in monitoring and managing pediatric sedation emergencies
		3b) A trained auxiliary	BLS & PEARS with board approved additional training in monitoring and managing pediatric sedation emergencies

PEARS means Pediatric Emergency Assessment, Recognitions and Stabilization course approved by the American Heart Association

ASDA PROPOSED STATEMENT MARCH 2020 DEEP SEDATION TO GENERAL ANESTHESIA

Patient 9 years and older	Minimum of 3 people	1) General Anesthesia Permit holder	ACLS training
		2a) An independently licensed provider	ACLS/PALS and 2 hours of simulation or clinical training every 2 years in assisting in the management of deep sedation general anesthesia emergencies provided by permit holder or board approved course
		2b) A trained auxiliary meeting requirements	 -28 hours didactic instruction physiology and interpretation of monitoring -8 hours of didactic instruction in office-based anesthesia and equipment -4 hours of simulation training in management of emergencies, including assisting in advanced airway management -BLS training (PEARS if documented pediatric emergency) -14 hours of instruction in dental office anesthesia, 4 hours must include simulation training in the management of emergencies, every 2 years
		3) Third staff member	BLS training

When the general anesthesia provider is also the operating dentist, the 2nd person shall be dedicated to monitoring the patient & relaying vital signs every 5 min or when variations noted

ASDA PROPOSED STATEMENT MARCH 2020 DEEP SEDATION TO GENERAL ANESTHESIA

Patients 8 years and younger	Minimum of 3 people	1) General Anesthesia Permit holder with Pediatric Endorsement	ACLS/ PALS training
		2) An independently licensed provider	ACLS/PALS and 2 hours of simulation or clinical training every 2 years in assisting in the management of deep sedation general anesthesia emergencies provided by permit holder or board approved course
		3) Third staff member	BLS training

If the operating dentist w/GA Permit determines and **documents** that an emergency exists (such as a painful abscessed tooth, avulsed tooth, alveolar fracture), and a second anesthesia provider is not immediately available that day, the general anesthesia permit holder with pediatric endorsement may also provide the dental/oral surgery treatment following the rules for patients 9 years and older.

SUMMARY OF POSSIBLE CHANGES BASED ON THE ASDA PROPOSED GUIDELINES

- THE ASDA HAS ASKED FOR COMMENTS FROM ALL ANESTHESIA PROVIDERS REGARDING THEIR PROPOSED STATEMENT.
- THEY PLAN TO TAKE THESE PROPOSED GUIDELINES TO ALL STATE BOARDS WITH A HIGH RECOMMENDATION FOR APPROVAL.
- IMPORTANT CHANGES FOR PEDIATRIC PROCEDURES:
 - A SECOND INDEPENDENTLY LICENSED PROVIDER OR ADVANCED TRAINING FOR STAFF MEMBER FOR MODERATE SEDATION WHEN BIDIRECTIONAL COMMUNICATION IS NOT POSSIBLE
 - A SECOND INDEPENDENTLY LICENSED PROVIDER IS REQUIRED FOR GENERAL ANESTHESIA FOR CHILDREN UNDER 8
- IMPORTANT CHANGES FOR ADULT PROCEDURES:
 - INCLUDES INCREASED TRAINING FOR REQUIRED ASSISTANTS OR USE OF A SECOND LICENSED PROVIDER.

WHAT'S THE BOTTOM LINE

- WITH THE BAD PUBLICITY, THERE HAS BEEN NO ATTEMPT TO REVOKE THE PRIVILEGES OF THE SINGLE OPERATOR MODEL.
- THERE HAS BEEN NO LEGISLATION OR DOCUMENTS BROUGHT FORTH TO ANY STATE BOARDS.
- THE ASA/AAP HAS GROUPED OMFS WITH DENTAL ANESTHESIOLOGISTS, GENERAL DENTISTS WITH SEDATION PERMITS, AND PEDIATRIC DENTISTS, WHICH HAS MADE IT DIFFICULT TO EVALUATE THE FAIRNESS OF THEIR PROPOSED CHANGES.

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