List of Written Comments Received from Stakeholders and Interested Parties in Response to the Dental Board of California Pediatric Anesthesia Study

(June 1 – August 19, 2016)

AMERICAN ACADEMY OF PEDIATRIC DENTISTRY (AAPD)

1. August 19, 2016 Letter from Jade Miller, DDS, President of AAPD and David Okawachi, DDS, President of California Society of Pediatric Dentistry

AMERICAN ACADEMY OF PEDIATRICS (AAP)

1. June 17, 2016 Letter from Karen Remley, MD, MBA, MPH, FAAP, CEO/Executive Director with Attachment
    - Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016
2. June 22, 2016 Letter from Roger F. Suchyta, MD, FAAP, Associate Executive Director
3. July 27, 2016 Letter Regarding AAP-CA Comment on Dental Board of California Pediatric Anesthesia Study

AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS (ASDA)

1. July 25, 2016 Letter from Steve Nguyen, DDS, ASDA President with Attachment
    - Periodontal Abstract, Volume 53,Number 2 – 2005 – Summary of the California Blue Ribbon Panel Report on Anesthesia

CALIFORNIA DENTAL ASSOCIATION (CDA)

1. June 30, 2016 Letter from Brianna Pittman, Legislative Director

CALIFORNIA SOCIETY OF ANESTHESIOLOGISTS (CSA)

1. June 30, 2016 Cover Letter and Attachments Submitted by Mark Zakowski, MD, President

    • 42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services: *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of*

medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.
• ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)
• ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)
• ASA Statement on the Anesthesia Care Team (October 16, 2013)
• ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)
• 42 C.F.R. § 482.13 Condition of Participation: Patient's Rights
• *"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"* Anesthesiology 2002; 96:1004–17
• *"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"* developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)
• CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)
• AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016 ***(Did not reprint – Refer to AAP for Document)***

2. July 28, 2016 Comments Delivered at Dental Board Workshop and submitted via fax by Dr. Mark Singleton

CALIFORNIA SOCIETY OF PEDIATRIC DENTISTRY (CSPD) – See American Academy of Pediatric Dentists Comment Above

ORAL AND FACIAL SURGEONS OF CALIFORNIA

1. August 11, 2016 Letter from Leonard M. Tyko II, DDS, MD, FACS, President with Attachment
    - Report, References, and Appendix A

INDIVIDUALS

1. Diana Belli, DDS (Dental Anesthesiologist) – Emails dated July 21, 2016 and July 22, 2016
2. David Crippen, DDS (Pediatric Dentist) – Email dated July 26, 2016
3. Skip Harris, DDS (Oral and Maxillofacial Surgeon in Arizona) – Email dated July 22, 2016
4. Annie Kaplan, MD – Emails dated June 15, 2016 and July 18, 2016 – Attachments
    - August 11, 2010, 12 page letter signed by Janet Woodcock, MD Center for Drug Evaluation and Research.
    - Caleb's Law – White Paper, March 29, 2016 (Author Unknown)

AMERICAN ACADEMY OF PEDIATRIC DENTISTRY (AAPD)

1. August 19, 2016 Letter from Jade Miller, DDS, President of AAPD and David Okawachi, DDS, President of California Society of Pediatric Dentistry

AMERICA'S PEDIATRIC DENTISTS

August 19, 2016

Dental Board of California
2005 Evergreen St, Suite 1550
Sacramento, CA 95815

Attn: Pediatric Anesthesia Subcommittee
Re: Progress of the Pediatric Anesthesia Study Requested by Senator Jerry Hill

The American Academy of Pediatric Dentistry (AAPD)[1] and the California Society of Pediatric Dentistry (CSPD)[2] commend the Dental Board of California and the Pediatric Anesthesia Subcommittee on the depth, breadth and attention to important detail contained in the *Anesthesia Working Document* of July 2016. It is evident the Board is addressing seriously its mandate of public protection and is researching responsibly what measures in law or regulation could make pediatric dental anesthesia even safer in the future than it is today.

We would respectfully submit a correction to the reference on page 26 of the *Working Document* regarding the process by which the joint American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures* (http://www.aapd.org/media/Policies_Guidelines/G_Sedation.pdf) is developed and approved by the governing bodies of both organizations. The document states:

> *It is unclear whether input is solicited from non-member dentists, outside organizations or the public. Detailed information is available to AAPD members only. AAPD guidelines are subsequently forwarded to the American Academy of Pediatrics for endorsement and are then published as a joint document.*

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[1]The **American Academy of Pediatric Dentistry** is the recognized authority on children's oral health. As advocates for children's oral health, the AAPD promotes evidence-based policies and clinical guidelines; educates and informs policymakers, parents and guardians, and other health care professionals; fosters research; and provides continuing professional education for pediatric dentists and general dentists who treat children. Founded in 1947, the AAPD is a not-for-profit professional membership association representing the specialty of pediatric dentistry. Its 10,000 members provide primary care and comprehensive dental specialty treatments for infants, children, adolescents and individuals with special health care needs

[2]The **California Society of Pediatric Dentistry** is the state's leading advocate and recognized authority on oral health issues affecting infants, children, adolescents and patients with special health care and developmental needs. The Society interacts with the state legislature, regulatory bodies, licensing bureaus, institutions of dental education, media outlets, and policy makers at all levels of public and private participation to promote and ensure optimal pediatric oral health throughout the state. CSPD is the professional membership organization of California's over 900 pediatric dental practitioners, educators and researchers.

This is incorrect. The guidelines are developed jointly by the both organizations and not merely forwarded to the AAP by the AAPD for endorsement. Physician anesthesiologists and other pediatric medical specialists are involved in the development of the document, as are AAPD specialists in dentist-administered anesthesia. Non-member dentists, representatives from outside organizations, and members of the public may attend AAPD reference committee hearings where a draft document is being considered before adoption and may ask to speak or provide testimony on any details of the proposed guideline.

The AAPD and CSPD look forward to the completion of the comprehensive and impartial analysis by the DBC of pediatric dental sedation and the laws, regulations and policies which govern its administration. We support and applaud the open and transparent process by which the subcommittee is moving forward to identify any necessary statutory or other changes to the administration of office-based sedation which improve the margin of safety for pediatric patients. We believe this information is essential in determining the course of action necessary to ensure the highest level of care for the patients we treat.

Jade Miller, DDS
President
American Academy of Pediatric Dentistry

David Okawachi, DDS
President
California Society of Pediatric Dentistry

AMERICAN ACADEMY OF PEDIATRICS (AAP)

1. June 17, 2016 Letter from Karen Remley, MD, MBA, MPH, FAAP, CEO/Executive Director with Attachment
    - Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016
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June 17, 2016

The Dental Board of California
c/o Ms. Karen Fischer
2005 Evergreen Street, Suite 1550
Sacramento, CA 91815

Dear Members of the The Dental Board of California,

Thank you for your letter dated June 1, 2016, regarding the anesthesia project you have underway. As you review the present laws, regulations, and policies in California to determine whether they provide sufficient protection to pediatric patients during dental anesthesia, we would encourage you to review the American Academy of Pediatrics (AAP)/American Academy of Pediatric Dentistry (AAPD) "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016" (Guidelines).

The AAP/AAPD Joint Guidelines are set to be released online on June 27, 2016, and to subsequently be published in the e-pages of *Pediatrics* on July 1, 2016. Enclosed with this letter is a pre-publication, embargoed copy of the Guidelines for your review and consideration. We ask that you please abide by the embargo and not publish, post, broadcast or distribute any details of the embargoed document before the embargo date and time (12:01 A.M. ET Monday June 27, 2016). Please review the Embargo Policy at www.aap.org/embargo.

If you should have any further questions, please contact Roger Suchyta, MD, FAAP, Associate Executive Director, at 800-433-9016, ext. 7111, or via email at rsuchyta@aap.org.

Thank You.

Karen Remley, MD, MBA, MPH, FAAP
CEO/Executive Director

KR/jgr

CC: John Rutkauskas, DDS, MBA, CAE, CEO, American Academy of Pediatric Dentistry;
Stuart Alan Cohen, MD, MPH, FAAP, Chair, AAP California District IX;
Kris Calvin, MA, Chief Executive Officer, AAP California District IX

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Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Charles J. Coté, Stephen Wilson, AMERICAN ACADEMY OF PEDIATRICS and AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

Pediatrics; originally published online June 27, 2016;
DOI: 10.1542/peds.2016-1212

The online version of this article, along with updated information and services, is located on the World Wide Web at:
/content/early/2016/06/24/peds.2016-1212.full.html

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CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

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Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Charles J. Coté, MD, FAAP, Stephen Wilson, DMD, MA, PhD, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

abstract

The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical/dental supervision, careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications, appropriate fasting for elective procedures and a balance between the depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure, a focused airway examination for large (kissing) tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction, a clear understanding of the medication's pharmacokinetic and pharmacodynamic effects and drug interactions, appropriate training and skills in airway management to allow rescue of the patient, age- and size-appropriate equipment for airway management and venous access, appropriate medications and reversal agents, sufficient numbers of staff to both carry out the procedure and monitor the patient, appropriate physiologic monitoring during and after the procedure, a properly equipped and staffed recovery area, recovery to the presedation level of consciousness before discharge from medical/dental supervision, and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children.

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical/dental care. Variations, taking into account individual circumstances, may be appropriate.

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DOI: 10.1542/peds.2016-1212

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

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To cite: Coté CJ, Wilson S, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics*. 2016; 138(1):e20161212

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INTRODUCTION

The number of diagnostic and minor surgical procedures performed on pediatric patients outside of the traditional operating room setting has increased in the past several decades. As a consequence of this change and the increased awareness of the importance of providing analgesia and anxiolysis, the need for sedation for procedures in physicians' offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, other inpatient hospital settings, and ambulatory surgery centers also has increased markedly.[1–52] In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and the American Academy of Pediatric Dentistry (AAPD) have published a series of guidelines for the monitoring and management of pediatric patients during and after sedation for a procedure.[53–58] The purpose of this updated report is to unify the guidelines for sedation used by medical and dental practitioners; to add clarifications regarding monitoring modalities, particularly regarding continuous expired carbon dioxide measurement; to provide updated information from the medical and dental literature; and to suggest methods for further improvement in safety and outcomes. This document uses the same language to define sedation categories and expected physiologic responses as The Joint Commission, the American Society of Anesthesiologists (ASA), and the AAPD.[56,57,59–61]

This revised statement reflects the current understanding of appropriate monitoring needs of pediatric patients both during and after sedation for a procedure.[3,4,11,18,20,21,23,24,33,39,41,44,47,51,62–73,] The monitoring and care outlined may be exceeded at any time on the basis of the judgment of the responsible practitioner. Although intended to encourage high-quality patient care, adherence to the recommendations in this document cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate these safety principles have been widely implemented and shown to reduce morbidity.[11,23,24,27,30–33,35,39,41,44,47,51,74–84] These practice recommendations are proffered with the awareness that, regardless of the intended level of sedation or route of drug administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression, laryngospasm, impaired airway patency, apnea, loss of the patient's protective airway reflexes, and cardiovascular instability.[38,43,45,47,48,59,62,63,85–112]

Procedural sedation of pediatric patients has serious associated risks.[2,5,38,43,45,47,48,62,63,71,83,85,88–105,107–138] These adverse responses during and after sedation for a diagnostic or therapeutic procedure may be minimized, but not completely eliminated, by a careful preprocedure review of the patient's underlying medical conditions and consideration of how the sedation process might affect or be affected by these conditions: for example, children with developmental disabilities have been shown to have a threefold increased incidence of desaturation compared with children without developmental disabilities.[74,78,103] Appropriate drug selection for the intended procedure, a clear understanding of the sedating medication's pharmacokinetics and pharmacodynamics and drug interactions, as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are critical.[42,48,62,63,92,97,99,125–127,132,133,139–158] Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for the accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.[44,63,64,67,68,74,90,96,110,159–174] The work of the Pediatric Sedation Research Consortium has improved the sedation knowledge base, demonstrating the marked safety of sedation by highly motivated and skilled practitioners from a variety of specialties practicing the above modalities and skills that focus on a culture of sedation safety.[45,83,95,128–138] However, these groundbreaking studies also show a low but persistent rate of potential sedation-induced life-threatening events, such as apnea, airway obstruction, laryngospasm, pulmonary aspiration, desaturation, and others, even when the sedation is provided under the direction of a motivated team of specialists.[129] These studies have helped define the skills needed to rescue children experiencing adverse sedation events.

The sedation of children is different from the sedation of adults. Sedation in children is often administered to relieve pain and anxiety as well as to modify behavior (eg, immobility) so as to allow the safe completion of a procedure. A child's ability to control his or her own behavior to cooperate for a procedure depends both on his or her chronologic age and cognitive/emotional development. Many brief procedures, such as suture of a minor laceration, may be accomplished with distraction and guided imagery techniques, along with the use of topical/local anesthetics and minimal sedation, if needed.[175–181] However, longer procedures that require immobility involving children younger than 6 years or those with developmental delay often require an increased depth of sedation to gain control of their behavior.[86,87,103] Children younger than 6 years (particularly those younger than 6 months) may be at greatest risk of an adverse event.[129] Children in this age group are particularly vulnerable

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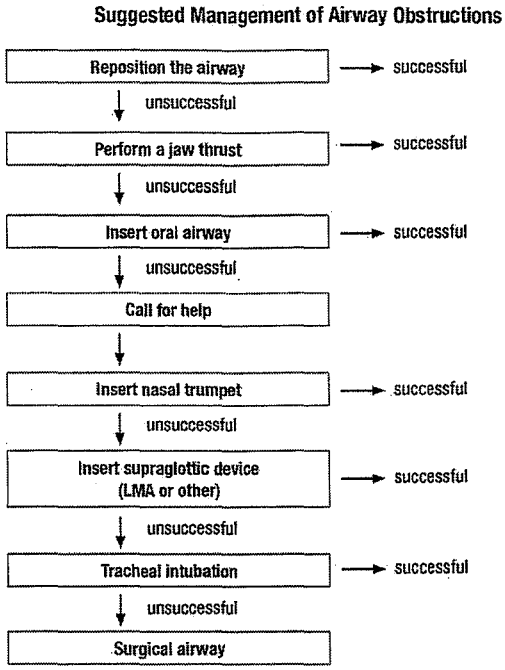

FIGURE 1
Suggested management of airway obstruction.

to the sedating medication's effects on respiratory drive, airway patency, and protective airway reflexes.[62,63] Other modalities, such as careful preparation, parental presence, hypnosis, distraction, topical local anesthetics, electronic devices with age-appropriate games or videos, guided imagery, and the techniques advised by child life specialists, may reduce the need for or the needed depth of pharmacologic sedation.[29,46,49,182–211]

Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation,[85,88,212,213] making the concept of rescue essential to safe sedation. Practitioners of sedation must have the skills to rescue the patient from a deeper level than that intended for the procedure. For example, if the intended level of sedation is "minimal," practitioners must be able to rescue from "moderate sedation"; if the intended level of sedation is "moderate," practitioners must have the skills to rescue from "deep sedation"; if the intended level of sedation is "deep," practitioners must have the skills to rescue from a state of "general anesthesia." The ability to rescue means that practitioners must be able to recognize the various levels of sedation and have the skills and age- and size-appropriate equipment necessary to provide appropriate cardiopulmonary support if needed.

These guidelines are intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office). Sedation and anesthesia in a nonhospital environment (eg, private physician's or dental office, freestanding imaging facility) historically have been associated with an increased incidence of "failure to rescue" from adverse events, because these settings may lack immediately available backup. Immediate activation of emergency medical services (EMS) may be required in such settings, but the practitioner is responsible for life-support measures while awaiting EMS arrival.[63,214] Rescue techniques require specific training and skills.[63,74,215,216] The maintenance of the skills needed to rescue a child with apnea, laryngospasm, and/or airway obstruction include the ability to open the airway, suction secretions, provide continuous positive airway pressure (CPAP), perform successful bag-valve-mask ventilation, insert an oral airway, a nasopharyngeal airway, or a laryngeal mask airway (LMA), and, rarely, perform tracheal intubation. These skills are likely best maintained with frequent simulation and team training for the management of rare events.[128,130,217–220] Competency with emergency airway management procedure algorithms is fundamental for safe sedation practice and successful patient rescue (see Figs 1, 2, and 3).[215,216,221–223]

Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications. A number of reviews and handbooks for sedating pediatric patients are available.[30,39,65,75,171,172,201,224–233] There are specific situations that are beyond the scope of this document. Specifically, guidelines for the delivery of general anesthesia and monitored anesthesia care (sedation or analgesia), outside or within the operating room by anesthesiologists or other practitioners functioning within a department of anesthesiology, are addressed by policies developed by the ASA and by individual departments of anesthesiology.[234] In addition, guidelines for the sedation of patients undergoing mechanical ventilation in a critical care environment or for providing analgesia for patients postoperatively, patients with chronic painful conditions, and patients in hospice care are beyond the scope of this document.

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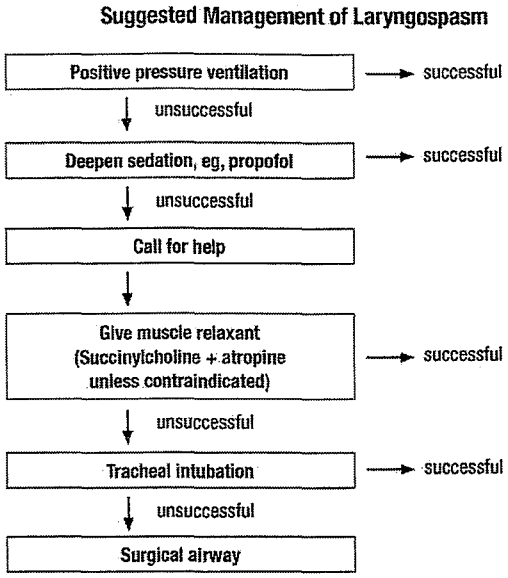

FIGURE 2
Suggested management of laryngospasm.

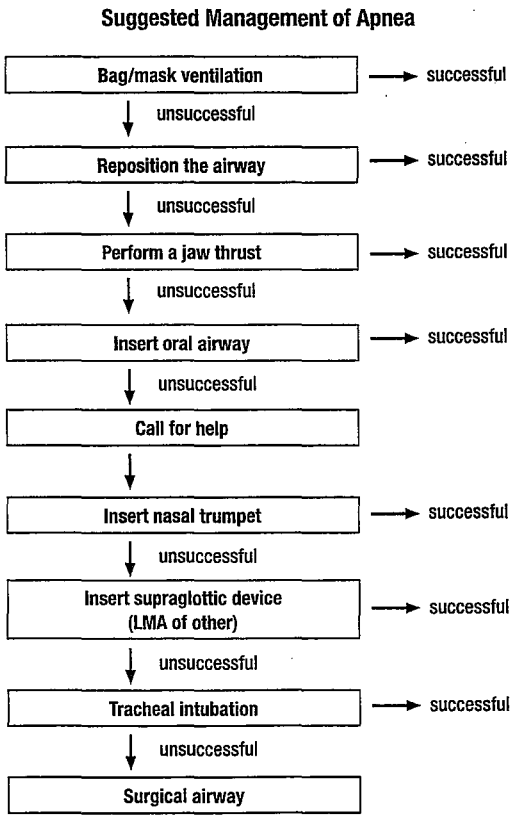

FIGURE 3
Suggested management of apnea.

GOALS OF SEDATION

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are as follows: (1) to guard the patient's safety and welfare; (2) to minimize physical discomfort and pain; (3) to control anxiety, minimize psychological trauma, and maximize the potential for amnesia; (4) to modify behavior and/or movement so as to allow the safe completion of the procedure; and (5) to return the patient to a state in which discharge from medical/dental supervision is safe, as determined by recognized criteria (Supplemental Appendix 1).

These goals can best be achieved by selecting the lowest dose of drug with the highest therapeutic index for the procedure. It is beyond the scope of this document to specify which drugs are appropriate for which procedures; however, the selection of the fewest number of drugs and matching drug selection to the type and goals of the procedure are essential for safe practice. For example, analgesic medications, such as opioids or ketamine, are indicated for painful procedures. For nonpainful procedures, such as computed tomography or magnetic resonance imaging (MRI), sedatives/hypnotics are preferred. When both sedation and analgesia are desirable (eg, fracture reduction), either single agents with analgesic/sedative properties or combination regimens are commonly used. Anxiolysis and amnesia are additional goals that should be considered in the selection of agents for particular patients. However, the potential for an adverse outcome may be increased when 2 or more sedating medications are administered.[62,127,136,173,235] Recently, there has been renewed interest in noninvasive routes of medication administration, including intranasal and inhaled routes (eg, nitrous oxide; see below).[236]

Knowledge of each drug's time of onset, peak response, and duration of action is important (eg, the peak electroencephalogram [EEG] effect of intravenous midazolam occurs at ~4.8 minutes, compared with that of diazepam at ~1.6 minutes[237–239]). Titration of drug to effect is an important concept;

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one must know whether the previous dose has taken full effect before administering additional drugs.[237] Drugs that have a long duration of action (eg, intramuscular pentobarbital, phenothiazines) have fallen out of favor because of unpredictable responses and prolonged recovery. The use of these drugs requires a longer period of observation even after the child achieves currently used recovery and discharge criteria.[62,238–241] This concept is particularly important for infants and toddlers transported in car safety seats; re-sedation after discharge attributable to residual prolonged drug effects may lead to airway obstruction.[62,63,242] In particular, promethazine (Phenergan; Wyeth Pharmaceuticals, Philadelphia, PA) has a "black box warning" regarding fatal respiratory depression in children younger than 2 years.[243] Although the liquid formulation of chloral hydrate is no longer commercially available, some hospital pharmacies now are compounding their own formulations. Low-dose chloral hydrate (10–25 mg/kg), in combination with other sedating medications, is used commonly in pediatric dental practice.

GENERAL GUIDELINES

Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Supplemental Appendix 2). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or moderate to severe tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.[68,244–249] Practitioners are encouraged to consult with appropriate subspecialists and/or an anesthesiologist for patients at increased risk of experiencing adverse sedation events because of their underlying medical/surgical conditions.

Responsible Person

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person. It is preferable to have 2 adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by 1 of the adults.[250]

Facilities

The practitioner who uses sedation must have immediately available facilities, personnel, and equipment to manage emergency and rescue situations. The most common serious complications of sedation involve compromise of the airway or depressed respirations resulting in airway obstruction, hypoventilation, laryngospasm, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from the inadequate recognition and treatment of respiratory compromise.[42,48,92,97,99,125,132,139–155,] Other rare complications also may include seizures, vomiting, and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

Back-up Emergency Services

A protocol for immediate access to back-up emergency services shall be clearly outlined. For nonhospital facilities, a protocol for the immediate activation of the EMS system for life-threatening complications must be established and maintained.[44] It should be understood that the availability of EMS does not replace the practitioner's responsibility to provide initial rescue for life-threatening complications.

On-site Monitoring, Rescue Drugs, and Equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain the necessary age- and size-appropriate equipment (oral and nasal airways, bag-valve-mask device, LMAs or other supraglottic devices, laryngoscope blades, tracheal tubes, face masks, blood pressure cuffs, intravenous catheters, etc) to resuscitate a nonbreathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the patient is being transported to a medical/dental facility or to another area within the facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Supplemental Appendices 3 and 4 for suggested drugs and emergency life support equipment to consider before the need for rescue occurs). Monitoring devices, such as electrocardiography (ECG) machines, pulse oximeters with size-appropriate probes, end-tidal carbon dioxide monitors, and defibrillators with size-appropriate patches/paddles, must have a safety and function check on a regular basis as required by local or state regulation. The use of emergency checklists is recommended, and these should be immediately available at all sedation locations; they can be obtained from http://www.pedsanesthesia.org/.

Documentation

Documentation prior to sedation shall include, but not be limited to, the following recommendations:

1. Informed consent: The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.[251,252]
2. Instructions and information provided to the responsible

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person: The practitioner shall provide verbal and/or written instructions to the responsible person. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation.[163,253–255] Special instructions shall be given to the adult responsible for infants and toddlers who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Transportation in a car safety seat poses a particular risk for infants who have received medications known to have a long half-life, such as chloral hydrate, intramuscular pentobarbital, or phenothiazine because deaths after procedural sedation have been reported.[62,63,238,242,256,257] Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (eg, only 1 adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem, an underlying medical condition such as significant obstructive sleep apnea (OSA), or a former preterm infant younger than 60 weeks' postconceptional age. A 24-hour telephone number for the practitioner or his or her associates shall be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

Dietary Precautions

Agents used for sedation have the potential to impair protective airway reflexes, particularly during deep sedation. Although a rare occurrence, pulmonary aspiration may occur if the child regurgitates and cannot protect his or her airway.[95,127,258] Therefore, the practitioner should evaluate preceding food and fluid intake before administering sedation. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulations.[259,260] However, the absolute risk of aspiration during elective procedural sedation is not yet known; the reported incidence varies from ~1 in 825 to ~1 in 30 037.[95,127,129,173,244,261] Therefore, standard practice for fasting before elective sedation generally follows the same guidelines as for elective general anesthesia; this requirement is particularly important for solids, because aspiration of clear gastric contents causes less pulmonary injury than aspiration of particulate gastric contents.[262,263]

For emergency procedures in children undergoing general anesthesia, the reported incidence of pulmonary aspiration of gastric contents from 1 institution is ~1 in 373 compared with ~1 in 4544 for elective anesthetics.[262] Because there are few published studies with adequate statistical power to provide guidance to the practitioner regarding the safety or risk of pulmonary aspiration of gastric contents during procedural sedation,[95,127,129,173,244,259–261,264–268] it is unknown whether the risk of aspiration is reduced when airway manipulation is not performed/anticipated (eg, moderate sedation). However, if a deeply sedated child requires intervention for airway obstruction, apnea, or laryngospasm, there is concern that these rescue maneuvers could increase the risk of pulmonary aspiration of gastric contents. For children requiring urgent/emergent sedation who do not meet elective fasting guidelines, the risks of sedation and possible aspiration are as-yet unknown and must be balanced against the benefits of performing the procedure promptly. For example, a prudent practitioner would be unlikely to administer deep sedation to a child with a minor condition who just ate a large meal; conversely, it is not justifiable to withhold sedation/analgesia from the child in significant pain from a displaced fracture who had a small snack a few hours earlier. Several emergency department studies have reported a low to zero incidence of pulmonary aspiration despite variable fasting periods[260,264,268]; however, each of these reports has, for the most part, clearly balanced the urgency of the procedure with the need for and depth of sedation.[268,269] Although emergency medicine studies and practice guidelines generally support a less restrictive approach to fasting for brief urgent/emergent procedures, such as care of wounds, joint dislocation, chest tube placement, etc, in healthy children, further research in many thousands of patients would be desirable to better define the relationships between various fasting intervals and sedation complications.[262–270]

Before Elective Sedation

Children undergoing sedation for elective procedures generally should follow the same fasting guidelines as those for general anesthesia (Table 1).[271] It is permissible for routine necessary medications (eg, antiseizure medications) to be taken with a sip of clear liquid or water on the day of the procedure.

For the Emergency Patient

The practitioner must always balance the possible risks of sedating nonfasted patients with the benefits of and necessity for completing the procedure. In particular, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity (BMI ≥95% for age and sex), pregnancy, or bowel motility dysfunction, require careful evaluation before the administration of sedatives. When proper fasting has not been ensured,

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the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. In this circumstance, additional techniques for achieving analgesia and patient cooperation, such as distraction, guided imagery, video games, topical and local anesthetics, hematoma block or nerve blocks, and other techniques advised by child life specialists, are particularly helpful and should be considered.[29,49,182–201, 274,275]

The use of agents with less risk of depressing protective airway reflexes, such as ketamine, or moderate sedation, which would also maintain protective reflexes, may be preferred.[276] Some emergency patients requiring deep sedation (eg, a trauma patient who just ate a full meal or a child with a bowel obstruction) may need to be intubated to protect their airway before they can be sedated.

TABLE 1 Appropriate Intake of Food and Liquids Before Elective Sedation

Ingested Material	Minimum Fasting Period, h
Clear liquids: water, fruit juices without pulp, carbonated beverages, clear tea, black coffee	2
Human milk	4
Infant formula	6
Nonhuman milk: because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.	6
Light meal: a light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.	6

Source: American Society of Anesthesiologists. Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. An updated report by the American Society of Anesthesiologists Committee on Standards and Practice Parameters. Available at: https://www.asahq.org/For-Members/Practice-Management/Practice-Parameters.aspx. For emergent sedation, the practitioner must balance the depth of sedation versus the risk of possible aspiration; see also Mace et al[272] and Green et al.[273]

Use of Immobilization Devices (Protective Stabilization)

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction.[277–281] The child's head position and respiratory excursions should be checked frequently to ensure airway patency. If an immobilization device is used, a hand or foot should be kept exposed, and the child should never be left unattended. If sedating medications are administered in conjunction with an immobilization device, monitoring must be used at a level consistent with the level of sedation achieved.

Documentation at the Time of Sedation

1. Health evaluation: Before sedation, a health evaluation shall be performed by an appropriately licensed practitioner and reviewed by the sedation team at the time of treatment for possible interval changes.[282] The purpose of this evaluation is not only to document baseline status but also to determine whether the patient has specific risk factors that may warrant additional consultation before sedation. This evaluation also facilitates the identification of patients who will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

An important concern for the practitioner is the widespread use of medications that may interfere with drug absorption or metabolism and therefore enhance or shorten the effect time of sedating medications. Herbal medicines (eg, St John's wort, ginkgo, ginger, ginseng, garlic) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations (midazolam, cyclosporine, tacrolimus).[283–292] Kava may increase the effects of sedatives by potentiating γ-aminobutyric acid inhibitory neurotransmission and may increase acetaminophen-induced liver toxicity.[293–295] Valerian may itself produce sedation that apparently is mediated through the modulation of γ-aminobutyric acid neurotransmission and receptor function.[291,296–299] Drugs such as erythromycin, cimetidine, and others may also inhibit the cytochrome P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.[300–304] Medications used to treat HIV infection, some anticonvulsants, immunosuppressive drugs, and some psychotropic medications (often used to treat children with autism spectrum disorder) may also produce clinically important drug-drug interactions.[305–314] Therefore, a careful drug history is a vital part of the safe sedation of children. The practitioner should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.[315–319] The US Food and Drug Administration issued a warning in February 2013 regarding the use of codeine for postoperative pain management in children undergoing tonsillectomy, particularly those with OSA. The safety issue is that some children have duplicated cytochromes that allow greater than expected conversion of the prodrug codeine to morphine, thus resulting in potential overdose; codeine should be avoided for postprocedure analgesia.[320–324]

The health evaluation should include the following:

- age and weight (in kg) and gestational age at birth (preterm infants may have associated

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sequelae such as apnea of prematurity); and

- health history, including (1) food and medication allergies and previous allergic or adverse drug reactions; (2) medication/drug history, including dosage, time, route, and site of administration for prescription, over-the-counter, herbal, or illicit drugs; (3) relevant diseases, physical abnormalities (including genetic syndromes), neurologic impairments that might increase the potential for airway obstruction, obesity, a history of snoring or OSA,[325–328] or cervical spine instability in Down syndrome, Marfan syndrome, skeletal dysplasia, and other conditions; (4) pregnancy status (as many as 1% of menarchal females presenting for general anesthesia at children's hospitals are pregnant)[329–331] because of concerns for the potential adverse effects of most sedating and anesthetic drugs on the fetus[329,332–338]; (5) history of prematurity (may be associated with subglottic stenosis or propensity to apnea after sedation); (6) history of any seizure disorder; (7) summary of previous relevant hospitalizations; (8) history of sedation or general anesthesia and any complications or unexpected responses; and (9) relevant family history, particularly related to anesthesia (eg, muscular dystrophy, malignant hyperthermia, pseudocholinesterase deficiency).

The review of systems should focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications. A specific query regarding signs and symptoms of sleep-disordered breathing and OSA may be helpful. Children with severe OSA who have experienced repeated episodes of desaturation will likely have altered mu receptors and be analgesic at opioid levels one-third to one-half those of a child without OSA[325–328,339,340]; lower titrated doses of opioids should be used in this population. Such a detailed history will help to determine which patients may benefit from a higher level of care by an appropriately skilled health care provider, such as an anesthesiologist. The health evaluation should also include:

- vital signs, including heart rate, blood pressure, respiratory rate, room air oxygen saturation, and temperature (for some children who are very upset or noncooperative, this may not be possible and a note should be written to document this circumstance);
- physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy [eg, mandibular hypoplasia], high Mallampati score [ie, ability to visualize only the hard palate or tip of the uvula]) to determine whether there is an increased risk of airway obstruction[74,341–344];
- physical status evaluation (ASA classification [see Appendix 2]); and
- name, address, and telephone number of the child's home or parent's, or caregiver's cell phone; additional information such as the patient's personal care provider or medical home is also encouraged.

For hospitalized patients, the current hospital record may suffice for adequate documentation of presedation health; however, a note shall be written documenting that the chart was reviewed, positive findings were noted, and a management plan was formulated. If the clinical or emergency condition of the patient precludes acquiring complete information before sedation, this health evaluation should be obtained as soon as feasible.

2. Prescriptions. When prescriptions are used for sedation, a copy of the prescription or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions that were given to the responsible person. **Prescription medications intended to accomplish procedural sedation must not be administered without the safety net of direct supervision by trained medical/dental personnel.** The administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats because deaths as a result of this practice have been reported.[63,257]

Documentation During Treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage/kilogram, and patient effect of administered drugs. Before sedation, a "time out" should be performed to confirm the patient's name, procedure to be performed, and laterality and site of the procedure.[59] During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administration, special attention must be paid to the calculation of dosage (ie, mg/kg); for obese patients, most drug doses should likely be adjusted lower to ideal body weight rather than actual weight.[345] When a programmable pump is used for the infusion of sedating medications, the dose/kilogram per minute or hour and the child's weight in kilograms should be double-checked and confirmed by a separate individual. The patient's chart shall contain documentation at the time of treatment that the patient's level of consciousness and responsiveness, heart rate, blood pressure, respiratory rate, expired carbon dioxide values, and oxygen saturation

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were monitored. Standard vital signs should be further documented at appropriate intervals during recovery until the patient attains predetermined discharge criteria (Appendix 1). A variety of sedation scoring systems are available that may aid this process.[212,238,346–348] Adverse events and their treatment shall be documented.

Documentation After Treatment

A dedicated and properly equipped recovery area is recommended (see Appendices 3 and 4). The time and condition of the child at discharge from the treatment area or facility shall be documented, which should include documentation that the child's level of consciousness and oxygen saturation in room air have returned to a state that is safe for discharge by recognized criteria (see Appendix 1). Patients receiving supplemental oxygen before the procedure should have a similar oxygen need after the procedure. Because some sedation medications are known to have a long half-life and may delay a patient's complete return to baseline or pose the risk of re-sedation[62,104,256,349,350] and because some patients will have complex multiorgan medical conditions, a longer period of observation in a less intense observation area (eg, a step-down observation area) before discharge from medical/dental supervision may be indicated.[239] Several scales to evaluate recovery have been devised and validated.[212,346–348,351,352] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238]

CONTINUOUS QUALITY IMPROVEMENT

The essence of medical error reduction is a careful examination of index events and root-cause analysis of how the event could be avoided in the future.[353–359] Therefore, each facility should maintain records that track all adverse events and significant interventions, such as desaturation; apnea; laryngospasm; need for airway interventions, including the need for placement of supraglottic devices such as an oral airway, nasal trumpet, or LMA; positive-pressure ventilation; prolonged sedation; unanticipated use of reversal agents; unplanned or prolonged hospital admission; sedation failures; inability to complete the procedure; and unsatisfactory sedation, analgesia, or anxiolysis.[360] Such events can then be examined for the assessment of risk reduction and improvement in patient/family satisfaction.

PREPARATION FOR SEDATION PROCEDURES

Part of the safety net of sedation is using a systematic approach so as to not overlook having an important drug, piece of equipment, or monitor immediately available at the time of a developing emergency. To avoid this problem, it is helpful to use an acronym that allows the same setup and checklist for every procedure. A commonly used acronym useful in planning and preparation for a procedure is **SOAPME**, which represents the following:

S = Size-appropriate suction catheters and a functioning suction apparatus (eg, Yankauer-type suction)

O = an adequate Oxygen supply and functioning flow meters or other devices to allow its delivery

A = size-appropriate Airway equipment (eg, bag-valve-mask or equivalent device [functioning]), nasopharyngeal and oropharyngeal airways, LMA, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask

P = Pharmacy: all the basic drugs needed to support life during an emergency, including antagonists as indicated

M = Monitors: functioning pulse oximeter with size-appropriate oximeter probes,[361,362] end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, ECG, stethoscope)

E = special Equipment or drugs for a particular case (eg, defibrillator)

SPECIFIC GUIDELINES FOR INTENDED LEVEL OF SEDATION

Minimal Sedation

Minimal sedation (old terminology, "anxiolysis") is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Children who have received minimal sedation generally will not require more than observation and intermittent assessment of their level of sedation. Some children will become moderately sedated despite the intended level of minimal sedation; should this occur, then the guidelines for moderate sedation apply.[85,363]

Moderate Sedation

Moderate sedation (old terminology, "conscious sedation" or "sedation/analgesia") is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands or after light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation; drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Because the patient who

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receives moderate sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to what is necessary for deep sedation.[85]

Personnel

THE PRACTITIONER. The practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be competent to use such techniques, to provide the level of monitoring described in these guidelines, and to manage complications of these techniques (ie, to be able to rescue the patient). Because the level of intended sedation may be exceeded, the practitioner must be sufficiently skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation should the child progress to a level of deep sedation. Training in, and maintenance of, advanced pediatric airway skills is required (eg, pediatric advanced life support [PALS]); regular skills reinforcement with simulation is strongly encouraged.[79,80,128,130,217–220, 364]

SUPPORT PERSONNEL. 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 may also be responsible for assisting with interruptible patient-related tasks of short duration, such as holding an instrument or troubleshooting equipment.[60] This individual should be trained in and capable of providing advanced airway skills (eg, PALS). The support person shall have specific assignments in the event of an emergency and current knowledge of the emergency cart inventory. The practitioner and all ancillary personnel should participate in periodic reviews, simulation of rare emergencies, and practice drills of the facility's emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.[133,365–367] It is recommended that at least 1 practitioner be skilled in obtaining vascular access in children.

Monitoring and Documentation

BASELINE. Before the administration of sedative medications, a baseline determination of vital signs shall be documented. For some children who are very upset or uncooperative, this may not be possible, and a note should be written to document this circumstance.

DURING THE PROCEDURE The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the qualified health care provider administering the medication to confirm the dose verbally before administration. There shall be continuous monitoring of oxygen saturation and heart rate; when bidirectional verbal communication between the provider and patient is appropriate and possible (ie, patient is developmentally able and purposefully communicates), monitoring of ventilation by (1) capnography (preferred) or (2) amplified, audible pretracheal stethoscope (eg, Bluetooth technology)[368–371] or precordial stethoscope is strongly recommended. If bidirectional verbal communication is not appropriate or not possible, monitoring of ventilation by capnography (preferred), amplified, audible pretracheal stethoscope, or precordial stethoscope is required. Heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide values should be recorded, at minimum, every 10 minutes in a time-based record. Note that the exact value of expired carbon dioxide is less important than simple assessment of continuous respiratory gas exchange. In some situations in which there is excessive patient agitation or lack of cooperation or during certain procedures such as bronchoscopy, dentistry, or repair of facial lacerations capnography may not be feasible, and this situation should be documented. For uncooperative children, it is often helpful to defer the initiation of capnography until the child becomes sedated. Similarly, the stimulation of blood pressure cuff inflation may cause arousal or agitation; in such cases, blood pressure monitoring may be counterproductive and may be documented at less frequent intervals (eg, 10–15 minutes, assuming the patient remains stable, well oxygenated, and well perfused). Immobilization devices (protective stabilization) should be checked to prevent airway obstruction or chest restriction. If a restraint device is used, a hand or foot should be kept exposed. The child's head position should be continuously assessed to ensure airway patency.

AFTER THE PROCEDURE. The child who has received moderate sedation must be observed in a suitably equipped recovery area, which must have a functioning suction apparatus as well as the capacity to deliver >90% oxygen and positive-pressure ventilation (bag-valve mask) with an adequate oxygen capacity as well as age- and size-appropriate rescue equipment and devices. The patient's vital signs should be recorded at specific intervals (eg, every 10–15 minutes). If the patient is not fully alert, oxygen saturation and heart rate monitoring shall be used continuously until appropriate discharge criteria are met (see Appendix 1). Because sedation medications with a long half-life

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may delay the patient's complete return to baseline or pose the risk of re-sedation, some patients might benefit from a longer period of less intense observation (eg, a step-down observation area where multiple patients can be observed simultaneously) before discharge from medical/dental supervision (see section entitled "Documentation Before Sedation" above).[62,256,349,350] A simple evaluation tool may be the ability of the infant or child to remain awake for at least 20 minutes when placed in a quiet environment.[238] Patients who have received reversal agents, such as flumazenil or naloxone, will require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, resulting in re-sedation.

Deep Sedation/General Anesthesia

"Deep sedation" ("deep sedation/analgesia") is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (eg, purposefully pushing away the noxious stimuli). Reflex withdrawal from a painful stimulus is not considered a purposeful response and is more consistent with a state of general anesthesia. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes. Patients may pass from a state of deep sedation to the state of general anesthesia. In some situations, such as during MRI, one is not usually able to assess responses to stimulation, because this would defeat the purpose of sedation, and one should assume that such patients are deeply sedated.

"General anesthesia" is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Personnel

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 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. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation.

Equipment

In addition to the equipment needed for moderate sedation, an ECG monitor and a defibrillator for use in pediatric patients should be readily available.

Vascular Access

Patients receiving deep sedation should have an intravenous line placed at the start of the procedure or have a person skilled in establishing vascular access in pediatric patients immediately available.

Monitoring

A competent individual shall observe the patient continuously. Monitoring shall include all parameters described for moderate sedation. Vital signs, including heart rate, respiratory rate, blood pressure, oxygen saturation, and expired carbon dioxide, must be documented at least every 5 minutes in a time-based record. Capnography should be used for almost all deeply sedated children because of the increased risk of airway/ventilation compromise. Capnography may not be feasible if the patient is agitated or uncooperative during the initial phases of sedation or during certain procedures, such as bronchoscopy or repair of facial lacerations, and this circumstance should be documented. For uncooperative children, the capnography monitor may be placed once the child becomes sedated. Note that if supplemental oxygen is administered, the capnograph may underestimate the true expired carbon dioxide value; of more importance than the numeric reading of exhaled carbon dioxide is the assurance of continuous respiratory gas exchange (ie, continuous waveform). Capnography is particularly useful for patients who are difficult to observe (eg, during MRI or in a darkened room).[64,67,72,90,96,110,159–162,164–166,167–170,372–375]

The physician/dentist or his or her designee shall document the name, route, site, time of administration, and dosage of all drugs administered. If sedation is being directed by a physician who is not personally administering the medications, then recommended practice is for the nurse administering the medication to confirm the dose verbally before administration. The inspired

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concentrations of inhalation sedation agents and oxygen and the duration of administration shall be documented.

Postsedation Care

The facility and procedures followed for postsedation care shall conform to those described under "moderate sedation." The initial recording of vital signs should be documented at least every 5 minutes. Once the child begins to awaken, the recording intervals may be increased to 10 to 15 minutes. Table 2 summarizes the equipment, personnel, and monitoring requirements for moderate and deep sedation.

TABLE 2 Comparison of Moderate and Deep Sedation Equipment and Personnel Requirements

	Moderate Sedation	Deep Sedation
Personnel	An observer who will monitor the patient but who may also assist with interruptible tasks; should be trained in PALS	An independent observer whose only responsibility is to continuously monitor the patient; trained in PALS
Responsible practitioner	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction including the ability to open the airway, suction secretions, provide CPAP, and perform successful bag-valve-mask ventilation; recommended that at least 1 practitioner should be skilled in obtaining vascular access in children; trained in PALS	Skilled to rescue a child with apnea, laryngospasm, and/or airway obstruction, including the ability to open the airway, suction secretions, provide CPAP, perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation; training in PALS is required; at least 1 practitioner skilled in obtaining vascular access in children immediately available
Monitoring	Pulse oximetry ECG recommended Heart rate Blood pressure Respiration Capnography recommended	Pulse oximetry ECG required Heart rate Blood pressure Respiration Capnography required
Other equipment	Suction equipment, adequate oxygen source/supply	Suction equipment, adequate oxygen source/supply, defibrillator required
Documentation	Name, route, site, time of administration, and dosage of all drugs administered Continuous oxygen saturation, heart rate, and ventilation (capnography recommended); parameters recorded every 10 minutes	Name, route, site, time of administration, and dosage of all drugs administered; continuous oxygen saturation, heart rate, and ventilation (capnography required); parameters recorded at least every 5 minutes
Emergency checklists	Recommended	Recommended
Rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4)	Required	Required
Dedicated recovery area with rescue cart properly stocked with rescue drugs and age- and size-appropriate equipment (see Appendices 3 and 4) and dedicated recovery personnel; adequate oxygen supply	Recommended; initial recording of vital signs may be needed at least every 10 minutes until the child begins to awaken, then recording intervals may be increased	Recommended; initial recording of vital signs may be needed for at least 5-minute intervals until the child begins to awaken, then recording intervals may be increased to 10–15 minutes
Discharge criteria	See Appendix 1	See Appendix 1

Special Considerations

Neonates and Former Preterm Infants

Neonates and former preterm infants require specific management, because immaturity of hepatic and renal function may alter the ability to metabolize and excrete sedating medications,[376] resulting in prolonged sedation and the need for extended postsedation monitoring. Former preterm infants have an increased risk of postanesthesia apnea,[377] but it is unclear whether a similar risk is associated with sedation, because this possibility has not been systematically investigated.[378]

Other concerns regarding the effects of anesthetic drugs and sedating medications on the developing brain are beyond the scope of this document. At this point, the research in this area is preliminary and inconclusive at best, but it would seem prudent to avoid unnecessary exposure to sedation if the procedure is unlikely to change medical/dental management (eg, a sedated MRI purely for screening purposes in preterm infants).[379–382]

Local Anesthetic Agents

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular weight-based attention should be paid to cumulative dosage in all children.[118,120,125,383–386] To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (eg, mg/kg) should be calculated before administration. There may be enhanced sedative effects when the highest recommended doses of local anesthetic drugs are used in combination with other sedatives or opioids (see Tables 3 and 4 for limits and conversion tables of commonly used local anesthetics).[118,125,387–400] In general, when administering local

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TABLE 3 Commonly Used Local Anesthetic Agents for Nerve Block or Infiltration: Doses, Duration, and Calculations

Local Anesthetic	Maximum Dose With Epinephrine,[a] mg/kg		Maximum Dose Without Epinephrine, mg/kg		Duration of Action,[b] min
	Medical	Dental	Medical	Dental	
Esters					
Procaine	10.0	6	7	6	60–90
Chloroprocaine	20.0	12	15	12	30–60
Tetracaine	1.5	1	1	1	180–600
Amides					
Lidocaine	7.0	4.4	4	4.4	90–200
Mepivacaine	7.0	4.4	5	4.4	120–240
Bupivacaine	3.0	1.3	2.5	1.3	180–600
Levobupivacaine[c]	3.0	2	2	2	180–600
Ropivacaine	3.0	2	2	2	180–600
Articaine[d]	—	7	—	7	60–230

Maximum recommended doses and durations of action are shown. Note that lower doses should be used in very vascular areas.

[a] These are maximum doses of local anesthetics combined with epinephrine; lower doses are recommended when used without epinephrine. Doses of amides should be decreased by 30% in infants younger than 6 mo. When lidocaine is being administered intravascularly (eg, during intravenous regional anesthesia), the dose should be decreased to 3 to 5 mg/kg; long-acting local anesthetic agents should not be used for intravenous regional anesthesia.

[b] Duration of action is dependent on concentration, total dose, and site of administration; use of epinephrine; and the patient's age.

[c] Levobupivacaine is not available in the United States.

[d] Use in pediatric patients under 4 years of age is not recommended.

TABLE 4 Local Anesthetic Conversion Chart

Concentration, %	mg/mL
4.0	40
3.0	30
2.5	25
2.0	20
1.0	10
0.5	5
0.25	2.5
0.125	1.25

TABLE 5 Treatment of Local Anesthetic Toxicity

1. Get help. Ventilate with 100% oxygen. Alert nearest facility with cardiopulmonary bypass capability.
2. Resuscitation: airway/ventilatory support, chest compressions, etc. Avoid vasopressin, calcium channel blockers, β-blockers, or additional local anesthetic. Reduce epinephrine dosages. Prolonged effort may be required.
3. Seizure management: benzodiazepines preferred (eg, intravenous midazolam 0.1–0.2 mg/kg); avoid propofol if cardiovascular instability.
4. Administer 1.5 mL/kg 20% lipid emulsion over ~1 minute to trap unbound amide local anesthetics. Repeat bolus once or twice for persistent cardiovascular collapse.
5. Initiate 20% lipid infusion (0.25 mL/kg per minute) until circulation is restored; double the infusion rate if blood pressure remains low. Continue infusion for at least 10 minutes after attaining circulatory stability. Recommended upper limit of ~10 mL/kg.
6. A fluid bolus of 10–20 mL/kg balanced salt solution and an infusion of phenylephrine (0.1 μg/kg per minute to start) may be needed to correct peripheral vasodilation.

Source: https://www.asra.com/advisory-guidelines/article/3/checklist-for-treatment-of-local-anesthetic-systemic-toxicity.

anesthetic drugs, the practitioner should aspirate frequently to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.[401] If high doses or injection of amide local anesthetics (bupivacaine and ropivacaine) into vascular tissues is anticipated, then the immediate availability of a 20% lipid emulsion for the treatment of local anesthetic toxicity is recommended (Tables 3 and 5).[402–409] Topical local anesthetics are commonly used and encouraged, but the practitioner should avoid applying excessive doses to mucosal surfaces where systemic uptake and possible toxicity (seizures, methemoglobinemia) could result and to remain within the manufacturer's recommendations regarding allowable surface area application.[410–415]

Pulse Oximetry

Newer pulse oximeters are less susceptible to motion artifacts and may be more useful than older oximeters that do not contain updated software.[416–420] Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. The oximeter probe must be properly positioned; clip-on devices are easy to displace, which may produce artifactual data (under- or overestimation of oxygen saturation).[361,362]

Capnography

Expired carbon dioxide monitoring is valuable to diagnose the simple presence or absence of respirations, airway obstruction, or respiratory depression, particularly in patients sedated in less-accessible locations, such as in MRI machines or darkened rooms.[64,66,67,72,90,96,110,159–162,164–170,372–375,421–427] In patients receiving supplemental oxygen, capnography facilitates the recognition of apnea or airway obstruction several minutes before the situation would be detected just by pulse oximetry. In this situation, desaturation would be delayed due to increased oxygen reserves; capnography would enable earlier intervention.[161] One study in children sedated in the emergency department found that the use of capnography reduced the incidence of hypoventilation and desaturation

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(7% to 1%).[174] The use of expired carbon dioxide monitoring devices is now required for almost all deeply sedated children (with rare exceptions), particularly in situations in which other means of assessing the adequacy of ventilation are limited. Several manufacturers have produced nasal cannulae that allow simultaneous delivery of oxygen and measurement of expired carbon dioxide values.[421,422,427] Although these devices can have a high degree of false-positive alarms, they are also very accurate for the detection of complete airway obstruction or apnea.[164,168,169] Taping the sampling line under the nares under an oxygen face mask or nasal hood will provide similar information. The exact measured value is less important than the simple answer to the question: Is the child exchanging air with each breath?

Processed EEG (Bispectral Index)

Although not new to the anesthesia community, the processed EEG (bispectral index [BIS]) monitor is slowly finding its way into the sedation literature.[428] Several studies have attempted to use BIS monitoring as a means of noninvasively assessing the depth of sedation. This technology was designed to examine EEG signals and, through a variety of algorithms, correlate a number with depth of unconsciousness: that is, the lower the number, the deeper the sedation. Unfortunately, these algorithms are based on adult patients and have not been validated in children of varying ages and varying brain development. Although the readings correspond quite well with the depth of propofol sedation, the numbers may paradoxically go up rather than down with sevoflurane and ketamine because of central excitation despite a state of general anesthesia or deep sedation.[429,430] Opioids and benzodiazepines have minimal and variable effects on the BIS. Dexmedetomidine has minimal effect with EEG patterns, consistent with stage 2 sleep.[431] Several sedation studies have examined the utility of this device and degree of correlation with standard sedation scales.[347,363,432–435] It appears that there is some correlation with BIS values in moderate sedation, but there is not a reliable ability to distinguish between deep sedation and moderate sedation or deep sedation from general anesthesia.[432] Presently, it would appear that BIS monitoring might provide useful information only when used for sedation with propofol[363]; in general, it is still considered a research tool and not recommended for routine use.

Adjuncts to Airway Management and Resuscitation

The vast majority of sedation complications can be managed with simple maneuvers, such as supplemental oxygen, opening the airway, suctioning, placement of an oral or nasopharyngeal airway, and bag-mask-valve ventilation. Rarely, tracheal intubation is required for more prolonged ventilatory support. In addition to standard tracheal intubation techniques, a number of supraglottic devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the LMA, the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.[436,437]

The largest clinical experience in pediatrics is with the LMA, which is available in multiple sizes, including those for late preterm and term neonates. The use of the LMA is now an essential addition to advanced airway training courses, and familiarity with insertion techniques can be life-saving.[438–442] The LMA can also serve as a bridge to secure airway management in children with anatomic airway abnormalities.[443,444] Practitioners are encouraged to gain experience with these techniques as they become incorporated into PALS courses.

Another valuable emergency technique is intraosseous needle placement for vascular access. Intraosseous needles are available in several sizes; insertion can be life-saving when rapid intravenous access is difficult. A relatively new intraosseous device (EZ-IO Vidacare, now part of Teleflex, Research Triangle Park, NC) is similar to a hand-held battery-powered drill. It allows rapid placement with minimal chance of misplacement; it also has a low-profile intravenous adapter.[445–450] Familiarity with the use of these emergency techniques can be gained by keeping current with resuscitation courses, such as PALS and advanced pediatric life support.

Patient Simulators

High-fidelity patient simulators are now available that allow physicians, dentists, and other health care providers to practice managing a variety of programmed adverse events, such as apnea, bronchospasm, and laryngospasm.[133,220,450–452] The use of such devices is encouraged to better train medical professionals and teams to respond more effectively to rare events.[128,131,451,453–455] One study that simulated the quality of cardiopulmonary resuscitation compared standard management of ventricular fibrillation versus rescue with the EZ-IO for the rapid establishment of intravenous access and placement of an LMA for establishing a patent airway in adults; the use of these devices resulted in more rapid establishment of vascular access and securing of the airway.[456]

Monitoring During MRI

The powerful magnetic field and the generation of radiofrequency emissions necessitate the use of special equipment to provide

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continuous patient monitoring throughout the MRI scanning procedure.[457–459] MRI-compatible pulse oximeters and capnographs capable of continuous function during scanning should be used in any sedated or restrained pediatric patient. Thermal injuries can result if appropriate precautions are not taken; the practitioner is cautioned to avoid coiling of all wires (oximeter, ECG) and to place the oximeter probe as far from the magnetic coil as possible to diminish the possibility of injury. ECG monitoring during MRI has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.[460–463] If sedation is achieved by using an infusion pump, then either an MRI-compatible pump is required or the pump must be situated outside of the room with long infusion tubing so as to maintain infusion accuracy. All equipment must be MRI compatible, including laryngoscope blades and handles, oxygen tanks, and any ancillary equipment. All individuals, including parents, must be screened for ferromagnetic materials, phones, pagers, pens, credit cards, watches, surgical implants, pacemakers, etc, before entry into the MRI suite.

Nitrous Oxide

Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100% and never less than 25% oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide >50% to oxygen that covers the mouth and nose must be used in conjunction with a calibrated and functional oxygen analyzer. All nitrous oxide-to-oxygen inhalation devices should be calibrated in accordance with appropriate state and local requirements. Consideration should be given to the National Institute of Occupational Safety and Health Standards for the scavenging of waste gases.[464] Newly constructed or reconstructed treatment facilities, especially those with piped-in nitrous oxide and oxygen, must have appropriate state or local inspections to certify proper function of inhalation sedation/analgesia systems before any delivery of patient care.

Nitrous oxide in oxygen, with varying concentrations, has been successfully used for many years to provide analgesia for a variety of painful procedures in children.[14,36,49,98,465–493] The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide of ≤50% with the balance as oxygen, without any other sedative, opioid, or other depressant drug before or concurrent with the nitrous oxide to an otherwise healthy patient in ASA class I or II. The patient is able to maintain verbal communication throughout the procedure. It should be noted that although local anesthetics have sedative properties, for purposes of this guideline they are not considered sedatives in this circumstance. If nitrous oxide in oxygen is combined with other sedating medications, such as chloral hydrate, midazolam, or an opioid, or if nitrous oxide is used in concentrations >50%, the likelihood for moderate or deep sedation increases.[107,197,492,494,495] In this situation, the practitioner is advised to institute the guidelines for moderate or deep sedation, as indicated by the patient's response.[496]

ACKNOWLEDGMENTS

The lead authors thank Dr Corrie Chumpitazi and Dr Mary Hegenbarth for their contributions to this document.

LEAD AUTHORS

Charles J. Coté, MD, FAAP
Stephen Wilson, DMD, MA, PhD

AMERICAN ACADEMY OF PEDIATRICS

AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

STAFF

Jennifer Riefe, MEd
Raymond J. Koteras, MHA

ABBREVIATIONS

AAP: American Academy of Pediatrics
AAPD: American Academy of Pediatric Dentistry
ASA: American Society of Anesthesiologists
BIS: bispectral index
CPAP: continuous positive airway pressure
ECG: electrocardiography
EEG: electroencephalogram/electroencephalography
EMS: emergency medical services
LMA: laryngeal mask airway
MRI: magnetic resonance imaging
OSA: obstructive sleep apnea
PALS: pediatric advanced life support

FINANCIAL DISCLOSURE: The authors have indicated they do not have a financial relationship 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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Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016

Charles J. Coté, Stephen Wilson, AMERICAN ACADEMY OF PEDIATRICS and AMERICAN ACADEMY OF PEDIATRIC DENTISTRY

Pediatrics; originally published online June 27, 2016;
DOI: 10.1542/peds.2016-1212

Updated Information & Services	including high resolution figures, can be found at: /content/early/2016/06/24/peds.2016-1212.full.html
Supplementary Material	Supplementary material can be found at: /content/suppl/2016/06/22/peds.2016-1212.DCSupplemental.html
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E-mail: kidsdocs@aap.org
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July 22, 2016

Steven G. Morrow, DDS, MS, President
Dental Board of California
2005 Evergreen Street, Suite 1550,
Sacramento, California 95815

Dear Dr Morrow,

Thank you for your letter of July 18.

The American Academy of Pediatrics is deeply committed to ensuring infants, children and adolescents receive the proper care to attain optimal health. For many years, the Academy has been concerned with the protection of pediatric patients during dental sedation, and have updated our "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016," a copy of which we recently submitted to the Dental Board.

We thank you for the invitation to participate in your July and August meetings. Inasmuch as our California District is as invested in this issue as the National Office, we defer to and are fully supportive of their efforts in California. By copy of this letter, I am asking Kris Calvin, MA, Executive Director, AAP-CA, to identify appropriate participants for the sessions.

We look forward to assisting you in promoting the best practices in dental sedation consistent with our Guidelines.

Sincerely,

Roger F Suchyta, MD, FAAP
Associate Executive Director

RFS/dc

cc: Karen Remley, MD, MBA, MPH, FAAP , Executive Director/CEO
Stu Cohen, MD, FAAP, District IX Chairperson
Yasuko Fukuda, MD, FAAP, District IX Vice Chairperson
Kris Calvin, MA, CEO, AAP-CA
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American Academy of Pediatrics, California
921 11th Street, Suite 1100, Sacramento CA 95814

Phone (626) 796 1632 | Fax (626) 628-3382
Email office@aap-ca.org | Website www.AAP-CA.org

July 27, 2016

Steven G. Morrow, DDS, MS
President, Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: AAP-CA Comment on Dental Board of California Pediatric Anesthesia Study

Dear Dr. Morrow:

The mission of the AAP-CA is to protect and promote the health and well-being of all children and youth living in California. Our mission applies in any circumstance and setting in which a child's health and well-being is nurtured or is at risk. Pediatricians' interest, expertise and training extend to the health of the whole child, and while distinct in important aspects, overlap with that of pediatric dentistry and oral surgery.

In situations where anesthesia is used on a child, it is often the pediatrician who clears the patient for anesthesia beforehand and the pediatrician who treats any adverse consequences that may arise afterwards.

It is also often the pediatrician who counsels and comforts a parent when a child dies, a child who that pediatrician has cared for since birth, irrespective of the circumstances in which the tragedy occurs.

It is important to note that pediatricians have absolutely no financial stake in how anesthesia is administered in a dental office; we gain no income regardless of who administers the anesthesia. In making our recommendations in this area, we are, therefore, able to consider only the evidence as it relates to the child's safety and well-being.

Given our primary involvement in children's health, we are disappointed that pediatricians have been relegated to act as external stakeholders in the California Dental Board's review of anesthesia practices for children, restricted to commenting on a draft report for which the issue has been framed and the questions have been asked in an internal and exclusionary process in which, as we understand it, an oral surgeon and a lawyer (with a seat on the dental board) have been the only primary authors, supported by Board staff.

We hope that enactment of AB 2235 (Thurmond)—supported not only by the AAP-CA as sponsors, but also by the California Dental Association— will occur, and that at that time the California Dental Board will establish a collaborative and inclusive process, through which the houses of medicine and dentistry will be able to step out of our respective silos and combine our knowledge and expertise to determine what is truly best for California's children who undergo anesthesia in a dental setting.

With respect to the Board's draft report, we have not had sufficient time to review line-by-line the recently released 150 page document or to put it through our formal process. **We can, however make initial comments, and greatly appreciate the careful work done by the Dental Board in the draft report on Appendix 2, in which current definitions/requirements in California law are compared to policy as put forth in the joint guidelines established by the American Academy of Pediatrics (AAP) in collaboration with the American**

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American Academy of Pediatrics, California
921 11th Street, Suite 1100, Sacramento CA 95814

Phone (626) 796 1632 | Fax (626) 628-3382
Email office@aap-ca.org | Website www.AAP-CA.org

Academy of Pediatric Dentistry (AAPD). (For purposes of comparison, it appears the Board's draft report utilizes an older version of these guidelines, which have since been updated and published in the July 2016 issue of the journal *Pediatrics* as "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016," by Charles J. Coté and Stephen Wilson.)

The AAP-AAPD guidelines, publicly available online, reflect our current position on addressing the needs of pediatric patients before, during, and after the administration of anesthesia.

With respect to the report under discussion here, we are deeply concerned by an area of disagreement between the AAP-AAPD guidelines and current CA law with respect to Personnel. California law requires that Personnel for deep sedation/general anesthesia only be the "same as moderate sedation". In contrast, The AAP-AAPD personnel guidelines for deep sedation/general anesthesia have additional requirements:

"There must be one person available 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. At least one individual must be present who is trained in, and capable of, providing advanced pediatric life support, and who is skilled in airway management and cardiopulmonary resuscitation; training in pediatric advanced life support is required."

The notion that the personnel necessary to monitor and administer anesthesia for a child under deep sedation/general anesthesia in a dental chair is no more than that required for moderate sedation seems, frankly, woefully inadequate. That would seem to hold true *only if there were no greater risk* to the child under deep sedation/general anesthesia than under moderate sedation.

In addition to asking that the above-referenced guidelines issued jointly by the American Academy of Pediatrics and the American Association of Pediatric Dentists (as updated in 2016) be adopted in their entirety as the basis for recommendations for improving California's laws and regulations in the area of pediatric anesthesia and dental care, we also endorse the position of the California Society of Anesthesiologists "...the standard of care regarding the administration and monitoring of anesthesia services must be consistent... whether anesthesia care is delivered in a dental office, ambulatory surgery center or acute care hospital."

The above requires that a dentist performing a dental procedure not be simultaneously responsible for anesthesia care, much as a surgeon does not perform anesthesia while operating but rather requires the assistance of an anesthesiologist. The fact that dental offices are typically located at some distance from hospital facilities means that more, rather than fewer, precautions should be taken with the use of pediatric anesthesia, as the relative inaccessibility of potentially life-saving emergency assistance stands to have disastrous consequences.

Please note: our national organization (the American Academy of Pediatrics based in Illinois) forwarded your request for comment to us, the American Academy of Pediatrics, California (AAP-CA). **We ask that any further communications regarding this issue be directed to our CEO, Kris Calvin at 626-796-1632/office@aap-ca.org.**

AMERICAN SOCIETY OF DENTIST ANESTHESIOLOGISTS (ASDA)

1. July 25, 2016 Letter from Steve Nguyen, DDS, ASDA President with Attachment
    - Periodontal Abstract, Volume 53,Number 2 – 2005 – Summary of the California Blue Ribbon Panel Report on Anesthesia

American Society of Dentist Anesthesiologists

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3443 Medina Road, Suite 105
Medina, OH 44256
330.952.1737
steve.nguyen@medinasurgical.com

President-Elect
JAMES W. TOM, DDS, MS
2145 Parnell Avenue
Los Angeles, CA 90025
310.474.1605
jtom@usc.edu

Vice President
CYNTHIA FUKAMI, DMD, MS
5519 E Calle Del Norte
Phoenix, AZ 85018
602.750.6533
mcfukami@gmail.com

Treasurer
JAMES W. CHANCELLOR, DDS
21922 Deer Canyon
Garden Ridge, TX 78266
210.364.3278
jchancelor@aol.com

Immediate Past President
MARK A. SAXEN, DDS, PhD
Indiana Office-Based Anesthesia
3750 Guion Road
Indianapolis, IN 46222
317.924.2390
msaxen@mw.net

Directors-At-Large

JAROM HEATON, DDS
1608 Oak Forest Drive
Round Rock, TX 78681
512.940.8601
sedadentanesthesia@gmail.com

ZAKARIA MESSIEHA, DDS
427 W. Windsor Avenue
Lombard, IL 60137
630.620.9199
messieha@uic.edu

RONALD J. REDDEN, DDS
1906 W. Summer Rain Court
Kingwood, TX 77339
281.703.5868
rjredden54@gmail.com

MICHELLE TANG, DDS, MSc
2376 Awenda Drive
Oakville, Ontario L6H 7P7
Canada
416.670.7882
michelle.tang@utoronto.ca

Executive Director
Amy L. Sarno, MBA
4411 Bee Ridge Road, #172
Sarasota, FL 34233
312.624.9591
FAX: 773.304.9894
abrown@asdahq.org

July 25, 2016

Steven G. Morrow, DDS, MS
President
Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

Dear Dr. Morrow:

The American Society of Dentist Anesthesiologists (ASDA) would like to thank the Dental Board of California for the invitation to provide comments to the California dental anesthesia issues surrounding the proposed AB2235, otherwise known as "Caleb's Law."

The ASDA is in accord with the California Society of Anesthesiologists' recommendation, as stated by Dr. Zakowski's letter to the Dental Board of California. The ASDA supports limiting deep sedation and general anesthesia to the most qualified providers. We also concur with Dr. Zakowski that the foundation for safe anesthesia practice is adequate training and continued training.

Few people outside of dentistry are aware of the wide range of anesthesia training across the dental profession: Dentist anesthesiologists, oral and maxillofacial surgeons, pediatric dentists, dentists with sedation training, and dental assistants and auxiliaries. In dentistry, the Commission on Dental Accreditation (CODA) develops and enforces standards that foster continuous quality improvements of dental and dental related educational programs.

Descriptions of CODA accredited programs are illustrated below (taken from CODA website and Standard):

- Dental Anesthesiology: These educational programs are designed to train the dental resident, in the most comprehensive manner, to use pharmacologic and non-pharmacologic methods to manage anxiety and pain of adults, children, and patients with special care needs undergoing dental, maxillofacial and adjunctive procedures, as well as to be qualified in the diagnosis and non-surgical treatment of acute orofacial pain and to participate in the management of patients with chronic orofacial pain.

CODA Standard 2-6: The following list represents the minimum clinical experiences that **must** be obtained by each resident in the program: Eight hundred (800) total cases of deep sedation/general anesthesia to include one hundred and twenty five (125) children aged *seven (7) and under*. Standard 2-7: General anesthesia experience/anesthesia service must include, at a minimum, a total of twenty-four (24) months over a thirty-six (36) month period **must** be devoted exclusively to clinical training in anesthesiology, of which a minimum of six (6) months are devoted to dental anesthesiology.

- Oral and Maxillofacial Surgery: Oral and maxillofacial surgery is the specialty of dentistry which includes the diagnosis, surgical and adjunctive treatment of diseases, injuries and defects involving both the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial region.
  CODA Standard 4-3.1: Anesthesia Service: The assignment **must** be for a minimum of 5 months, should be consecutive and one of these months should be dedicated to pediatric anesthesia. The resident **must** function as an anesthesia resident with commensurate level of responsibility.
  CODA Standard 4-9: The off-service rotation in anesthesia **must** be supplemented by longitudinal and progressive experience throughout the training program in all aspects of pain and anxiety control. The outpatient surgery experience must ensure adequate training to competence in general anesthesia/deep sedation for oral and maxillofacial surgery procedures on adult and pediatric patients. This includes the competence on managing the airway.
  CODA Standard 4-9.1: The cumulative experience of each graduating resident **must** include administration of general anesthesia/deep sedation to a minimum of 300 patients. A minimum of 150 of these cases must be ambulatory anesthetics for oral and maxillofacial surgery. A minimum of 50 of the 300 patients must be pediatric (*18 years of age or younger*).

- Pediatric Dentistry: Pediatric Dentistry is an age-defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs. Pediatric dentists are dedicated to improving the oral health of infants, children, adolescents and patients with special health care needs.
  CODA Standard 4-6: Clinical experiences in behavior guidance **must** enable students/residents to achieve competency in patient management using behavior guidance: A. Experiences must include infants, children and adolescents including patients with special health care needs, using: 1) Non-pharmacological techniques. 2) Sedation; and 3) Inhalation analgesia. B. Students/Residents **must** perform adequate patient encounters to achieve competency: 1) Students/Residents **must** complete 20 nitrous oxide analgesia patient encounters as primary operator; and 2) Students/Residents **must** complete a minimum of 50 patient encounters in which sedative agents other than nitrous oxide. The agents may be administered by any route. All sedation cases **must** be completed in accordance with the recommendations and guidelines of AAPD/AAP, the ADA's *Teaching of Pain Control and Sedation to Dentists and Dental Students*, and relevant institutional policies.

- Dentists with Moderate Sedation Permit: Currently, the American Dental Association (ADA) is revising its ADA's *Teaching of Pain Control and Sedation to Dentists and Dental Students.* The un-revised Standard: To administer moderate sedation, the dentist must demonstrate competency by having have successfully completed: A. A comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the ADA *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced, or B. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines.

The practice mode in which dental anesthesia services are delivered also varies widely across dentistry and dental settings. Dentist anesthesiologists practice primarily as independent anesthesia providers congruent with their physician-based training model and standards. In contrast, nearly all oral and maxillofacial surgeons practice the operator-anesthetist mode in providing general anesthesia and oral surgery simultaneously. The majority of other dentists primarily perform minimal or moderate sedation also as operator anesthetists.

Further, the ASDA supports current AAP-AAPD guidelines on the training and personnel guidelines for deep sedation and general anesthesia. Specifically, the recommendation of prescribed by the AAP-AAPD where

> During deep sedation, there **must** be one person whose only responsibility is to 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 and capable of assisting with any emergency event. At least one individual must be present who is trained in and capable of providing advanced pediatric life support and who skilled to rescue a child who has apnea, laryngospasm, and/or airway obstruction. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, LMA), and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation. The definition of a pediatric patient, for intents and purposes, is any individual below or at the age of 18 years.

The ASDA also recommends that the Dental Board of California explicitly follow the recommendations of the Blue Ribbon Panel convened to thoroughly examine dental anesthesia within the State of California. The very first recommendation by the Blue Ribbon Panel was to establish a Dental Board-sponsored or independent "Anesthesia Review Committee" composed of a multidisciplinary panel that included dentist and physician anesthesiologists, general dentists, pediatric dentists, periodontists, oral surgeons, and other healthcare professionals. This recommendation has not been initiated from the time of the 2005 report (*see attached*).

The ASDA recommends that the California statutes and regulations be updated to delete the archaic terms "conscious sedation" and "anxiolysis" to avoid any ambiguity with current and accepted American Dental Association and American Society of Anesthesiologists' terms describing the continuum of sedation and anesthesia. Additionally, the statutes and regulations must be revised to conform to current training standards and educational requirements of CODA and ADA.

Removal of one year training requirements for general anesthesia permits must be revised to the accurately reflect the current 36 month, CODA-accredited standards for dental anesthesiology residency programs.

The ASDA explicitly recommends, for the purpose of longitudinal data collection and outcomes based research in patient safety, that the Dental Board of California begin to collect the following information regarding any 1680(z) reports from practitioners and the subsequent investigations that follow:

a) Patient age and intended procedure
b) Medical history and pertinent co-morbidities
c) Training of practitioner and auxiliaries (if applicable)
d) Medications, dosages, and techniques used in the conduct of the anesthetic
e) Intended level of sedation or anesthesia
f) Intervening actions to rescue the patient
g) Conclusions and determinations made by the Dental Board of CA.

In closing, the American Society of Dentist Anesthesiologists would like to thank the Dental Board of California and the California Legislature for their continuing efforts to improve the safe delivery of office-based anesthesia services to the citizens of California.

Sincerely,

Steve Nguyen, DDS
ASDA President

Enclosure

CALIFORNIA DENTAL ASSOCIATION (CDA)

1. June 30, 2016 Letter from Brianna Pittman, Legislative Director

June 30, 2016

Steven G. Morrow, DDS, MS
President, Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

Dear Dr. Morrow:

The California Dental Association is deeply saddened by death and is committed to taking actions that support the safe provision of dental care to every person, every day. We also understand the desire for action to prevent tragedies such as this from ever occurring again. We are concerned, however, that the bill proposal that has arisen from this heartbreaking event, AB 2235 (Thurmond), has brought forward unsubstantiated claims about the risks associated with pediatric dental sedation, alarming the public and generating fear. This is especially troubling for parents whose children may require sedation to receive the dental care they require for their health and wellbeing. We know that the Dental Board of California (board) shares our concerns and our commitment to safety.

CDA appreciates that the board responded immediately to Senator Hill's request that it evaluate whether the state's policies are sufficient to provide the safest and most appropriate administration of anesthesia to pediatric patients and understand that the board is undergoing a comprehensive review at this time. CDA believes that an evidenced-based approach is essential to properly identifying effective solutions and to adopting sound state policy. We have steadfastly supported this in our testimony and public comments throughout this process.

We write to you now, though, to express our concern and dismay that it has taken the board more than three months to report on the number of pediatric sedation deaths that have occurred in California over the last five years. As CDA meets with legislators and legislative staff, all are wondering just how significant a problem the legislature is trying to address. This unknown has left CDA and other advocates unable to rebut claims that children are unsafe if dentists are permitted to continue with current sedation practices and has left legislators who believe that dentistry is safe without data to support that position.

We strongly urge that the board direct all available resources to completing its assessment of deaths related to dental care and release this data as soon as possible. This information is critical to providing context to the legislature's informed consideration of AB 2235 and essential to parents' understanding of this issue as they consider care options

California Dental Association
1201 K Street, 14th Floor
Sacramento, CA 95814

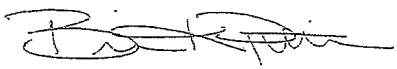
916.443.0505
800.232.7645
916.443.2943 fax
cda.org

for their child. This data, while not the entire picture, is essential to informed problem solving.

Further, CDA urges the board to include in its report its plans to ensure that data on deaths related to dental care will be available in the future in a timely and accurate manner, including its recommendations for collecting data utilizing a standardized and comprehensive methodology.

These matters are of great concern to the public and the profession. CDA appreciates the opportunity to work with the board to support the public's understanding and confidence in the care they receive and to ensure this care is provided safely every day to every person.

Sincerely,



Brianna Pittman
Legislative Director

c: Karen Fischer, Executive Office
Dental Board of California Board Members

CALIFORNIA SOCIETY OF ANESTHESIOLOGISTS (CSA)

1. June 30, 2016 Cover Letter and Attachments Submitted by Mark Zakowski, MD, President

   • 42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services: *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.*
   • ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)
   • ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)
   • ASA Statement on the Anesthesia Care Team (October 16, 2013)
   • ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)
   • 42 C.F.R. § 482.13 Condition of Participation: Patient's Rights
   • *"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"* Anesthesiology 2002; 96:1004–17
   • *"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"* developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)
   • CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)
   • AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016 ***(Did not reprint – Refer to AAP for Document)***
2. July 28, 2016 Comments Delivered at Dental Board Workshop and submitted via fax by Dr. Mark Singleton

California Society of
ANESTHESIOLOGISTS
Physicians for Vital Times

Phone (916) 290 5830
Fax (916) 444 7462
Web csahq.org
Address One Capitol Mall, Suite 800
Sacramento, CA 95814

June 30, 2016

Steven G. Morrow, DDS, MS
President, Dental Board of California
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

RE: CSA Response to Dental Board of California Anesthesia Project Invitation

Dear Dr. Morrow:

The California Society of Anesthesiologists (*hereafter*; CSA) greatly appreciates your invitation to provide you and the Dental Board of California (*hereafter*; DBC) with input into the safe administration and monitoring of sedation and general anesthesia, and assessment of whether or not California law provides sufficient protection to pediatric patients during dental anesthesia procedures.

CSA has been on record several times this year by way of AB 2235 (Thurmond), stating that we collectively must do everything in our power to prevent the inappropriate use of anesthesia and the adverse events that can result. To that end, we applaud the DBC in taking a leadership role in addressing those issues raised by State Senator Jerry Hill (D-San Mateo) in his letter to the DBC on February 8, 2016.

We await your draft report prior to the full DBC meeting in Sacramento on August 18-19, 2016, and the opportunity to provide additional comments at that time. To that end, you will find attached documents that we hope will suggest further ways for California law, regulations, and/or policies to protect pediatric patients during dental anesthesia procedures:

- **42 C.F.R. § 482.52 Condition of Participation: Anesthesia Services:** *Please note the five classes of healthcare practitioners who may provide anesthesia services. The five classes are: physician anesthesiologists; other doctors of medicine or osteopathy; certain dentists, oral surgeons and podiatrists; nurse anesthetists; and anesthesiologist assistants.*
- **ASA Policy on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (October 15, 2014)**
- **ASA Statement on Granting Privileges to Non-Anesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (October 17, 2012)**
- **ASA Statement on the Anesthesia Care Team (October 16, 2013)**
- **ASA Standards for Basic Anesthetic Monitoring (October 28, 2015)**
- **42 C.F.R. § 482.13 Condition of Participation: Patient's Rights**
- ***"Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists"* Anesthesiology 2002; 96:1004–17**
- ***"Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"* developed and endorsed by the American Academy of Pediatrics and the American Academy of Pediatric Dentistry (adopted 2006; reaffirmed 2011)**
- **CSA Patient Safety Bill of Rights: Patient Safety Across the Continuum for Deep Sedation/General Anesthesia (adopted June 5, 2016)**
- **AAP Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016**

Although we at the CSA are not experts in the practice of dentistry, it is important to note that physician anesthesiologists are the only medical professionals recognized by the Institutes of Medicine for implementing patient safety measures and protocols that have resulted in a 50-fold decrease in deaths.[1] Therefore, we strongly believe that the standard of care regarding the administration and monitoring of anesthesia services must be consistent, whether the patient is six years of age or 60, and whether anesthesia care is delivered in a dental office, ambulatory surgery center or acute care hospital.

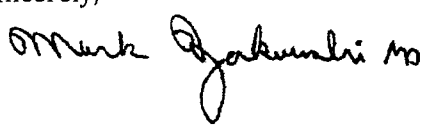
To ensure patient safety, many states require cardiac monitoring for deep sedation. Because sedation is a continuum, moderate sedation can easily progress to deep sedation. As a result, the monitors required for deep sedation should be applied equally to cases under moderate sedation. These include pulse oximetry, ECG and capnography. Otherwise, each time a patient slips into deep sedation (which can happen frequently), the facility runs the risk of non-compliance.

As reported in a national audit in the United Kingdom, "Emergency airway management outside the operating theater is known to be associated with more frequent problems than routine anaesthesia."[2] They found the second most common factor in avoidable airway events/deaths was education and training. These facts support limiting deep sedation and general anesthesia to the most qualified providers, as these techniques may lead to avoidable patient deaths in the hands of personnel with less training. It is critical for the facility and staff at all times to maintain the ability to manage emergency airway complications, including laryngospasm, with appropriate drugs and equipment. The definitive treatment for life-threatening laryngospasm is the administration of succinylcholine, a fast acting muscle relaxant (i.e. paralytic), (listed in Appendix 3, AAP/AAPD guideline). Please note that facilities which stock or use succinylcholine are also required to have a Malignant Hyperthermia kit immediately available on site to treat this life-threatening side effect of succinylcholine in genetically susceptible individuals.

Again, the CSA appreciates the opportunity to provide our insights. We also reaffirm our commitment and unconditional willingness to continue working with you, the Dental Board of California and all other stakeholders to ensure we are doing everything in our power to protect all patients.

Please feel free to contact CSA Legislative Advocate Bryce Docherty, at 916-448-2162 or via e-mail at bdocherty@ka-pow.com should you have any further questions or need additional information.

Sincerely,



Mark Zakowski, MD
President

cc: Karen Fischer, Executive Director, Dental Board of California
Honorable Jerry Hill (D-San Mateo)
Honorable Tony Thurmond (D-Richmond)
Bryce Docherty, KP Public Affairs

---

[1] *To Err is Human*, Institute of Medicine, 1999

[2] Cook TM, Woodall N, Frerk C; Fourth National Audit Project. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. http://www.rcoa.ac.uk/nap4

Code of Federal Regulations
Title 42. Public Health
Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)
Subchapter G. Standards and Certification (Refs & Annos)
Part 482. Conditions of Participation for Hospitals (Refs & Annos)
Subpart D. Optional Hospital Services

42 C.F.R. § 482.52

§ 482.52 Condition of participation: Anesthesia services.

Effective: January 1, 2008
Currentness

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

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(2) An intraoperative anesthesia record.

(3) A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

(4) [Reserved by 72 FR 66934]

(c) Standard: State exemption.

(1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

Credits

[57 FR 33900, July 31, 1992; 66 FR 4686, Jan. 18, 2001; 66 FR 15352, March 19, 2001; 66 FR 27598, May 18, 2001; 66 FR 56768, 56769, Nov. 13, 2001; 71 FR 68694, Nov. 27, 2006; 72 FR 66934, Nov. 27, 2007]

SOURCE: 51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 41338, Nov. 14, 1986; 53 FR 6549, March 1, 1988; 57 FR 7136, Feb. 28, 1992; 57 FR 33899, July 31, 1992, unless otherwise noted; 59 FR 46514, Sept. 8, 1994; 60 FR 50442, Sept. 29, 1995; 64 FR 66279, Nov. 24, 1999; 71 FR 71334, Dec. 8, 2006; 72 FR 15273, March 30, 2007; 77 FR 29028, May 16, 2012, unless otherwise noted.

AUTHORITY: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Current through April 21, 2016; 81 FR 23441.

End of Document

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American Society of Anesthesiologists®

CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 13, 1999, and last amended on October 15, 2014)

	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia ("Conscious Sedation")*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is 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.

* Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

STATEMENT ON GRANTING PRIVILEGES TO NONANESTHESIOLOGIST PHYSICIANS FOR PERSONALLY ADMINISTERING OR SUPERVISING DEEP SEDATION

(Approved by the ASA House of Delegates on October 18, 2006, and amended on October 17, 2012)

Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges for deep sedation should be granted only to nonanesthesiologist physicians who are qualified and trained in the medical practice of deep sedation and the recognition of and rescue from general anesthesia.

Nonanesthesiologist physicians may neither delegate nor supervise the administration or monitoring of deep sedation by individuals who are not themselves qualified and trained to administer deep sedation, and the recognition of and rescue from general anesthesia.

American Society of Anesthesiologists®

STATEMENT ON THE ANESTHESIA CARE TEAM

Committee of Origin: Anesthesia Care Team

(Approved by the ASA House of Delegates on October 26, 1982, and last amended on October 16, 2013)

Anesthesiology is the practice of medicine including, but not limited to, preoperative patient evaluation, anesthetic planning, intraoperative and postoperative care and the management of systems and personnel that support these activities. In addition, anesthesiology includes perioperative consultation, the management of coexisting disease, the prevention and management of untoward perioperative patient conditions, the treatment of acute and chronic pain, and the practice of critical care medicine. This care is personally provided by or directed by the anesthesiologist.

In the interests of patient safety and quality of care, the American Society of Anesthesiologists believes that the involvement of an anesthesiologist in the perioperative care of every patient is necessary. Almost all anesthesia care is either provided personally by an anesthesiologist or is provided by a non-physician anesthesia practitioner directed by an anesthesiologist. The latter mode of anesthesia delivery is called the Anesthesia Care Team and involves the delegation of monitoring and appropriate tasks by the physician to non-physicians. Such delegation should be specifically defined by the anesthesiologist and should also be consistent with state law or regulations and medical staff policy. Although selected tasks of overall anesthesia care may be delegated to qualified members of the Anesthesia Care Team, overall responsibility for the Anesthesia Care Team and patients' safety ultimately rests with the anesthesiologist.

Definitions

1. Core Members of the Anesthesia Care Team

The Anesthesia Care Team includes both physicians and non-physicians. All members of the team have an obligation to accurately identify themselves and other team members to patients and families. Anesthesiologists should not permit the misrepresentation of non-physician personnel as resident physicians or practicing physicians. The nomenclature below is appropriate terminology for this purpose.

a. Physicians

ANESTHESIOLOGIST: **Director of the Anesthesia Care Team;** a **physician** licensed to practice medicine who has successfully completed a training program in anesthesiology accredited by the ACGME, the American Osteopathic Association or equivalent organizations.

ANESTHESIOLOGY FELLOW: An **anesthesiologist** enrolled in a training program to obtain additional education in one of the subdisciplines of anesthesiology.

ANESTHESIOLOGY RESIDENT: A **physician** enrolled in an accredited anesthesiology residency program.

b. Non-physicians

ANESTHETIST: A **nurse anesthetist** or **anesthesiologist assistant**, as each is defined below. (Note: In some countries where non-physicians do not participate in the administration of anesthesia, a physician who practices anesthesiology is known as an "anaesthetist" or "anesthetist")

NURSE ANESTHETIST: A **registered nurse** who has satisfactorily completed an accredited nurse anesthesia training program and certifying examination (also, "CRNA").

ANESTHESIOLOGIST ASSISTANT: A **health professional** who has satisfactorily completed an accredited anesthesiologist assistant training program and certifying examination (also, "AA").

STUDENT NURSE ANESTHETIST: A **registered nurse** who is enrolled in an accredited nurse anesthesia training program.

ANESTHESIOLOGIST ASSISTANT STUDENT: A **health profession graduate student** who has satisfied all prerequisite coursework typical of an accredited school of medicine and is enrolled in an accredited anesthesiologist assistant training program.

NON-PHYSICIAN ANESTHESIA STUDENT: Student nurse anesthetists, anesthesiologist assistant students, dental anesthesia students and others who are enrolled in accredited anesthesia training programs.

OTHERS: Although not considered core members of the Anesthesia Care Team, other health care professionals make important contributions to the perianesthetic care of the patient (see Addendum A).

2. Additional Terms

ANESTHESIA CARE TEAM: Anesthesiologists supervising resident physicians and/or directing qualified non-physician anesthesia practitioners in the provision of anesthesia care, wherein the physician may delegate monitoring and appropriate tasks while retaining overall responsibility for the patient.

QUALIFIED ANESTHESIA PERSONNEL OR PRACTITIONERS: Anesthesiologists, anesthesiology fellows, anesthesiology residents, oral surgery residents, anesthesiologist assistants, and nurse anesthetists.

MEDICAL SUPERVISION AND MEDICAL DIRECTION: Terms used to describe the physician work required to oversee, manage and guide both residents and non-physician members of the Anesthesia Care Team. For the purposes of this statement, supervision

and direction are interchangeable and have no relation to the billing, payment or regulatory definitions that provide distinctions between these two terms (see Addendum B).

SEDATION NURSE AND SEDATION PHYSICIAN ASSISTANT: A licensed registered nurse, advanced practice nurse or physician assistant who is trained in compliance with all relevant local, institutional, state and/or national standards, policies or guidelines to administer prescribed sedating and analgesic medications and monitor patients during minimal sedation ("anxiolysis") or moderate sedation ("conscious sedation"), but not deeper levels of sedation or general anesthesia. Sedation nurses and sedation physician assistants may only work under the direct supervision of a properly trained and privileged physician (MD or DO).

PROCEDURE ROOM: An operating room or other location where an operation or procedure is performed under anesthesia care.

IMMEDIATELY AVAILABLE: Wherever it appears in this document, the phrase "immediately available" is used as defined in the ASA policy statement "Definition of 'Immediately Available' When Medically Directing" (see Addendum C).

Safe Conduct of the Anesthesia Care Team

In order to achieve optimum patient safety, the anesthesiologist who directs the Anesthesia Care Team is responsible for the following:

1. **Management of personnel**: Anesthesiologists should assure the assignment of appropriately skilled physician and/or non-physician personnel for each patient and procedure.

2. **Preanesthetic evaluation of the patient**: A preanesthetic evaluation allows for the development of an anesthetic plan that considers all conditions and diseases of the patient that may influence the safe outcome of the anesthetic. Although non-physicians may contribute to the preoperative collection and documentation of patient data, the anesthesiologist is responsible for the overall evaluation of each patient.

3. **Prescribing the anesthetic plan**: The anesthesiologist is responsible for prescribing an anesthesia plan aimed at the greatest safety and highest quality for each patient. The anesthesiologist discusses with the patient or guardian, as appropriate, the anesthetic risks, benefits and alternatives, and obtains informed consent. When part of the anesthetic care will be performed by another qualified anesthesia practitioner, the anesthesiologist should inform the patient that delegation of anesthetic duties is included in care provided by the Anesthesia Care Team.

4. **Management of the anesthetic**: The management of an anesthetic is dependent on many factors including the unique medical conditions of individual patients and the procedures being performed. Anesthesiologists will determine which perioperative tasks, if any, may be delegated. The anesthesiologist may delegate specific tasks to qualified

non-anesthesiologist members of the Anesthesia Care Team providing that quality of care and patient safety are not compromised, will participate in critical parts of the anesthetic, and will remain immediately available for management of emergencies regardless of the type of anesthetic (see Addendum C).

5. **Postanesthesia care**: Routine postanesthesia care is delegated to postanesthesia nurses. The evaluation and treatment of postanesthetic complications are the responsibility of the anesthesiologist.

6. **Anesthesia consultation**: Like other forms of medical consultation, this is the practice of medicine and should not be delegated to non-physicians.

Safe Conduct of Minimal and Moderate Sedation Utilizing Sedation Nurses and Physician Assistants

The supervising physician is responsible for all aspects of the continuum of care: pre-, intra-, and post-procedure. While a patient is sedated, the responsible physician must be physically present and immediately available in the procedure suite. Although the supervising physician is primarily responsible for pre-procedure patient evaluation, sedation practitioners must be trained adequately in pre-procedure patient evaluation to recognize when risk may be increased, and related policies and procedures must allow sedation practitioners to refuse to participate in specific cases if they perceive a threat to quality of care or patient safety.

The supervising physician is responsible for leading any acute resuscitation needs, including emergency airway management. Therefore, ACLS (PALS or NALS where appropriate) certification must be a standard requirement for sedation practitioners and for credentialing and privileging the non-anesthesiologist physicians who supervise them. However, because non-anesthesia professionals seldom perform controlled mask ventilation or tracheal intubation often enough to remain proficient, their training should emphasize avoidance of excessive sedation over rescue techniques.

Medical Supervision of Nurse Anesthetists by Non-Anesthesiologist Physicians

Note: In this section, the term "surgeon" may refer to any appropriately trained, licensed and credentialed non-anesthesiologist physician who may supervise nurse anesthetists when consistent with applicable law.

General anesthesia, regional anesthesia, and monitored anesthesia care expose patients to risks. Non-anesthesiologist physicians may not possess the expertise that uniquely qualifies and enables anesthesiologists to manage the most clinically challenging medical situations that arise during the perioperative period. While a few surgical training programs (such as oral surgery and maxillofacial surgery) provide some anesthesia-specific education, no non-anesthesiology programs prepare their graduates to provide an anesthesiologist's level of medical supervision and perioperative clinical expertise. However, surgeons and other physicians significantly add to patient safety and quality of care by assuming medical responsibility for perioperative care when an anesthesiologist is not present.

Anesthetic and surgical complications often arise unexpectedly and require immediate medical diagnosis and treatment, even if state law or regulation says a physician is not required to supervise non-physician anesthesia practitioners. The surgeon may be the only physician on site. Whether the need is preoperative medical assessment or intraoperative resuscitation from an unexpected complication, the surgeon may be called upon, as the most highly trained professional present, to provide medical direction of perioperative health care, including nurse anesthesia care. To optimize patient safety, careful consideration is required when a surgeon will be the only physician available, as in some small hospitals, freestanding surgery centers, and surgeons' offices. In the event of an emergency, lack of immediate support from other physicians trained in critical medical management may reduce the likelihood of successful resuscitation. This should be taken into account when deciding which procedures should be performed in settings without an anesthesiologist, and which patients are appropriate candidates.

Medical Supervision of Non-Physician Anesthesia Students

Anesthesiologists who teach non-physician anesthesia students are dedicated to their education and to providing optimal safety and quality of care to every patient. The ASA Standards for Basic Anesthetic Monitoring define the minimum conditions necessary for the safe conduct of anesthesia. The first standard states, "Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care." This statement does not completely address the issue of safe patient care during the training of non-physician student anesthetists. Further clarification of the issues involved is in the best interests of patients, students, and anesthesia practitioners.

During 1:1 supervision of non-physician anesthesia students, it may become necessary for the supervising anesthesiologist or nurse anesthetist to leave briefly to attend to other urgent needs or duties. This should only occur in circumstances judged to cause no significant increased risk to the patient.

This practice is to be distinguished from that of scheduling a non-physician student as the primary anesthetist, meaning that no fully-trained anesthesia practitioner is also continuously present to monitor the anesthetized patient. Though the brief interruption of 1:1 student supervision may be unavoidable for the efficient and safe functioning of a department of anesthesiology, the use of non-physician students as primary anesthetists in place of fully trained and credentialed anesthesia personnel is not endorsed as a best practice by the ASA. While the education of non-physician anesthesia students is an important goal, patient safety remains paramount. Therefore, the supervision of students at a ratio other than 1:1 must meet criteria designed to protect the safety and rights of patients and students, as well as the best interests of all other parties directly or indirectly involved: anesthesia practitioners, families, and health care institutions.

1. **Delegation**: All delegating anesthesiologists and the department chairperson must deem non-physician student anesthetists fully capable of performing all duties delegated to them, and all students must express agreement with accepting responsibility delegated to them.

2. **Privileging**: An official privileging process must individually deem each student as qualified to be supervised 1:2 by an anesthesiologist who remains immediately available (see Addendum C). Students must not be so privileged until they have completed a significant portion of their didactic and clinical training and have achieved expected levels of safety and quality (if at all, no earlier than the last 3-4 months of training). Privileging must be done under the authority of the chair of anesthesiology and in compliance with all federal, state, and professional organization and institutional requirements.

3. **Case Assignment and Supervision**: Students must be supervised at a 1:1 or 1:2 anesthesiologist to student ratio. Assignment of cases to students must be done in a manner that assures the best possible outcome for patients and the best education of students, and must be commensurate with the skills, training, experience, knowledge and willingness of each individual non-physician student. Care should be taken to avoid placing students in situations beyond their level of skill. It is expected that most students will gain experience caring for high-risk patients under the continuous supervision of qualified anesthesia practitioners. This is in the best interest of education and patient safety. The degree of continuous supervision must be at a higher level than that required for fully credentialed anesthesiologist assistants and nurse anesthetists. If an anesthesiologist is engaged in the supervision of non-physician students, he/she must remain immediately available. This means not leaving the procedure suite to provide other concurrent services or clinical duties that would be considered appropriate if directing fully credentialed anesthesiologist assistants or nurse anesthetists.

4. **Back-up Support**: If an anesthesiologist is concurrently supervising two non-physician students assigned as primary anesthetists (meaning the only anesthesia personnel continuously present with a patient), the anesthesiologist could be needed simultaneously in both rooms. To mitigate this potential risk, one other qualified anesthesia practitioner must also be designated to provide back-up support and must remain immediately available.

5. **Informed Consent**: The chair of anesthesiology is responsible for assuring that every patient (or the patient's guardian) understands through a standardized departmental informed consent process that the patient may be in the procedure room with only a non-physician student physically present, although still directed by the responsible anesthesiologist. In the best interest of all involved parties, documentation of this aspect of informed consent must be included in the informed consent statement.

6. **Disclosure to Professional Liability Carrier**: To be assured of reliable professional liability insurance coverage for all involved (qualified anesthesia practitioners, their employers and the institution), the chair of anesthesiology must notify the responsible professional liability carrier(s) of the practice of allowing non-physician anesthesia students to provide care without continuous direct supervision by a fully trained, credentialed and qualified anesthesia practitioner.

ADDENDUM A

1. **Other personnel involved in perianesthetic care:**

   POSTANESTHESIA NURSE: A **registered nurse** who cares for patients recovering from anesthesia.

   PERIOPERATIVE NURSE: A **registered nurse** who cares for the patient in the procedure room.

   CRITICAL CARE NURSE: A **registered nurse** who cares for patients in a special care area such as an intensive care unit.
   OBSTETRIC NURSE: A **registered nurse** who provides care to patients during labor and delivery.

   NEONATAL NURSE: A **registered nurse** who provides cares to neonates in special care units.

   RESPIRATORY THERAPIST: An **allied health professional** who provides respiratory care to patients.

   CARDIOVASCULAR PERFUSIONIST: An **allied health professional** who operates cardiopulmonary bypass machines.

2. **Support personnel for technical procedures, equipment, supply and maintenance:**

   ANESTHESIA TECHNOLOGISTS AND TECHNICIANS
   ANESTHESIA AIDES
   BLOOD GAS TECHNICIANS
   RESPIRATORY TECHNICIANS
   MONITORING TECHNICIANS

ADDENDUM B

Commonly Used Payment Rules and Definitions

ASA recognizes the existence of commercial and governmental payer rules applicable to payment for anesthesia services and encourages its members to comply with them. Commonly prescribed duties include:

- Performing a preanesthetic history and physical examination of the patient;
- Prescribing the anesthetic plan;
- Personal participation in the most demanding portions of the anesthetic, including induction and emergence, where applicable;
- Delegation of anesthesia care only to qualified anesthesia practitioners;

- Monitoring the course of anesthesia at frequent intervals;
- Remaining immediately available for diagnosis and treatment while medically responsible;
- Providing indicated postanesthesia care;
- Performing and documenting a post-anesthesia evaluation.

ASA also recognizes the lack of total predictability in anesthesia care and the variability in patient needs. In certain rare circumstances, it may be inappropriate from the viewpoint of overall patient safety and quality to comply with all payment rules at every moment in time. Reporting of services for payment must accurately reflect the services provided. The ability to prioritize duties and patient care needs, moment to moment, is a crucial skill of the anesthesiologist functioning safely within the Anesthesia Care Team. Anesthesiologists must strive to provide the highest quality of care and greatest degree of patient safety to all patients in the perioperative environment at all times.

MEDICAL "DIRECTION" by anesthesiologists: A payment term describing the specific anesthesiologist work required and restrictions involved in billing payers for the management and oversight of non-physician anesthesia practitioners. This pertains to situations where anesthesiologists are involved in not more than four concurrent anesthetics.

MEDICAL "SUPERVISION" by anesthesiologists: Medicare payment policy contains a special payment formula for "medical supervision" which applies "when the anesthesiologist is involved in furnishing more than four procedures concurrently or is performing other services while directing the concurrent procedures." [Note: The word "supervision" may also be used outside of the Anesthesia Care Team to describe the perioperative medical oversight of non-physician anesthesia practitioners by the operating practitioner/surgeon. Surgeon-provided supervision pertains to general medical management and to the components of anesthesia care that are physician and not nursing functions (e.g., determining medical readiness of patients for anesthesia and surgery, and providing critical medical management of unexpected emergencies).]

See the Medicare Claims Processing Manual (Chapter 12, Section 50.C-D) and individual payer manuals for additional information.

ADDENDUM C

Definition of "Immediately Available" When Medically Directing (HOD 2012)

A medically directing anesthesiologist is immediately available if s/he is in physical proximity that allows the anesthesiologist to return to re-establish direct contact with the patient to meet medical needs and address any urgent or emergent clinical problems. These responsibilities may also be met through coordination among anesthesiologists of the same group or department.

Differences in the design and size of various facilities and demands of the particular surgical procedures make it impossible to define a specific time or distance for physical proximity.

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, last amended on October 20, 2010, and last affirmed on October 28, 2015)

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual† monitoring may be unavoidable. These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

1. STANDARD I

Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

1.1 Objective –

Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

2. STANDARD II

During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

2.1 Oxygenation –

2.1.1 Objective –

To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

2.2 Methods –

2.2.1 Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

2.2.2 Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.* When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.* Adequate illumination and exposure of the patient are necessary to assess color.*

3. VENTILATION

3.1 Objective –

To ensure adequate ventilation of the patient during all anesthetics.

3.2 Methods –

3.2.1 Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*

3.2.2 When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.* When capnography or capnometry is utilized, the end tidal CO2 alarm shall be audible to the anesthesiologist or the anesthesia care team personnel.*

3.2.3 When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

3.2.4 During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep 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.

4. CIRCULATION

4.1 Objective –

To ensure the adequacy of the patient's circulatory function during all anesthetics.

4.2 Methods –

4.2.1 Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*

4.2.2 Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*

4.2.3 Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

5. BODY TEMPERATURE

5.1 Objective –

To aid in the maintenance of appropriate body temperature during all anesthetics.

5.2 Methods –

Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

† Note that "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

* Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.

Code of Federal Regulations
Title 42. Public Health
Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)
Subchapter G. Standards and Certification (Refs & Annos)
Part 482. Conditions of Participation for Hospitals (Refs & Annos)
Subpart B. Administration

42 C.F.R. § 482.13

§ 482.13 Condition of participation: Patient's rights.

Effective: July 16, 2012
Currentness

A hospital must protect and promote each patient's rights.

(a) Standard: Notice of rights—

(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) Standard: Exercise of rights.

(1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) Standard: Privacy and safety.

(1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) Standard: Confidentiality of patient records.

(1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) Standard: Restraint or seclusion. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) Definitions.

(i) A restraint is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

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(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician or other licensed independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

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(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1–hour face-to-face evaluation.

(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

(i) The 1–hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and

(v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) Standard: Restraint or seclusion: Staff training requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

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(1) Training intervals. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) Training content. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1–hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) Trainer requirements. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) Training documentation. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

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(g) Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c), medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) Standard: Patient visitation rights. A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Credits

[64 FR 36088, July 2, 1999; 71 FR 71426, Dec. 8, 2006; 75 FR 70844, Nov. 19, 2010; 77 FR 29074, May 16, 2012]

SOURCE: 51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 41338, Nov. 14, 1986; 53 FR 6549, March 1, 1988; 57 FR 7136, Feb. 28, 1992; 57 FR 33899, July 31, 1992, unless otherwise noted; 59 FR 46514, Sept. 8, 1994; 60 FR 50442, Sept. 29, 1995; 64 FR 66279, Nov. 24, 1999; 71 FR 71334, Dec. 8, 2006; 72 FR 15273, March 30, 2007; 77 FR 29028, May 16, 2012, unless otherwise noted.

AUTHORITY: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Notes of Decisions (9)

Current through May 12, 2016; 81 FR 29694.

End of Document

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Anesthesiology 2002; 96:1004-17 © 2002 American Society of Anesthesiologists, Inc. Lippincott Williams & Wilkins, Inc.

Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists

An Updated Report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists

ANESTHESIOLOGISTS possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called on to participate in the development of institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists (ASA) has developed these "Guidelines for Sedation and Analgesia by Non-Anesthesiologists."

Practice guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. The guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.

This revision includes data published since the "Guidelines for Sedation and Analgesia by Non-Anesthesiologists" were adopted by the ASA in 1995; it also includes data and recommendations for a wider range of sedation levels than was previously addressed.

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to the following address, click on Enhancements Index, and then scroll down to find the appropriate article and link. http://www.anesthesiology.org

Definitions

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia. Definitions of levels of sedation–analgesia, as developed and adopted by the ASA, are given in table 1. These Guidelines specifically apply to levels of sedation corresponding to moderate sedation (frequently called conscious sedation) and deep sedation, as defined in table 1.

Focus

These Guidelines are designed to be applicable to procedures performed in a variety of settings (*e.g.*, hospitals, freestanding clinics, physician, dental, and other offices) by practitioners who are not specialists in anesthesiology. Because minimal sedation (anxiolysis) entails minimal risk, the Guidelines specifically exclude it. Examples of minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either (1) less than 50% nitrous oxide (N_2O) in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The Guidelines also exclude patients who are not undergoing a diagnostic or therapeutic procedure (*e.g.*, postoperative analgesia, sedation for treatment of insomnia). Finally, the Guidelines do not apply to patients receiving general or major conduction anesthesia (*e.g.*, spinal or epidural/caudal block), whose care should be provided, medically directed, or supervised by an anesthesiologist, the operating practitioner, or another licensed physician with specific training in sedation, anesthesia, and rescue techniques appropriate to the type of sedation or anesthesia being provided.

Purpose

The purpose of these Guidelines is to allow clinicians to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Se-

Developed by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists: Jeffrey B. Gross, M.D. (Chair), Farmington, CT; Peter L. Bailey, M.D., Rochester, NY; Richard T. Connis, Ph.D., Woodinville, WA; Charles J. Coté, M.D., Chicago, IL; Fred G. Davis, M.D., Burlington, MA; Burton S. Epstein, M.D., Washington, DC; Lesley Gilbertson, M.D., Boston, MA; David G. Nickinovich, Ph.D., Bellevue, WA; John M. Zerwas, M.D., Houston, TX; Gregory Zuccaro, Jr., M.D., Cleveland, OH.

Submitted for publication November 30, 2001. Accepted for publication November 30, 2001. Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chairman, Committee on Practice Parameters. Approved by the House of Delegates, October 17, 2001. A list of the references used to develop these Guidelines is available by writing to the American Society of Anesthesiologists. These Guidelines have been endorsed by The American College of Radiology, The American Association of Oral and Maxillofacial Surgeons, and The American Society for Gastrointestinal Endoscopy.

The accompanying Web site enhancement is a bibliography.

Address reprint requests to American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

Table 1. Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) = a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (Conscious Sedation) = 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.

Deep Sedation/Analgesia = a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia = a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering *Moderate Sedation/Analgesia (Conscious Sedation)* should be able to rescue patients who enter a state of *Deep Sedation/Analgesia*, while those administering *Deep Sedation/Analgesia* should be able to rescue patients who enter a state of general anesthesia.

* Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Developed by the American Society of Anesthesiologists; approved by the ASA House of Delegates October 13, 1999.

dation/analgesia provides two general types of benefit: (1) sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain; and (2) in children and uncooperative adults, sedation-analgesia may expedite the conduct of procedures that are not particularly uncomfortable but that require that the patient not move. At times, these sedation practices may result in cardiac or respiratory depression, which must be rapidly recognized and appropriately managed to avoid the risk of hypoxic brain damage, cardiac arrest, or death. Conversely, inadequate sedation-analgesia may result in undue patient discomfort or patient injury because of lack of cooperation or adverse physiologic or psychological response to stress.

Application

These Guidelines are intended to be general in their application and broad in scope. The appropriate choice of agents and techniques for sedation/analgesia is dependent on the experience and preference of the individual practitioner, requirements or constraints imposed by the patient or procedure, and the likelihood of producing a deeper level of sedation than anticipated. Because it is not always possible to predict how a specific patient will respond to sedative and analgesic medications, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. For moderate sedation, this implies the ability to manage a compromised airway or hypoventilation in a patient who *responds purposefully* after repeated or painful stimulation, whereas for deep sedation, this implies the ability to manage respiratory or cardiovascular instability in a patient who *does not respond purposefully* to painful or repeated stimulation. Levels of sedation referred to in the recommendations relate to the level of sedation intended by the practitioner. Examples are provided to illustrate airway assessment, preoperative fasting, emergency equipment, and recovery procedures; however, clinicians and their institutions have ultimate responsibility for selecting patients, procedures, medications, and equipment.

Unauthorized Use Prohibited

Task Force Members and Consultants

The ASA appointed a Task Force of 10 members to (1) review the published evidence; (2) obtain the opinion of a panel of consultants, including non-anesthesiologist physicians and dentists who routinely administer sedation-analgesia, as well as of anesthesiologists with a special interest in sedation-analgesia (see Appendix I); and (3) build consensus within the community of practitioners likely to be affected by the Guidelines. The Task Force included anesthesiologists in both private and academic practices from various geographic areas of the United States, a gastroenterologist, and methodologists from the ASA Committee on Practice Parameters.

This Practice Guideline is an update and revision of the ASA "Guidelines for Sedation and Analgesia by Non-

Anesthesiologists."[1] The Task Force revised and updated the Guidelines by means of a five-step process. First, original published research studies relevant to the revision and update were reviewed and analyzed; only articles relevant to the administration of sedation by nonanesthesiologists were evaluated. Second, the panel of expert consultants was asked to (1) participate in a survey related to the effectiveness and safety of various methods and interventions that might be used during sedation–analgesia, and (2) review and comment on the initial draft report of the Task Force. Third, the Task Force held open forums at two major national meetings to solicit input on its draft recommendations. National organizations representing most of the specialties whose members typically administer sedation–analgesia were invited to send representatives. Fourth, the consultants were surveyed to assess their opinions on the feasibility and financial implications of implementing the revised and updated Guidelines. Finally, all of the available information was used by the Task Force to finalize the Guidelines.

Availability and Strength of Evidence

Evidence-based Guidelines are developed by a rigorous analytic process. To assist the reader, the Guidelines make use of several descriptive terms that are easier to understand than the technical terms and data that are used in the actual analyses. These descriptive terms are defined below.

The following terms describe the strength of scientific data obtained from the scientific literature:

Supportive: There is sufficient quantitative information from adequately designed studies to describe a statistically significant relationship ($P < 0.01$) between a clinical intervention and a clinical outcome, using metaanalysis.

Suggestive: There is enough information from case reports and descriptive studies to provide a directional assessment of the relationship between a clinical intervention and a clinical outcome. This type of qualitative information does not permit a statistical assessment of significance.

Equivocal: Qualitative data have not provided a clear direction for clinical outcomes related to a clinical intervention, and (1) there is insufficient quantitative information or (2) aggregated comparative studies have found no quantitatively significant differences among groups or conditions.

The following terms describe the *lack* of available scientific evidence in the literature:

Inconclusive: Published studies are available, but they cannot be used to assess the relation between a clinical intervention and a clinical outcome because the studies either do not meet predefined criteria for content as defined in the "Focus" of these Guidelines, or do not provide a clear causal interpretation of findings because of research design or analytic concerns.

Insufficient: There are too few published studies to investigate a relationship between a clinical intervention and clinical outcome.

Silent: No studies that address a relationship of interest were found in the available published literature.

The following terms describe survey responses from the consultants for any specified issue. Responses were solicited on a five-point scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with a score of 3 being neutral.

Strongly Agree: median score of 5
Agree: median score of 4
Equivocal: median score of 3
Disagree: median score of 2
Strongly Disagree: median score of 1

Guidelines

Patient Evaluation

There is insufficient published evidence to evaluate the relationship between sedation–analgesia outcomes and the performance of a preprocedure patient evaluation. There is suggestive evidence that some preexisting medical conditions may be related to adverse outcomes in patients receiving either moderate or deep sedation/analgesia. The consultants strongly agree that appropriate preprocedure evaluation (history, physical examination) increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes for both moderate and deep sedation.

Recommendations. Clinicians administering sedation/analgesia should be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia. These include: (1) abnormalities of the major organ systems; (2) previous adverse experience with sedation/analgesia as well as regional and general anesthesia; (3) drug allergies, current medications, and potential drug interactions; (4) time and nature of last oral intake; and (5) history of tobacco, alcohol, or substance use or abuse. Patients presenting for sedation/analgesia should undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway. (Example I). Preprocedure laboratory testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia. These evaluations should be confirmed immediately before sedation is initiated.

Example I. Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation–analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

History
- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (*e.g.*, trisomy 21)

Physical Examination
- Habitus
  - Significant obesity (especially involving the neck and facial structures)
- Head and Neck
  - Short neck, limited neck extension, decreased hyoid–mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (*e.g.*, Pierre-Robin syndrome)
- Mouth
  - Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
- Jaw
  - Micrognathia, retrognathia, trismus, significant malocclusion

Preprocedure Preparation

The literature is insufficient regarding the benefits of providing the patient (or legal guardian, in the case of a child or impaired adult) with preprocedure information about sedation and analgesia. For moderate sedation the consultants agree, and for deep sedation the consultants strongly agree that appropriate preprocedure counseling of patients regarding risks, benefits, and alternatives to sedation and analgesia increases patient satisfaction.

Sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation–analgesia achieved. This dependence on level of sedation is reflected in the consultants opinion: They agree that preprocedure fasting decreases risks during moderate sedation, while strongly agreeing that it decreases risks during deep sedation. In emergency situations, when preprocedure fasting is not practical, the consultants agree that the target level of sedation should be modified (*i.e.*, less sedation should be administered) for moderate sedation, while strongly agreeing that it should be modified for deep sedation. The literature does not provide sufficient evidence to test the hypothesis that preprocedure fasting results in a decreased incidence of adverse outcomes in patients undergoing either moderate or deep sedation.

Recommendations. Patients (or their legal guardians in the case of minors or legally incompetent adults) should be informed of and agree to the administration of sedation/analgesia, including its benefits, risks, and limitations associated with this therapy, as well as possible alternatives. Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure, as recommended by the ASA "Guidelines for Preoperative Fasting"[2] (Example II). In urgent, emergent, or other situations in which gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed, or (3) whether the trachea should be protected by intubation.

Monitoring

Level of Consciousness. The response of patients to commands during procedures performed with sedation/analgesia serves as a guide to their level of consciousness. Spoken responses also provide an indication that the patients are breathing. Patients whose only response is reflex withdrawal from painful stimuli are deeply sedated, approaching a state of general anesthesia, and should be treated accordingly. The literature is silent regarding whether monitoring patients' level of consciousness improves patient outcomes or decreases risks. The consultants strongly agree that monitoring level of consciousness reduces risks for both moderate and deep sedation. The members of the Task Force believe that many of the complications associated with sedation and analgesia can be avoided if adverse drug responses are detected and treated in a timely manner (*i.e.*, before the development of cardiovascular decompensation or cerebral hypoxia). Patients given sedatives or analgesics in unmonitored settings in anticipation of a subsequent procedure may be at increased risk of these complications.

Example II. Summary of American Society of Anesthesiologists Preprocedure Fasting Guidelines[2]*

Ingested Material	Minimum Fasting Period†
Clear liquids‡	2 h
Breast milk	4 h
Infant formula	6 h
Nonhuman milk§	6 h
Light meal‖	6 h

* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee a complete gastric emptying has occurred.

† The fasting periods apply to all ages.

‡ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

§ Since nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

‖ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

Pulmonary Ventilation. It is the opinion of the Task Force that the primary causes of morbidity associated with sedation/analgesia are drug-induced respiratory depression and airway obstruction. For both moderate and deep sedation, the literature is insufficient to evaluate the benefit of monitoring ventilatory function by observation or auscultation. However, the consultants strongly agree that monitoring of ventilatory function by observation or auscultation reduces the risk of adverse outcomes associated with sedation/analgesia. The consultants were equivocal regarding the ability of capnography to decrease risks during moderate sedation, while agreeing that it may decrease risks during deep sedation. In circumstances in which patients are physically separated from the caregiver, the Task Force believes that automated apnea monitoring (by detection of exhaled carbon dioxide or other means) may decrease risks during both moderate and deep sedation, while cautioning practitioners that impedance plethysmography may fail to detect airway obstruction. The Task Force emphasizes that because ventilation and oxygenation are separate though related physiologic processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function.

Oxygenation. Published data suggest that oximetry effectively detects oxygen desaturation and hypoxemia in patients who are administered sedatives/analgesics. The consultants strongly agree that early detection of hypoxemia through the use of oximetry during sedation-analgesia decreases the likelihood of adverse outcomes such as cardiac arrest and death. The Task Force agrees that hypoxemia during sedation and analgesia is more likely to be detected by oximetry than by clinical assessment alone.

Hemodynamics. Although there are insufficient published data to reach a conclusion, it is the opinion of the Task Force that sedative and analgesic agents may blunt the appropriate autonomic compensation for hypovolemia and procedure-related stresses. On the other hand, if sedation and analgesia are inadequate, patients may develop potentially harmful autonomic stress responses (*e.g.*, hypertension, tachycardia). Early detection of changes in patients' heart rate and blood pressure may enable practitioners to detect problems and intervene in a timely fashion, reducing the risk of these complications. The consultants strongly agree that regular monitoring of vital signs reduces the likelihood of adverse outcomes during both moderate and deep sedation. For both moderate and deep sedation, a majority of the consultants indicated that vital signs should be monitored at 5-min intervals once a stable level of sedation is established. The consultants strongly agree that continuous electrocardiography reduces risks during deep sedation, while they were equivocal regarding its effect during moderate sedation. However, the Task Force believes that electrocardiographic monitoring of selected patients (*e.g.*, with significant cardiovascular disease or dysrhythmias) may decrease risks during moderate sedation.

Recommendations. Monitoring of patient response to verbal commands should be routine during moderate sedation, except in patients who are unable to respond appropriately (*e.g.*, young children, mentally impaired or uncooperative patients), or during procedures where movement could be detrimental. During deep sedation, patient responsiveness to a more profound stimulus should be sought, unless contraindicated, to ensure that the patient has not drifted into a state of general anesthesia. During procedures where a verbal response is not possible (*e.g.*, oral surgery, upper endoscopy), the ability to give a "thumbs up" or other indication of consciousness in response to verbal or tactile (light tap) stimulation suggests that the patient will be able to control his airway and take deep breaths if necessary, corresponding to a state of moderate sedation. Note that a response limited to reflex withdrawal from a painful stimulus is not considered a purposeful response and thus represents a state of general anesthesia.

All patients undergoing sedation/analgesia should be monitored by pulse oximetry with appropriate alarms. If available, the variable pitch "beep," which gives a continuous audible indication of the oxygen saturation reading, may be helpful. In addition, ventilatory function should be continually monitored by observation or auscultation. Monitoring of exhaled carbon dioxide should be considered for all patients receiving deep sedation and for patients whose ventilation cannot be directly observed during moderate sedation. When possible, blood pressure should be determined before sedation/analgesia is initiated. Once sedation-analgesia is established, blood pressure should be measured at 5-min intervals during the procedure, unless such monitoring interferes with the procedure (*e.g.*, pediatric magnetic resonance imaging, where stimulation from the blood pressure cuff could arouse an appropriately sedated patient). Electrocardiographic monitoring should be used in all patients undergoing deep sedation. It should also be used during moderate sedation in patients with significant cardiovascular disease or those who are undergoing procedures where dysrhythmias are anticipated.

Recording of Monitored Parameters

The literature is silent regarding the benefits of contemporaneous recording of patients' level of consciousness, respiratory function, or hemodynamics. Consultant opinion agrees with the use of contemporaneous recording for moderate sedation and strongly agrees with its use for patients undergoing deep sedation. It is the consensus of the Task Force that, unless technically precluded (*e.g.*, uncooperative or combative patient), vital signs and respiratory variables should be recorded before initiating sedation/analgesia, after administration

of sedative-analgesic medications, at regular intervals during the procedure, on initiation of recovery, and immediately before discharge. It is the opinion of the Task Force that contemporaneous recording (either automatic or manual) of patient data may disclose trends that could prove critical in determining the development or cause of adverse events. In addition, manual recording ensures that an individual caring for the patient is aware of changes in patient status in a timely fashion.

Recommendations. For both moderate and deep sedation, patients' level of consciousness, ventilatory and oxygenation status, and hemodynamic variables should be assessed and recorded at a frequency that depends on the type and amount of medication administered, the length of the procedure, and the general condition of the patient. At a minimum, this should be: (1) before the beginning of the procedure; (2) after administration of sedative-analgesic agents; (3) at regular intervals during the procedure, (4) during initial recovery; and (5) just before discharge. If recording is performed automatically, device alarms should be set to alert the care team to critical changes in patient status.

Availability of an Individual Responsible for Patient Monitoring

Although the literature is silent on this issue, the Task Force recognizes that it may not be possible for the individual performing a procedure to be fully cognizant of the patient's condition during sedation/analgesia. For moderate sedation, the consultants agree that the availability of an individual other than the person performing the procedure to monitor the patient's status improves patient comfort and satisfaction and that risks are reduced. For deep sedation, the consultants strongly agree with these contentions. During moderate sedation, the consultants strongly agree that the individual monitoring the patient may assist the practitioner with interruptible ancillary tasks of short duration; during deep sedation, the consultants agree that this individual should have no other responsibilities.

Recommendation. A designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation/analgesia. During deep sedation, this individual should have no other responsibilities. However, during moderate sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation-analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.

Training of Personnel

Although the literature is silent regarding the effectiveness of training on patient outcomes, the consultants strongly agree that education and training in the pharmacology of agents commonly used during sedation-analgesia improves the likelihood of satisfactory sedation and reduces the risk of adverse outcomes from either moderate or deep sedation. Specific concerns may include: (1) potentiation of sedative-induced respiratory depression by concomitantly administered opioids; (2) inadequate time intervals between doses of sedative or analgesic agents, resulting in a cumulative overdose; and (3) inadequate familiarity with the role of pharmacologic antagonists for sedative and analgesic agents.

Because the primary complications of sedation/analgesia are related to respiratory or cardiovascular depression, it is the consensus of the Task Force that the individual responsible for monitoring the patient should be trained in the recognition of complications associated with sedation/analgesia. Because sedation/analgesia constitutes a continuum, practitioners administering moderate sedation should be able to rescue patients who enter a state of deep sedation, whereas those intending to administer deep sedation should be able to rescue patients who enter a state of general anesthesia. Therefore, the consultants strongly agree that at least one qualified individual trained in basic life support skills (cardiopulmonary resuscitation, bag-valve-mask ventilation) should be present in the procedure room during both moderate and deep sedation. In addition, the consultants strongly agree with the immediate availability (1-5 min away) of an individual with advanced life support skills (*e.g.*, tracheal intubation, defibrillation, use of resuscitation medications) for moderate sedation and in the procedure room itself for deep sedation.

Recommendations. Individuals responsible for patients receiving sedation-analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. Individuals monitoring patients receiving sedation/analgesia should be able to recognize the associated complications. At least one individual capable of establishing a patent airway and positive pressure ventilation, as well as a means for summoning additional assistance, should be present whenever sedation-analgesia is administered. It is recommended that an individual with advanced life support skills be immediately available (within 5 min) for moderate sedation and within the procedure room for deep sedation.

Availability of Emergency Equipment

Although the literature is silent, the consultants strongly agree that the ready availability of appropriately sized emergency equipment reduces risks associated with both moderate and deep sedation. The literature is also silent regarding the need for cardiac defibrillators during sedation/analgesia. During moderate sedation, the consultants agree that a defibrillator should be immediately available for patients with both mild (*e.g.*, hypertension) and severe (*e.g.*, ischemia, congestive failure) cardiovascular disease. During deep sedation, the

consultants agree that a defibrillator should be immediately available for all patients.

Recommendations. Pharmacologic antagonists as well as appropriately sized equipment for establishing a patent airway and providing positive pressure ventilation with supplemental oxygen should be present whenever sedation–analgesia is administered. Suction, advanced airway equipment, and resuscitation medications should be immediately available and in good working order (Example III). A functional defibrillator should be immediately available whenever deep sedation is administered and when moderate sedation is administered to patients with mild or severe cardiovascular disease.

Example III. Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

Intravenous equipment
- Gloves
- Tourniquets
- Alcohol wipes
- Sterile gauze pads
- Intravenous catheters [24-22-gauge]
- Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
- Intravenous fluid
- Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
- Appropriately sized syringes [1-ml syringes]
- Tape

Basic airway management equipment
- Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
- Source of suction
- Suction catheters [pediatric suction catheters]
- Yankauer-type suction
- Face masks [infant/child]
- Self-inflating breathing bag-valve set [pediatric]
- Oral and nasal airways [infant/child-sized]
- Lubricant

Advanced airway management equipment (for practitioners with intubation skills)
- Laryngeal mask airways [pediatric]
- Laryngoscope handles (tested)
- Laryngoscope blades [pediatric]
- Endotracheal tubes
  - Cuffed 6.0, 7.0, 8.0 mm ID
  - [Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm ID]
- Stylet (appropriately sized for endotracheal tubes)

Pharmacologic Antagonists
- Naloxone
- Flumazenil

Emergency medications
- Epinephrine
- Ephedrine
- Vasopressin
- Atropine
- Nitroglycerin (tablets or spray)
- Amiodarone
- Lidocaine
- Glucose, 50% [10 or 25%]
- Diphenhydramine
- Hydrocortisone, methylprednisolone, or dexamethasone
- Diazepam or midazolam

Use of Supplemental Oxygen

The literature supports the use of supplemental oxygen during moderate sedation and suggests that supplemental oxygen be used during deep sedation to reduce the frequency of hypoxemia. The consultants agree that supplemental oxygen decreases patient risk during moderate sedation, while strongly agreeing with this view for deep sedation.

Recommendations. Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered. Supplemental oxygen should be considered for moderate sedation and should be administered during deep sedation unless specifically contraindicated for a particular patient or procedure. If hypoxemia is anticipated or develops during sedation/analgesia, supplemental oxygen should be administered.

Combinations of Sedative–Analgesic Agents

The literature suggests that combining a sedative with an opioid provides effective moderate sedation; it is equivocal regarding whether the combination of a sedative and an opioid may be more effective than a sedative or an opioid alone in providing adequate moderate sedation. For deep sedation, the literature is insufficient to compare the efficacy of sedative–opioid combinations with that of a sedative alone. The consultants agree that combinations of sedatives and opioids provide satisfactory moderate and deep sedation. However, the published data also suggest that combinations of sedatives and opioids may increase the likelihood of adverse outcomes, including ventilatory depression and hypoxemia; the consultants were equivocal on this issue for both moderate and deep sedation. It is the consensus of the Task Force that fixed combinations of sedative and analgesic agents may not allow the individual components of sedation/analgesia to be appropriately titrated to meet the individual requirements of the patient and procedure while reducing the associated risks.

Recommendations. Combinations of sedative and analgesic agents may be administered as appropriate for the procedure being performed and the condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (*e.g.*, additional analgesic medication to relieve pain; additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to cause respiratory depression and airway obstruction emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.

Unauthorized use prohibited

Titration of Intravenous Sedative-Analgesic Medications

The literature is insufficient to determine whether administration of small, incremental doses of intravenous sedative/analgesic drugs until the desired level of sedation or analgesia is achieved is preferable to a single dose based on patient size, weight, or age. The consultants strongly agree that incremental drug administration improves patient comfort and decreases risks for both moderate and deep sedation.

Recommendations. Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired end points of analgesia and sedation. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (*e.g.*, oral, rectal, intramuscular, transmucosal), allowance should be made for the time required for drug absorption before supplementation is considered. Because absorption may be unpredictable, administration of repeat doses of oral medications to supplement sedation/analgesia is not recommended.

Anesthetic Induction Agents Used for Sedation/Analgesia (Propofol, Methohexital, Ketamine)

The literature suggests that, when administered by non-anesthesiologists, propofol and ketamine can provide satisfactory moderate sedation, and suggests that methohexital can provide satisfactory deep sedation. The literature is insufficient to evaluate the efficacy of propofol or ketamine administered by non-anesthesiologists for deep sedation. There is insufficient literature to determine whether moderate or deep sedation with propofol is associated with a different incidence of adverse outcomes than similar levels of sedation with midazolam. The consultants are equivocal regarding whether use of these medications affects the likelihood of producing satisfactory moderate sedation, while agreeing that using them increases the likelihood of satisfactory deep sedation. However, the consultants agree that avoiding these medications decreases the likelihood of adverse outcomes during moderate sedation and are equivocal regarding their effect on adverse outcomes during deep sedation.

The Task Force cautions practitioners that methohexital and propofol can produce rapid, profound decreases in level of consciousness and cardiorespiratory function, potentially culminating in a state of general anesthesia. The Task Force notes that ketamine also produces dose-related decreases in level of consciousness, culminating in general anesthesia. Although it may be associated with less cardiorespiratory depression than other sedatives, airway obstruction, laryngospasm, and pulmonary aspiration may still occur with ketamine. Furthermore, because of its dissociative properties, some of the usual signs of depth of sedation may not apply (*e.g.*, the patient's eyes may be open while in a state of deep sedation or general anesthesia). The Task Force also notes that there are no specific pharmacologic antagonists for any of these medications.

Recommendations. Even if moderate sedation is intended, patients receiving propofol or methohexital by any route should receive care consistent with that required for deep sedation. Accordingly, practitioners administering these drugs should be qualified to rescue patients from any level of sedation, including general anesthesia. Patients receiving ketamine should be cared for in a manner consistent with the level of sedation that is achieved.

Intravenous Access

Published literature is equivocal regarding the relative efficacy of sedative-analgesic agents administered intravenously as compared with those administered by nonintravenous routes to achieve moderate sedation; the literature is insufficient on this issue for deep sedation. The literature is equivocal regarding the comparative safety of these routes of administration for moderate sedation and is insufficient for deep sedation. The consultants strongly agree that intravenous administration of sedative and analgesic medications increases the likelihood of satisfactory sedation for both moderate and deep sedation. They also agree that it decreases the likelihood of adverse outcomes. For both moderate and deep sedation, when sedative-analgesic medications are administered intravenously, the consultants strongly agree with maintaining intravenous access until patients are no longer at risk for cardiovascular or respiratory depression, because it increases the likelihood of satisfactory sedation and decreases the likelihood of adverse outcomes. In situations where sedation is initiated by nonintravenous routes (*e.g.*, oral, rectal, intramuscular), the need for intravenous access is not sufficiently addressed in the literature. However, initiation of intravenous access after the initial sedation takes effect allows additional sedative-analgesic and resuscitation drugs to be administered if necessary.

Recommendations. In patients receiving intravenous medications for sedation/analgesia, vascular access should be maintained throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. In patients who have received sedation-analgesia by nonintravenous routes, or whose intravenous line has become dislodged or blocked, practitioners should determine the advisability of establishing or reestablishing intravenous access on a case-by-case basis. In all instances, an individual with the skills to establish intravenous access should be immediately available.

Reversal Agents

Specific antagonist agents are available for the opioids (*e.g.*, naloxone) and benzodiazepines (*e.g.*, flumazenil). The literature supports the ability of naloxone to reverse opioid-induced sedation and respiratory depression. Practitioners are cautioned that acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema. The literature supports the ability of flumazenil to antagonize benzodiazepine-induced sedation and ventilatory depression in patients who have received benzodiazepines alone or in combination with an opioid. The consultants strongly agree that the immediate availability of reversal agents during both moderate and deep sedation is associated with decreased risk of adverse outcomes. It is the consensus of the Task Force that respiratory depression should be initially treated with supplemental oxygen and, if necessary, positive pressure ventilation by mask. The consultants disagree that the use of sedation regimens that are likely to require routine reversal with flumazenil or naloxone improves the quality of sedation or reduces the risk of adverse outcomes.

Recommendations. Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone or flumazenil may be administered to improve spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines, respectively. This may be especially helpful in cases where airway control and positive pressure ventilation are difficult. Before or concomitantly with pharmacologic reversal, patients who become hypoxemic or apneic during sedation/analgesia should: (1) be encouraged or stimulated to breathe deeply; (2) receive supplemental oxygen; and (3) receive positive pressure ventilation if spontaneous ventilation is inadequate. After pharmacologic reversal, patients should be observed long enough to ensure that sedation and cardiorespiratory depression does not recur once the effect of the antagonist dissipates. The use of sedation regimens that include routine reversal of sedative or analgesic agents is discouraged.

Recovery Care

Patients may continue to be at significant risk for developing complications after their procedure is completed. Decreased procedural stimulation, delayed drug absorption following nonintravenous administration, and slow drug elimination may contribute to residual sedation and cardiorespiratory depression during the recovery period. Examples include intramuscular meperidine-promethazine-chlorpromazine mixtures and oral or rectal chloral hydrate. When sedation-analgesia is administered to outpatients, it is likely that there will be no medical supervision once the patient leaves the medical facility. Although there is not sufficient literature to examine the effects of postprocedure monitoring on patient outcomes, the consultants strongly agree that continued observation, monitoring, and predetermined discharge criteria decrease the likelihood of adverse outcomes for both moderate and deep sedation. It is the consensus of the Task Force that discharge criteria should be designed to minimize the risk for cardiorespiratory depression after patients are released from observation by trained personnel.

Recommendations. Following sedation/analgesia, patients should be observed in an appropriately staffed

Example IV. Recovery and Discharge Criteria after Sedation and Analgesia

Each patient-care facility in which sedation–analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures. Some of the basic principles that might be incorporated in these criteria are enumerated below.

General principles

1. Medical supervision of recovery and discharge after moderate or deep sedation is the responsibility of the operating practitioner or a licensed physician.
2. The recovery area should be equipped with, or have direct access to, appropriate monitoring and resuscitation equipment.
3. Patients receiving moderate or deep sedation should be monitored until appropriate discharge criteria are satisfied. The duration and frequency of monitoring should be individualized depending on the level of sedation achieved, the overall condition of the patient, and the nature of the intervention for which sedation/analgesia was administered. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.
4. Level of consciousness, vital signs, and oxygenation (when indicated) should be recorded at regular intervals.
5. A nurse or other individual trained to monitor patients and recognize complications should be in attendance until discharge criteria are fulfilled.
6. An individual capable of managing complications (*e.g.*, establishing a patent airway and providing positive pressure ventilation) should be immediately available until discharge criteria are fulfilled.

Guidelines for discharge

1. Patients should be alert and oriented; infants and patients whose mental status was initially abnormal should have returned to their baseline status. Practitioners and parents must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat.
2. Vital signs should be stable and within acceptable limits.
3. Use of scoring systems may assist in documentation of fitness for discharge.
4. Sufficient time (up to 2 h) should have elapsed after the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal effects have worn off.
5. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications.
6. Outpatients and their escorts should be provided with written instructions regarding postprocedure diet, medications, activities, and a phone number to be called in case of emergency.

and equipped area until they are near their baseline level of consciousness and are no longer at increased risk for cardiorespiratory depression. Oxygenation should be monitored periodically until patients are no longer at risk for hypoxemia. Ventilation and circulation should be monitored at regular intervals until patients are suitable for discharge. Discharge criteria should be designed to minimize the risk of central nervous system or cardiorespiratory depression after discharge from observation by trained personnel (Example IV).

Special Situations

The literature suggests and the Task Force members concur that certain types of patients are at increased risk for developing complications related to sedation/analgesia unless special precautions are taken. In patients with significant underlying medical conditions (*e.g.*, extremes of age; severe cardiac, pulmonary, hepatic, or renal disease; pregnancy; drug or alcohol abuse) the consultants agree that preprocedure consultation with an appropriate medical specialist (*e.g.*, cardiologist, pulmonologist) decreases the risks associated with moderate sedation and strongly agree that it decreases the risks associated with deep sedation. In patients with significant sedation-related risk factors (*e.g.*, uncooperative patients, morbid obesity, potentially difficult airway, sleep apnea), the consultants are equivocal regarding whether preprocedure consultation with an anesthesiologist increases the likelihood of satisfactory moderate sedation, while agreeing that it decreases adverse outcomes. The consultants strongly agree that preprocedure consultation increases the likelihood of satisfactory outcomes while decreasing risks associated with deep sedation. The Task Force notes that in emergency situations, the benefits of awaiting preprocedure consultations must be weighed against the risk of delaying the procedure.

For moderate sedation, the consultants are equivocal regarding whether the immediate availability of an individual with postgraduate training in anesthesiology increases the likelihood of a satisfactory outcome or decreases the associated risks. For deep sedation, the consultants agree that the immediate availability of such an individual improves the likelihood of satisfactory sedation and that it will decrease the likelihood of adverse outcomes.

Recommendations. Whenever possible, appropriate medical specialists should be consulted before administration of sedation to patients with significant underlying conditions. The choice of specialists depends on the nature of the underlying condition and the urgency of the situation. For severely compromised or medically unstable patients (*e.g.*, anticipated difficult airway, severe obstructive pulmonary disease, coronary artery disease, or congestive heart failure), or if it is likely that sedation to the point of unresponsiveness will be necessary to obtain adequate conditions, practitioners who are not trained in the administration of general anesthesia should consult an anesthesiologist.

References

1. 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. ANESTHESIOLOGY 1996; 84:459–71

2. Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures: A report by the American Society of Anesthesiologist Task Force on Preoperative Fasting. ANESTHESIOLOGY 1999; 90:896–905

Appendix I: Methods and Analyses†

The scientific assessment of these Guidelines was based on the following statements or evidence linkages. These linkages represent directional statements about relationships between sedation/analgesia interventions by non-anesthesiologists and clinical outcomes.

1. A preprocedure patient evaluation, (i.e., history, physical examination, laboratory evaluation, consultation)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
2. Preprocedure preparation of the patient (*e.g.*, counseling, fasting)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
3. Patient monitoring (*i.e.*, level of consciousness, pulmonary ventilation [observation, auscultation], oxygenation [pulse oximetry], automated apnea monitoring [capnography], hemodynamics [electrocardiogram, blood pressure, heart rate])
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
4. Contemporaneous recording of monitored parameters (*e.g.*, level of consciousness, respiratory function, hemodynamics) at regular intervals in patients receiving sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
5. Availability of an individual who is dedicated solely to patient monitoring and safety
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6a. Education and training of sedation and analgesia providers in the pharmacology of sedation–analgesia agents
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

6b. The presence of an individual(s) capable of establishing a patent airway, positive pressure ventilation, and resuscitation (*i.e.*, advanced life-support skills) during a procedure
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

7. Availability of appropriately sized emergency and airway equipment (*e.g.*, laryngeal mask airway, defibrillators)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)

†Readers with special interest in the statistical analysis used in establishing these Guidelines can receive further information by writing to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

b. Reduces adverse outcomes

8. The use of supplemental oxygen during procedures performed with sedation or analgesia
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
9. Use of sedative agents combined with analgesic agents (*e.g.*, sedative-analgesic cocktails, fixed combinations of sedatives and analgesics, titrated combinations of sedatives and analgesics)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
10. Titration of intravenous sedative-analgesic medications to achieve the desired effect
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
11. Intravenous sedation-analgesic medications specifically designed to be used for general anesthesia (*i.e.*, methohexital, propofol, and ketamine)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12a. Administration of sedative-analgesic agents by the intravenous route
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

12b. Maintaining or establishing intravenous access during sedation or analgesia until the patient is no longer at risk for cardiorespiratory depression
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

13. Availability of reversal agents (naloxone and flumazenil only) for the sedative or analgesic agents being administered
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes
14. Postprocedural recovery observation, monitoring, and predetermined discharge criteria reduce adverse outcomes
15. Special regimens (*e.g.*, preprocedure consultation, specialized monitoring, special sedatives-techniques) for patients with special problems (*e.g.*, uncooperative patients; extremes of age; severe cardiac, pulmonary, hepatic, renal, or central nervous system disease; morbid obesity; sleep apnea; pregnancy; drug or alcohol abuse; emergency-unprepared patients; metabolic and airway difficulties)
   a. Improves clinical efficacy (*i.e.*, satisfactory sedation and analgesia)
   b. Reduces adverse outcomes

Scientific evidence was derived from aggregated research literature and from surveys, open presentations, and other consensus-oriented activities. For purposes of literature aggregation, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. The electronic search covered a 36-yr period from 1966 through 2001. The manual search covered a 44-yr period from 1958 through 2001. More than 3,000 citations were initially identified, yielding a total of 1,876 nonoverlapping articles that addressed topics related to the 15 evidence linkages. After review of the articles, 1,519 studies did not provide direct evidence and were subsequently eliminated. A total of 357 articles contained direct linkage-related evidence.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment of support for each linkage. Literature pertaining to three evidence linkages contained enough studies with well-defined experimental designs and statistical information to conduct formal metaanalyses. These three linkages were: linkage 8 [supplemental oxygen], linkage 9 [benzodiazepines combined with opioids *vs.* benzodiazepines alone], and linkage 13 [naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations].

Combined probability tests were applied to continuous data, and an odds-ratio procedure was applied to dichotomous study results. Two combined probability tests were employed as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported P values from the independent studies; and (2) the Stouffer combined test, providing weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds-ratio procedure based on the Mantel-Haenszel method for combining study results using 2×2 tables was used with outcome frequency information. An acceptable significance level was set at $P < 0.01$ (one-tailed), and effect size estimates were calculated. Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. Der Simonian-Laird random-effects odds ratios were calculated when significant heterogeniety was found. To assess potential publishing bias, a "fail-safe N" value was calculated for each combined probability test. No search for unpublished studies was conducted, and no reliability tests for locating research results were performed.

Metaanalytic results are reported in table 2. The following outcomes were found to be significant for combined probability tests: (1) *oxygen saturation*, linkage 8 (supplemental oxygen); (2) *sedation recovery*, linkage 13 (naloxone for antagonism of opioids and flumazenil for antagonism of benzodiazepine-opioid combinations); (3) *psychomotor recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (4) *respiratory-ventilatory recovery*, linkage 13 (naloxone for antagonism of opioids, flumazenil for antagonism of benzodiazepines, and flumazenil for antagonism of benzodiazepine-opioid combinations). To be considered acceptable findings of significance, both the Fisher and weighted Stouffer combined test results must agree. Weighted effect size values for these linkages ranged from $r = 0.19$ to 0.80, representing moderate to high effect size estimates.

Mantel-Haenszel odds ratios were significant for the following outcomes: (1) *hypoxemia*, linkage 8 (supplemental oxygen) and linkage 9 (benzodiazepine-opioid combinations *vs.* benzodiazepines alone); (2) *sedation recovery*, linkage 13 (flumazenil for antagonism of benzodiazepines); and (3) *recall of procedure*, linkage 9 (benzodiazepine-opioid combinations). To be considered acceptable findings of significance, Mantel-Haenszel odds ratios must agree with combined test results when both types of data are assessed.

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a Kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.25$–0.64; (2) type of analysis, $\kappa = 0.36$–0.83; (3) evidence linkage assignment, $\kappa = 0.78$–0.89; and (4) literature inclusion for database, $\kappa = 0.71$–1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.45, Var (Sav) = 0.012; (2) type of analysis, Sav = 0.51, Var (Sav) = 0.015; (3) linkage assignment, Sav = 0.81 Var (Sav) = 0.006; (4) literature database inclusion, Sav = 0.84 Var (Sav) = 0.046. These values represent moderate to high levels of agreement.

The findings of the literature analyses were supplemented by the opinions of Task Force members as well as by surveys of the opinions of a panel of consultants drawn from the following specialties where sedation and analgesia are commonly administered: Anesthesiology, 8; Cardiology, 2; Dental Anesthesiology, 3; Dermatology, 2; Emergency Medicine, 5; Gastroenterology, 9; Intensive Care, 1; Oral and Maxillofacial Surgery, 5; Pediatrics, 1; Pediatric Dentistry, 3; Pharmacology, 1; Pulmonary Medicine, 3; Radiology, 3; Surgery, 3; and Urology, 2. The rate of return for this Consultant survey was 78% (n = 51/65). Median agreement scores from the Consultants regarding each linkage are reported in table 3.

Table 2. Meta-analysis Summary

Linkages	No. Studies	Fisher Chi-square	P	Weighted Stouffer Zc	P	Effect Size	Mantel-Haenszel Chi-square	P	Odds Ratio	Heterogeneity Significance	Heterogeneity Effect Size
Supplemental oxygen											
Oxygen saturation*	5	71.40	<0.001	5.44	<0.001	0.40	—	—	—	>0.90 (NS)	>0.50 (NS)
Hypoxemia*	7	—	—	—	—	—	44.15	<0.001	0.20	—	>0.50 (NS)
Sedatives/Opioids combined:											
Benzodiazepines + opioids											
Sedation efficacy	7	—	—	—	—	—	3.79	>0.05 (NS)	1.87§	—	<0.01
Recall of procedure	6	—	—	—	—	—	18.47	<0.001	2.18§	—	<0.01
Hypoxemia	5	—	—	—	—	—	11.78	<0.001	2.37	—	>0.05 (NS)
Naloxone for opioids											
Sedation recovery at 5 min*,†,‡	5	38.36	<0.001	3.13	<0.001	0.23	—	—	—	>0.30 (NS)	>0.02 (NS)
Respiration/ventilation*,†,‡	5	38.72	<0.001	3.97	<0.001	0.33	—	—	—	>0.10 (NS)	<0.001
Flumazenil for benzodiazepines											
Sedation recovery at 5 min	6	—	—	—	—	—	104.76	<0.001	8.15	—	>0.10 (NS)
Psychomotor recovery											
at 15 min	5	41.80	<0.001	1.69	0.046 (NS)	0.20	—	—	—	>0.70 (NS)	>0.50 (NS)
at 30 min	5	43.02	<0.001	3.36	<0.001	0.19	—	—	—	>0.90 (NS)	>0.50 (NS)
Respiration/ventilation†,‡	6	53.25	<0.001	5.03	<0.001	0.80	—	—	—	<0.01	<0.001
Flumazenil for benzodiazepine-opioid combinations											
Sedation recovery at 5 min	5	72.12	<0.001	6.76	<0.001	0.37	—	—	—	<0.001	<0.001
Respiration/ventilation†,‡	6	55.06	<0.001	5.11	<0.001	0.25	—	—	—	>0.10 (NS)	<0.001
Nausea/vomiting	5	—	—	—	—	—	0.28	>0.80 (NS)	1.22	—	>0.70 (NS)

* Nonrandomized comparative studies are included; † Studies in which anesthesiologist administered benzodiazepines, opioids, or reversal agents are included; ‡ Studies in which subjects consist of intensive care unit patients, postoperative patients, or volunteers with no procedures are included.

§ Der Simonian-Laird random-effects odds ratio.

For moderate sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 3 (electrocardiogram monitoring and capnography), linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives for improving satisfactory sedation), linkage 13b (routine administration of naloxone), linkage 13c (routine administration of flumazenil), and linkage 15b (anesthesiologist consultation for patients with medical conditions to provide satisfactory moderate sedation). In addition, Consultants were equivocal regarding whether postgraduate training in anesthesiology improves moderate sedation or reduces adverse outcomes.

For deep sedation, Consultants were supportive of all of the linkages with the following exceptions: linkage 9 (sedatives combined with analgesics for reducing adverse outcomes), linkage 11 (avoiding general anesthesia sedatives), linkage 13b (routine administration of naloxone), and linkage 13c (routine administration of flumazenil).

The Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the updated Guidelines were instituted. The rate of return was 57% (n = 37/65). The percent of responding Consultants expecting no change associated with each linkage were as follows: preprocedure patient evaluation, 94%; preprocedure patient preparation, 91%; patient monitoring, 80%; contemporaneous recording of monitored parameters, 91%; availability of individual dedicated solely to patient monitoring and safety, 91%; education and training of sedation-analgesia providers in pharmacology, 89%; presence of an individual(s) capable of establishing a patent airway, 91%; availability of appropriately sized emergency and airway equipment, 94%; use of supplemental oxygen during procedures, 100%; use of sedative agents combined with analgesic agents, 91%; titration of sedatives-analgesics, 97%; intravenous sedation-analgesia with agents designed for general anesthesia, 77%; administration of sedative-analgesic agents by the intravenous route, 94%; maintaining or establishing intravenous access, 97%; availability-use of flumazenil, 94%; availability-use of naloxone, 94%; observation and monitoring during recovery, 89%; special care for patients with underlying medical problems, 91%; and special care for uncooperative patients, 94%. Seventy-four percent of the respondents indicated that the Guidelines would have no effect on the amount of time spent on a typical case. Nine respondents (26%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of these Guidelines. The amount of increased time anticipated by these respondents ranged from 1 to 60 min.

Table 3. Consultant Survey Summary

Intervention or Linkage	Outcome	Moderate Sedation N	Moderate Sedation Median* or Percent	Deep Sedation N	Deep Sedation Median* or Percent
1. Preprocedure patient evaluation	Satisfactory sedation	51	5	51	5
	Adverse outcomes	51	5	51	5
2. Preprocedure fasting	Satisfactory sedation	51	4	51	5
	Adverse outcomes	51	4	51	5
3. Monitoring					
a. Level of consciousness	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
b. Breathing (observation/auscultation)	Satisfactory sedation	51	5	49	5
	Adverse outcomes	51	5	50	5
c. Pulse oximetry	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
d. Blood pressure/heart rate	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
e. Electrocardiogram	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	49	5
f. Capnography	Satisfactory sedation	50	3	48	4
	Adverse outcomes	50	3	49	4
4. Contemporaneous recording	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
5. Individual for patient monitoring	Satisfactory sedation	49	4	48	5
	Adverse outcomes	49	4	48	5
6a. Education and training	Satisfactory sedation	50	5	49	5
	Adverse outcomes	50	5	49	5
6b. Individual with basic life support skills present in room		50	5	49	5
6c. Availability of advanced life support skills					
In the procedure room		2	4.2%	39	79.6%
Immediate vicinity (1–5 min)		27	56.2%	8	16.3%
Same building (5–10 min)		14	29.2%	2	4.1%
Outside provider		5	10.4%	0	0.0%
7. Emergency intravenous and airway equipment	Adverse outcomes	51	5	49	5
8. Supplemental oxygen	Adverse outcomes	50	4	49	5
9. Sedatives combined with analgesics	Satisfactory sedation	50	4	49	4
	Adverse outcomes	50	3	49	3
10. Titration	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	5	50	5
11. Avoiding general anesthetic sedatives	Satisfactory sedation	50	3	49	2
	Adverse outcomes	50	4	49	3
12a. Intravenous sedatives	Satisfactory sedation	51	5	50	5
	Adverse outcomes	51	4	50	4
12b. Intravenous access	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	5	49	5
13a. Immediate availability of naloxone or flumazenil	Adverse outcomes	51	5	51	5
13b. Routine administration of naloxone	Satisfactory sedation	37	2	37	2
	Adverse outcomes	37	2	37	2
13c. Routine administration of flumazenil	Satisfactory sedation	37	1	37	2
	Adverse outcomes	37	2	37	2
14. Observation, monitoring, and discharge criteria	Adverse outcomes	50	5	49	5
15a. Medical specialist consultation, patients with underlying medical conditions	Satisfactory sedation	50	4	49	5
	Adverse outcomes	50	4	49	5
15b. Anesthesiologist consultation, patients with underlying medical conditions	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	4	50	5
15c. Anesthesiologist consultation, patients with significant sedation risk factors	Satisfactory sedation	51	4	50	5
	Adverse outcomes	51	4	50	5
16. Postgraduate training in anesthesiology	Satisfactory sedation	51	3	50	4
	Adverse outcomes	51	3	50	4
17. In emergency situations, sedate patients less deeply		51	4	51	5

* Strongly agree: Median score of 5; Agree: Median score of 4; Equivocal: Median score of 3; Disagree: Median score of 2; Strongly disagree: Median score of 1.

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Appendix II: Summary of Guidelines‡

Except as noted, recommendations apply to both moderate and deep sedation.

1. Preprocedure evaluation
   - Relevant history (major organ systems, sedation-anesthesia history, medications, allergies, last oral intake)
   - Focused physical examination (to include heart, lungs, airway)
   - Laboratory testing guided by underlying conditions and possible effect on patient management
   - Findings confirmed immediately before sedation
2. Patient counseling
   - Risks, benefits, limitations, and alternatives
3. Preprocedure fasting
   - Elective procedures—sufficient time for gastric emptying
   - Urgent or emergent situations—potential for pulmonary aspiration considered in determining target level of sedation, delay of procedure, protection of trachea by intubation
   - See ASA Guidelines for Preoperative Fasting[2]
4. Monitoring
   (Data to be recorded at appropriate intervals before, during, and after procedure)
   - Pulse oximetry
   - Response to verbal commands when practical
   - Pulmonary ventilation (observation, auscultation)
   - Exhaled carbon dioxide monitoring considered when patients separated from caregiver
   - Blood pressure and heart rate at 5-min intervals unless contraindicated
   - Electrocardiograph for patients with significant cardiovascular disease

   For deep sedation:
   - Response to verbal commands or more profound stimuli unless contraindicated
   - Exhaled CO_2 monitoring considered for all patients
   - Electrocardiograph for all patients
5. Personnel
   - Designated individual, other than the practitioner performing the procedure, present to monitor the patient throughout the procedure
   - This individual may assist with minor interruptible tasks once patient is stable

   For deep sedation:
   - The monitoring individual may not assist with other tasks
6. Training
   - Pharmacology of sedative and analgesic agents
   - Pharmacology of available antagonists
   - Basic life support skills—present
   - Advanced life support skills—within 5 min

   For deep sedation:
   - Advanced life support skills in the procedure room
7. Emergency Equipment
   - Suction, appropriately sized airway equipment, means of positive-pressure ventilation
   - Intravenous equipment, pharmacologic antagonists, and basic resuscitative medications
   - Defibrillator immediately available for patients with cardiovascular disease

   For deep sedation:
   - Defibrillator immediately available for all patients
8. Supplemental Oxygen
   - Oxygen delivery equipment available
   - Oxygen administered if hypoxemia occurs

   For deep sedation:
   - Oxygen administered to all patients unless contraindicated
9. Choice of Agents
   - Sedatives to decrease anxiety, promote somnolence
   - Analgesics to relieve pain
10. Dose Titration
    - Medications given incrementally with sufficient time between doses to assess effects
    - Appropriate dose reduction if both sedatives and analgesics used
    - Repeat doses of oral medications not recommended
11. Use of anesthetic induction agents (methohexital, propofol)
    - Regardless of route of administration and intended level of sedation, patients should receive care consistent with deep sedation, including ability to rescue from unintended general anesthesia
12. Intravenous Access
    - Sedatives administered intravenously—maintain intravenous access
    - Sedatives administered by other routes—case-by-case decision
    - Individual with intravenous skills immediately available
13. Reversal Agents
    - Naloxone and flumazenil available whenever opioids or benzodiazepines administered
14. Recovery
    - Observation until patients no longer at risk for cardiorespiratory depression
    - Appropriate discharge criteria to minimize risk of respiratory or cardiovascular depression after discharge
15. Special Situations
    - Severe underlying medical problems—consult with appropriate specialist if possible
    - Risk of severe cardiovascular or respiratory compromise or need for complete unresponsiveness to obtain adequate operating conditions—consult anesthesiologist

‡This is a summary of the Guidelines. The body of the document should be consulted for complete details.

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Comments to DBC July 28, 2016

Draft

Good afternoon and thank you for the opportunity to address this group on behalf of the California Society of Anesthesiologists as a past president of that organization from 2006-2007. I am Dr. Mark Singleton and I am currently a professor of pediatric anesthesiology, at both Stanford University and the University of California, San Francisco where I teach and supervise residents and fellows; and I am also an active medical staff member of the UCSF Benioff Children's Hospital Oakland. For 30 years I was a partner in a large private anesthesiology practice in San Jose, and have, throughout my career, administered anesthesia and sedation to countless numbers of children undergoing dental procedures in hospital, outpatient as well as dental and oral/maxillofacial surgical office settings.

We are gathered here today, representing multiple medical and dental specialties, as well as agencies entrusted with ensuring patient safety and advancing public policies, in an effort to prevent the tragic deaths and serious injuries that continue to occur in association with sedation and anesthesia during pediatric dental procedures. The motto of the American Society of Anesthesiologists displays the word "vigilance", and that single word summarizes the message I wish to convey today. We who specialize in the administration of anesthesia and sedation are in effect, poison managers, who carefully manipulate the unconscious state, breathe for patients whose ability to do so we have intentionally obliterated, and continuously measure and monitor a multitude of vital signs that allow us to keep our patients within the balance between life and death. Although we have learned to do this with ease and skill, it is in fact inherently fraught with inevitable and unforeseeable hazards, coupled with sudden, unexpected demands for split second and near perfect responses. These skills and knowledge are acquired through years of daily experience accruing far beyond residency training, and require continual practice to maintain proficiency, as is so with all specialized disciplines. It is not reasonable, nor rational to expect health practitioners, even those who have received advanced training in patient rescue and resuscitation, airway management, laryngoscopy and tracheal intubation and other life saving measures, to reliability and successfully perform those actions in the chaos of an unexpected crisis, when they almost never do so in their usual practice. This is why, when these situations do rarely occur, as we continue to witness across this country, the outcome is so often a shattering nightmare that forever mares the lives of all involved.

Therefore, I believe firmly that if we are to save the lives of future pediatric dental patients undergoing sedation or anesthesia, from that extraordinarily rare, unimaginably horrible, and too often irreversible spiral into the dark domain that we have named the "code blue", it will be through the principle of prevention. Whatever measures are debated and adopted, they should be aimed at keeping patients as far from that event horizon as possible. This requires vigilance and most importantly the specific requirements that enable and guarantee it. First and foremost in my opinion, is the absolute requirement for the assurance of the continuous adequacy of breath-to-breath

ventilation. This means that a qualified member of the procedural team, whose qualifications are determined by the needs of the patient and nature of the procedures, will be responsible **solely** to monitor every single breath the patient takes along with measuring other vital signs, as their **primary duty**. The use of a capnographic device, which measures exhaled carbon dioxide and has for decades been a ubiquitous monitor for general anesthesia in ORs across the nation, is now mandated as a standard by the ASA in all settings where patients receive procedural sedation, in an effort to ensure this necessary level of vigilance. An overarching principle being that for any intended levels of sedation, regardless of the drugs used or the route of administration or the setting in which they are given, the level of care and monitoring for adequacy of ventilation should be the same, because the risk that a patient may stop breathing is the same in a dental or oral surgeon's office as it is in the hospital OR.

This meeting today is evidence that the dental and oral surgery professions are coming to recognize what the anesthesiologists and other surgical specialties have been adapting to for several decades; that our youngest and most fragile patients require care from practitioners with specialized training, experience and skill provided in facilities with resources optimal for their needs. The American Academy of Pediatrics Section on Anesthesia and Pain Medicine, the Society for Pediatric Anesthesia, the American and California Societies of Anesthesiologists, and recently the American College of Surgeons all recommend and promote requirements of specialized qualifications for providers of anesthetic and surgical care for pediatric patients in stratified risk categories based on age, co-existing disease, and complexity of procedures. The Dental Board of California should adopt the same approach. Additional, separate requirements for documented ongoing experience and proficiency in the administration of deep sedation/anesthesia of the youngest patients should be established and enforced, as should requirements for monitoring standards proven to improve outcomes for this at-risk population. The DBC makes the distinction between pediatric and adult patients in issuing permits for oral conscious sedation but not for the higher risk undertaking of deep sedation/anesthesia, which leaves an unaddressed opportunity to protect children, and makes no sense. Parents are appropriately concerned, increasingly well informed and legitimately insistent that the care of their children be provided by professionals with special training and expertise in pediatric care and in a setting where that care can be optimally provided. No one benefits from cutting corners or ignoring mounting evidence of potential hazard, and certainly not the unfortunate practitioner upon whom such a career destroying disaster falls.

It has been suggested that additional requirements for qualified professionals to administer and monitor patients undergoing dental sedation and anesthesia will create a "barrier of access to care". This is an unfounded "straw man" argument, a hypothetical suggestion that serves only to continue a status quo, which has repeatedly failed the families of countless pediatric dental patients who have been harmed or lost their lives. Evidence shows us, in fact, that when we as professional societies and regulatory agencies, advance the definitions safety and protection for our most vulnerable patients, access to care is never diminished. We learn to improve our practices, we provide a higher level of care, we increase safety and protect patients, and our patients, families,

and even our insurers and third party payers appreciate the obvious benefits and seek our services with a greater sense of security and trust. This is the essence of our most essential mission as health professionals.

Thank you for the opportunity to express these comments.

CALIFORNIA SOCIETY OF PEDIATRIC DENTISTRY (CSPD)

See American Academy of Pediatric Dentists Comment

ORAL AND FACIAL SURGEONS OF CALIFORNIA

1. August 11, 2016 Letter from Leonard M. Tyko II, DDS, MD, FACS, President with Attachment
    - Report, References, and Appendix A

11 August 2016

RE: Invitation to Participate in the Dental Board of California's Anesthesia Project

Ms. Karen Fischer
2005 Evergreen Street, Suite 1550
Sacramento, CA 95815

Dear Ms. Fischer,

In response to the Dental Board of California's invitation to participate in the Anesthesia Project, the Oral & Facial Surgeons of California submit the attached report. If the Board has any questions about this report, we are happy to elaborate. OFSOC plans to attend all of the upcoming DBC's Anesthesia Projects meetings.

Sincerely,

Leonard M. Tyko II, DDS, MD, FACS
President, Oral & Facial Surgeons of California
950 Reserve Drive, Suite 120
Roseville, CA 95678

Oral & Facial Surgeons of California

Introduction

In response to the Dental Board of California's (DBC) 1 June 2016, invitation to participate in the Dental Board of California's Anesthesia Project, the Oral & Facial Surgeons of California (OFSOC) respectfully submit this report that describes the Oral & Maxillofacial Surgery Team Model of out-patient anesthesia delivery.

For more than 60 years, California Oral & Maxillofacial Surgeons (OMS's) have held the practice authority to provide deep sedation/general anesthesia in an out of hospital setting. During short, potentially painful, and anxiety provoking procedures, it is common for OMS's to provide deep sedation and general anesthesia for in-office surgery via the Oral & Maxillofacial Surgery Team Model. Professional outcomes data show that the OMS anesthesia model delivers care that is safe and cost-effective. This model increases access to necessary oral health care for individuals who otherwise are unable to afford hospital-based surgical care.

What is an Oral & Maxillofacial Surgeon?

Oral & maxillofacial surgeons are the surgical specialists of dentistry. There are two paths to becoming an OMS. The first route requires the completion of 4 years of dental school and a 4-year, hospital-based residency program. The second route includes the completion of both dental school and medical school and a 4-year residency program. Oral Maxillofacial surgeons have between 8-12 years of post-graduate clinical training.

Procedures within the OMS's scope of practice include: surgery to correct maxillofacial trauma (e.g. motor vehicle accidents, gunshot wounds, industrial accidents, interpersonal violence); corrective jaw surgery for developmental deformities of the face and jaws; surgical treatment of head, neck and oral pathology, including benign lesions and cancer; cosmetic surgery; reconstructive surgery, including bone and skin grafts and dental implants; jaw joint surgery; and dental extractions. OMS's operate in both hospital and outpatient settings. While major and lengthy surgeries are carried out in a hospital setting, minor surgeries, on otherwise healthy individuals, are typically performed in an office setting. To facilitate office-based surgery, OMS's are trained to administer all forms of anesthesia.

OMS Team Model of Anesthesia

The OMS Team Model of anesthesia delivery is a core clinical competency taught throughout the residency program and requires post residency specialty licensure. This

specialized training during residency includes a 5-month medical anesthesiology rotation. While in this rotation, the OMS functions as an anesthesiology resident, along side the other medical anesthesiology residents. The OMS Resident is supervised by medical anesthesiologists and performs a minimum of 300 general anesthetics. This anesthesia training includes: evaluation of patients for anesthesia, risk assessment, diagnosis and treatment of complications, appropriate patient monitoring and post-anesthesia care, and techniques to administer of all levels of anesthesia. As the anesthesiology resident, the OMS trainee performs local anesthetic techniques as well as general anesthesia for all types of major, hospital based surgical procedures.

In addition to their anesthesiology rotation, OMS residents continue their anesthetic training in the OMS outpatient clinic under faculty supervision in their clinical specialty. Throughout training, the OMS performs hundreds of office-based surgeries delivered under all forms of anesthesia while directing the anesthesia team.[1] In addition, OMS residents must complete Pediatric Advanced Life Support (PALS) and Advanced Cardiac Life Support (ACLS) training.

In order to provide deep sedation and general anesthesia, the practicing OMS must secure and maintain a separate General Anesthesia Permit issued by the Dental Board of California. California regulations require this General Anesthesia Permit in addition to (and separate from) their medical and/or dental license. As part of the anesthetic permit maintenance, the Dental Practice Act requires the OMS to obtain on-going anesthesia-related continuing education as well as completing Basic Life Support and Advanced Cardiac Life Support every two years. California regulations also require anesthesia permit holders to undergo regular, in-office evaluations by the Dental Board of California. These evaluations include a site inspection, observation of the OMS and his/her team during a surgery with general anesthesia delivery, and the successful completion drills of 13 medical emergency scenarios.

OMS Team Members

The Oral & Maxillofacial Surgery Anesthesia Team consists of the surgeon and at least two, trained assistants. The first assistant monitors the patient and maintains the airway as his/her only duties during the procedure. The second assistant assists the OMS in performing the surgery. Assistants achieve certification via completion of the California's Oral & Maxillofacial Surgery Assistants (OMSA) Program or the Dental Anesthesia Assistant National Certification Examination (DAANCE). Assistants are trained in the use of anesthesia monitoring equipment equivalent to the monitors found in many hospital surgical suites and are trained in the latest medical anesthesia protocols. Monitoring patients' vital signs, anticipating, and if needed, reacting to emergency situations are a major focus of the assistants' training and on-going performance evaluation.

Growing Role of Sedation out of the Operating Room

OMS's have a long history of administering anesthetics to patients undergoing short, interruptible, minor surgeries. However, OMS are not the only practitioners who provide out-of-operating-room anesthesia without an anesthesiologist.[2-3] The delivery of sedation has become common, and as many providers argue, is the standard of care for uncomfortable or painful diagnostic and treatment procedures. Sedation helps patients tolerate lengthy MRI or nuclear medicine scans. Cardiologists and emergency department physicians provide procedural sedation and analgesia. Gastroenterologists routinely provide sedation for endoscopy. In fact, a survey by the American College of Gastroenterology found more than 98% of providers in the United States routinely administer sedation.[4] Providers cite difficulty obtaining operating room time, excessive costs for in-patient care, and reimbursement challenges as reasons for providing more outpatient anesthetics. Multiple studies have demonstrated the safety of anesthesia in the above situations when administered to *appropriate patients* by *well-trained providers*. Furthermore, many studies report decreased patient anxiety and increased patient satisfaction with procedures performed under outpatient anesthesia. Together, these factors provide the basis for a multi-specialty practice of providing safe and affordable single-provider, outpatient anesthesia.

OMS Safety Record

All surgical procedures and all forms of anesthesia in every healthcare setting carry risks. The overall estimated mortality rate from hospital-based anesthesia in the United States is approximately 1 in 100,000.[5-6] In comparison, the overall estimated mortality rate from office-based OMS anesthetics is 1 in 648,794.[7-22] This difference is striking, but not surprising. One would expect a lower mortality rate with the OMS Team Model. Unlike other operating room surgeries, the typical, office-based anesthetic is less deep, the surgeries are minor, short and interruptible, and the patients are relatively healthy individuals. Multiple academic papers published in peer-reviewed, scientific journals attest to this safety record.

Repeatedly, retrospective and prospective studies, individual case studies, surveys, and closed claims reports report very low morbidity and mortality rates for OMS anesthesia delivery.[7-22] In a 2003, prospective, cohort study of more than 34,000 patients, Perrott et al., reported an overall complication rate of 1.3% for office-based ambulatory anesthesia by the OMS Anesthesia Team Model.[20] Most complications were minor and self-limiting, and no complication resulted in long-term adverse sequelae. There were no deaths reported in this study of more than 34,000 patients.

Most recently, Inverso et al., 2016, published a multi-center, prospective study of 29,548 adolescent patients undergoing moderate sedation or deep sedation/general anesthesia in an outpatient setting.[22] They reported overall complication rates for moderate sedation of 0.5% and 0.9% for deep sedation/general anesthesia. The most common

complications were vomiting and prolonged emergence from anesthesia. Multivariable logistic regression analysis showed no increase in risk between deep sedation/general anesthesia and moderate sedation in an out patient setting. As in earlier studies, Inverso reported no deaths in this large, multi-center trial. Inverso's findings are particularly relevant to discussions surrounding AB 2235, as all of the 29,548 subjects were pediatric patients less than 21 years old.

Large, randomized, cohort studies are expensive and difficult to conduct. As such, closed case claims reviews are an established method to look for low incident events. The American Society of Anesthesia used closed case reviews to help lower complication rates by identifying scenarios that led to poor outcomes.[22-23]

In a similar fashion, the OMS National Insurance Company (OMSNIC) recently completed its own closed case claims review of pediatric, anesthesia claims. OMSNIC is the largest OMS malpractice insurance company in the country, insuring approximately 80% of the United States 9,500 OMS's. They evaluated California claims from 2005 through 2015 for patients less than 21 years old and found 5 claims related to the delivery of anesthesia. Four claims were related to anesthesia care in an office setting and one claim involved a patient treated in a hospital. During the period of review, 2005 though 2015, there were no claims of a pediatric patient anesthetic death (see Appendix A).

It is important to note that in a detailed review of the OMS literature, no study demonstrates an increase in anesthetic complication rates in appropriately screened individuals, including pediatric patients, with the OMS Team Model of Anesthesia. As multiple researchers explain, office-based oral surgeries are minor procedures, performed on carefully screened, low risk individuals in an area that allows for direct monitoring of the airway. Given these findings, it is reasonable to conclude that for relatively healthy patients undergoing brief, interruptible surgeries in the head and neck region, the OMS Anesthesia Model provides a safe and effective standard for out patient anesthesia.

Efforts to Establish California Complication Rates

Currently, the DBA is compiling a report of adverse clinical events in pediatric patient between 2011 and 2016. In order to calculate complication rates for California OMS practicing under the current OMS Anesthesia Team Model, investigators need to know the number of anesthetics given by a practicing provider. There have been a number of past surveys in the United States and Canada attempting to estimate this denominator. [6-19]

In order to obtain the most current number of deep sedations/general anesthetics provided by an average California OMS, OFSOC is conducting a survey of its active membership. Including residents, candidates, affiliates, and active members, OFSOC has a total membership 953 OMS's. Out of the total membership, there are 725 active

members. We assume that the vast majority of active members have general anesthesia permits. As of this report's submission date, 284 active members of OFSOC responded to the survey, for an overall response rate of 39%. OFSOC members were asked to provide the number of pediatric (less than 21 years old) and adult (21 years old and older) anesthetics. Members were requested to obtain the data from their practice management software by searching for anesthesia codes CDT 9220 and CDT 9223. Tables 1-5 summarize this data.

Table 1: Number of Deep Sedation/General Anesthetics Per Year

Year	Pediatric Patients Deep Sedation/ General Anesthetics	Adult Patients Deep Sedation/ General Anesthetics	Total Deep Sedation/ General Anesthetics
2011	68,290	77,398	145,688
2012	71,070	82,445	153,515
2013	76,606	85,561	162,167
2014	78,639	86,613	165,252
2015	83,737	88,694	172,431
2016 (partial year)	53,003	56,210	109,213

Table 2: Number Of OMS Reporting By Year

Year	Number of Responders
2011	234
2012	244
2013	258
2014	268
2015	279
2016 (partial year)	270

Table 3: Average Number of Pediatric Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	292
2012	291
2013	297
2014	293
2015	300
2016 (partial year)	196

Table 4: Average Number of Adult Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	331
2012	338
2013	332
2014	323
2015	318
2016 (partial year)	208

Table 5: Average Number of Deep Sedation/ General Anesthetics Per OMS Per Year

Year	Average
2011	623
2012	629
2013	629
2014	617
2015	618
2016 (partial year)	404

Data collection is on-going, but thus far, OFSOC survey results correlate closely with previously published papers.[6-19] OFSOC anticipates that the results of this survey will be combined with the DBC's data to generate OMS anesthesia morbidity and mortality rates during the period of 2011-2016.

Legal & Professional Standards to Ensure Patient Safety

The California Dental Practice Act defines the legal standards of practice for dentists in California. The requirements for obtaining and maintaining an anesthesia permit are contained within the Act. Permit holders are required to undergo office anesthesia evaluations (OAE) by the Dental Board of California as previously discussed. These evaluations of the OMS and his/her team include a site inspection, observation of a surgery with anesthetic delivery, and medical emergency scenario drills. The purpose of the OAE is to assess the OMS's ability to gauge a patient's anesthetic risk and to ensure the facility is prepared for emergencies associated with the administration of anesthesia in all types of patients, including pediatric individuals.

In order to give clear direction to the practicing OMS beyond the legal dictates of the Dental Practice Act, state and national professional societies define the standards of care for OMS. Beyond a general ethic of "do no harm," oral and maxillofacial surgeons are professionally bound to the specific principles outlined by the mission, actions, and publications of the OFSOC and AAOMS. Of the nearly 1,000 California OMS's, 953 are members of OFSOC and AAOMS.

The purpose of OFSOC is to contribute to the public welfare by advancement of the profession of dentistry and in particular the specialty of oral and maxillofacial surgery; to foster programs of education, research, standards of practice and scientific investigation in the specialty of oral and maxillofacial surgery; to provide a means of self-government relating to professional standards, ethical behavior and responsibilities of its fellows and members; to provide opportunities for social and professional development.[25] In order to qualify for membership in OFSOC and AAOMS, OMS's must undergo a professional evaluation. Once a member, the OMS is required to adhere to a code of professional conduct and a code of ethics; and to submit to peer review and to an ongoing evaluation of their office, staff and office procedures related to the anesthesia team model. Through their membership in the professional organization, OMS commit to following evidence-based standards of practice to insure safe anesthesia delivery.

Two AAOMS publications set the standards for OMS office-based anesthesia: *AAOMS Parameters of Care for Anesthesia in Outpatient Facilities* and the *Office Anesthesia Evaluation* (OAE) program.[26-27] More rigorous than the California Dental Practice Act, the *AAOMS Parameters of Care* describes criteria and parameters for pain and anxiety control in the ambulatory surgery setting. Subjects covered within this document include: informed consent, proper documentation, facility attributes and required equipment, pre-anesthetic physical and laboratory assessment, perioperative

complications and emergencies, general therapeutic goals, general risk factors that may exclude a patient from office-based surgery, desired outcomes, and risks and complications of anesthesia. This publication also outlines special considerations for pediatric, pregnant, and obese patients.

Each subject within the *AAOMS Parameters of Care* outlines what is expected of the OMS. For example, the operating theater must be large enough and equipped to allow for ACLS. Readily available mobile auxiliary sources of light and suction that can be used in a power failure must be present. Back up oxygen that can be delivered under positive pressure is required. Further, during deep sedation and general anesthesia, the *Parameters* call for the use of anesthesia monitoring equipment that is similar to those used in the operating room: blood pressure readings every 5 minutes, evaluation of the heart rate and rhythm by ECG, continuous evaluation of the patient by observation, pulse oximetry, and end-tidal CO_2 by capnography. Of note, OFSOC and AAOMS require monitoring devices that exceed those mandated in the California Dental Practice Act. The *Parameters of Care for Anesthesia in Outpatient Facilities* is regularly updated (at more frequent intervals than that of the Dental Practice Act) to ensure that the document reflects current, evidenced-based standards of care.

Both OFSOC and AAOMS require continuing education courses specific to anesthesia. OFSOC offers to its members and allied staff six to seven educational opportunities per year, with subjects ranging from medical emergencies, to anesthesia, to ACLS, to surgical updates, to the Oral & Maxillofacial Surgery Assistance (OMSA) program.

Finally, the AAOMS promotes many practices originally promulgated by the aviation industry to foster a culture of safety. The AAOMS publication *Culture of Safety in the OMS Office* defines policies and actions to ensure patient safety. Adopted by JCAHO and numerous healthcare entities, the pre-surgical "time out," promotion of the team concept, cross training, collaboration, transparency, accountability, and systematic evaluation are all tools endorsed by AAOMS to help prevent potential errors. A full description of the *Culture of Safety in the OMS Office* is available on the AAOMS website. In March 2017, AAOMS will host a Patient Safety Summit to highlight their efforts in this arena.

Future Pathways to Increase Patient Safety

Despite outcomes data demonstrating extremely low complication rates, OFSOC and AAOMS strive to increase safety in the delivery of anesthesia. To that end, OFSOC and AAOMS continuously review, revise, and develop standards, policies, and educational opportunities for their members. Though rare in their occurrence, research points to airway problems as a major component of poor anesthesia outcomes. To further improve outcomes and to help its members better manage rare airway emergencies, AAOMS developed an emergency airway management simulation program, BEAM (Basic Emergency Airway Management), to be implemented in 2017.

painful surgeries. Lightly sedated patients often lose inhibitions and, correspondingly, their ability to tolerate the noises, pressures, and pain that accompany surgery. This typically results in a combative patient, which increases overall risk both to him/herself and to their providers. Appropriate level anesthesia is critical to the delivery of safe oral and maxillofacial surgical care.

According to the Dental Board of California's working document, there were nine pediatric death during the study period of 2011-2016; only one of these was attributed to an OMS. During this period of study, it is estimated that 1,069,375 (average of 295 pediatric anesthetics (Table 3) multiplied by 725 active California OMSs times 5 years) pediatric anesthetics were administered. These data establish an office-based, mortality rate of less than 1 in a million for the OMS Anesthesia Team Model when applied to pediatric patients.

When properly performed, the OMS Anesthesia Team Model is a proven safe and effective method to provide care for patients who meet the specific risk criteria for office sedation and surgical procedures. OMS education, professional standards, and staff preparation establish an environment of safety. Multiple studies demonstrate safety of the OMS Anesthesia Model, and legal and professional systems exist to ensure individual providers are practicing within these safety standards. Current outcomes data validate the effectiveness of the current method.

Despite the proven safety record, every system can be improved. Patient safety is our paramount concern. To that end, OFSOC recommends the following enhancements to the Dental Practice Act's section on deep sedation & general anesthesia.

1. Adopt the standards outlined in *AAOMS Parameters of Care for Anesthesia in Outpatient Facilities*

OFSOC feels strongly that no professional organization's name should be codified into the California Dental Practice Act. However, OFSOC suggests changing the California Dental Practice Act's section on deep sedation/general anesthesia to parallel the *AAOMS Parameters of Care*. These standards are the most complete and most rigorous, in all of dentistry. This change would update California law to the current standards of outpatient anesthesiology, and require all dentists who provide sedation or general anesthesia to abide by the same rigorous standards.

2. Require the presence of 2 trained assistants during moderate sedation and deep sedation/general anesthesia

OFSOC recommends the presence of two, certified assistants where one assistant is tasked solely with providing continuous, direct observation and monitoring of the patient's status.

3. Add Capnography to the required monitoring equipment during moderate sedation and deep sedation/general anesthesia.

In dentistry, airway complications are the most common pathway to an anesthetic complication. As such, OFSOC advocates for the use of operating room level patient monitors during all moderate and deep sedation/general anesthesia procedures. The currently required monitors include an ECG, blood pressure, and pulse oximetry. OFSOC and AAOMS suggest the addition of monitoring exhaled carbon dioxide via capnography. Capnography provides immediate and constant data on an anesthetized patient's respiratory status. Monitoring exhaled carbon dioxide is the standard of care in the hospital operating room. The American Society of Anesthesiologists and American Heart Association include this level of monitoring in their parameters of care. OFSOC understands that the use of capnography is somewhat limited in patients who are not intubated. However, implementation of capnography would provide another layer of patient safety.

Respectfully submitted,

Leonard M Tyko II, DDS, MD, FACS
President, Oral & Facial Surgeons of California

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Appendix A

OMS NATIONAL
INSURANCE COMPANY, RRG

6133 N. River Road, Suite 650
Rosemont, IL 60018-5173
(800) 522-6670
Fax: (847) 384-0070
www.omsnic.com

August 6, 2016

Dr. Leonard Tyko II
President
Oral and Facial Surgeons of California
950 Reserve Drive, Suite 120
Roseville, CA 95676-1351

Dear Dr. Tyko:

The following outlines the results of a review performed by OMSNIC earlier this year on its closed claim data on pediatric anesthesia related claims in California. This information is provided per the request of Ms. Pamela Congdon, Executive Director of OFSoC.

We reviewed OMSNIC's claim statistics based on the following criteria:

- Claims closed from 2005-2015
- Patient age range: 21 years or younger

A query of the Company's database of all closed claims of individuals under 21 years of age in California for the period from 2005 to 2015 was made. This query revealed a total of fifty four (54) claims involving patients age 21 or under. These claims were reviewed by experienced risk management personnel overseen by the Company's Chief Operating Officer, who herself has thirty years of insurance experience, to determine which claims were due to the administration of anesthesia. Five (5) of the fifty four claims identified were found to be related to the administration of anesthesia. Of these five, four (4) claims involved patients treated in an office setting and one (1) claim involved a patient treated in a hospital. We note that none of the claims resulted in a patient's death.

The time period reviewed covers an estimated 2,682 mature equivalent exposures (MEEs). The MEE is calculated as follows. A full-time OMS who is mature for purposes of claims-made liability coverage (i.e., practicing for five years or more) is equal to 1.00 for each year and cumulatively as 11.00 over the full period under review. Part-time or new-to-practice OMS are included at a fraction of 1.00 based on OMSNIC's claims-made factors. For example, an OMS practicing part-time would be included as .50 MEE for each year and 5.50 cumulatively. Put differently, each MEE approximates a full year of an OMS's practice.

On this basis, the incidence of closed pediatric anesthesia related claims for the period under review was 5 claims divided by 2,682 MEEs, or 0.2%. The incidence of pediatric anesthesia related death claims was Nil as there were no closed claims of this nature during the period under review.

Information regarding Mature Equivalent Exposures ("MEE") was prepared by me from proprietary Company actuarial data. I am a certified public accountant with twenty-four years of experience with OMSNIC and over thirteen years of public accounting experience. The MEE represents a more refined calculation of the risks insureds for the time period the claims were reviewed.

OMSNIC insured an average of 316 OMS in California for the time period between 2011 and 2015 based on the year-end policyholder counts for those years. The number can fluctuate during any given year but this average is a reasonable approximation.

Appendix A

Finally, the findings outlined above were reviewed by the five OMS directors of OMSNIC. Each of these directors is a practicing OMS with twenty or more years in practice and related activities.

In summary, the information was accumulated by very experienced Company personnel and was overseen and reviewed by individuals at the highest levels of our organization.

We understand this information will be used for the purpose of study and potential advocacy efforts by the California Dental Board. The data outlined above is provided solely for this purpose. Also, please note OMSNIC is providing this information without any position for or against any current or pending California legislation.

Sincerely,

William C. Passolt
President and CEO

cc: Ms. Pamela Congdon, CAE, IOM – Executive Director, Oral and Facial Surgeons of California

INDIVIDUALS

1. Diana Belli, DDS (Dental Anesthesiologist) – Emails dated July 21, 2016 and July 22, 2016
2. David Crippen, DDS (Pediatric Dentist) – Email dated July 26, 2016
3. Skip Harris, DDS (Oral and Maxillofacial Surgeon in Arizona) – Email dated July 22, 2016
4. Annie Kaplan, MD – Emails dated June 15, 2016 and July 18, 2016 – Attachments
    - August 11, 2010, 12 page letter signed by Janet Woodcock, MD Center for Drug Evaluation and Research.
    - Caleb's Law – White Paper, March 29, 2016 (Author Unknown)

Fischer, Karen@DCA

From: DrDianaBelli.com <email@drdianabelli.com>
Sent: Thursday, July 21, 2016 7:55 PM
To: Fischer, Karen@DCA
Cc: Wallace, Sarah@DCA
Subject: Feedback to AB2355 Pediatric Anesthesia Study

Dear Karen,

I am writing you this letter regarding AB2235 for which a subcommittee is writing a Pediatric Anesthesia Study. I had the opportunity to review the draft and would like to offer my professional feedback on what I read.

First of all, I am a DDS Anesthesiologist and I completed a 2 year CODA approved anesthesiology residency at Lutheran Medical Center in Brooklyn, NY. I hold both a California DDS license as well as a California General Anesthesia permit, however, I do not practice dentistry. I only provide anesthesia services at various dental practices.

My first concern affects public knowledge about pediatric sedation for dentistry. The second concern affects how dentists practice. Here are the items I noted in the draft that the public, the media and practitioners need to be on the same page on.

1) Are the studies on patient deaths including the distinction of whether there was a separate anesthesia provider from the dental provider? I believe this is a critical question and is a distinction that must be made in the research.

2) The report does not make the distinction between adjunct training in various forms of anesthesia and the higly specialized training residencies in dental anesthesiology. Although the draft report mentions the ADSA in the discussion on the history of anesthesia in dentistry (Par1 Pg3), it does not "highlight" the specialized training programs in dental anesthesiology in the history, that they parallel the medical anesthesia residency training programs. The mention of dental anesthesiology residencies in General Anesthesia Training (P13) doesn't really point this matter out either.

3) Nowhere in the report does it mention that there are licensed dentists in California who attended these programs and that they are called "dental anesthesiologists". Regardless of whether the ADA wants to recognize us as a specialty, it is an accepted title (by ADSA and ASDA) and we are still highly specialty trained in our field. Many of us if not the majority practice ONLY anesthesia.

4) Under Permit Types on page 11, it might be helpful if there were a second column that identifies the ***type*** of ***dental*** practitioner eligible for each type of permit.(apart from the training requirements) to make the distinctions even clearer:

   Minimal Sedation – Any licensed dentist
   Moderate Enteral Sedation – Any licensed dentist
   Moderate Parenteral Sedation – Any licensed dentist
   Deep Sedation / General Anesthesia – Oral Surgeons, Dental Anesthesiologists

5) There is no mention that there are 2 practice models; single-practitioner doing the anesthesia, monitoring and the surgery, and the dual-practitioner model where there is a separate anesthesiologist dedicated to the anesthesia and monitoring, and the dental practitioner who is dedicated to the dentistry. This is not public knowledge and it is not currently a requirement that patients or parents be given that information or an opportunity to choose.

Unfortunately neither the media or the general public currently understands these distinctions and when these tragedies occur, the result is an assumption that general anesthesia or sedation in and of itself, is unsafe for pediatric dentistry, when in fact it is beneficial. If we want to provide laws and guidelines that optimize the safety of all patients, and justify them, then patients must be properly informed and everyone needs to be on the same page.

I hope you will pass this information on to the subcommittee for review and thank you so much for your time.

Sincerely,
Dr. Diana Belli
DDS Anesthesiologist
855-773-7363
www.drdianabelli.com

Fischer, Karen@DCA

From: DrDianaBelli.com <email@drdianabelli.com>
Sent: Friday, July 22, 2016 1:41 PM
To: Fischer, Karen@DCA
Cc: Wallace, Sarah@DCA
Subject: Additional feedback on the Pediatric Anesthesia Study

To whom it may concern,

There are a few more points I think are important in this matter.

California's current definition of General Anesthesia is "an induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway independently and respond purposefully to physical stimulation or verbal command".

1) If a pediatric dentist administers oral sedation to a child who becomes unconscious and unresponsive to verbal command, they are considered to be under general anesthesia and are practicing outside of the law. Pediatric dentists who have NOT also completed an anesthesiology residency, are not qualified or trained in advanced airway management when a patient loses their airway reflexes. Many pediatric dentists use oral medications that can often cause loss of consciousness and patient response is unpredictable. When a patient is unconscious, there is no way to accurately assess whether the airway reflexes are intact.

2) If the majority of these deaths are occurring in pediatric dental offices or offices under the operator/anesthetist model (single practitioner model where one party does the surgery, anesthesia and monitoring), then the issue is about practitioner judgement as to when it is more responsible to call in an anesthesiologist.

In order to determine what the underlying patterns are, any beneficial study must ask the following minimal set of questions:

a) was the case performed under the single-practitioner, or two-practitioner model
b) what as the training of the practitioner(s) involved in the incident
c) who was monitoring the patient and what was being monitored
d) what medications were given, what doses and by what route (oral, I.V., I.M....)
e) was an IV in place
f) what were the events that lead up to the outcome
g) how was the airway managed and by whom (open airway, nasal hood, LMA, Nasal/Endotracheal intubation)
h) what were the dental procedures being done
i) was proper medical history obtained and by whom
j) what were the preoperative steps taken
k) who recovered the patient and in what setting

Just to name a few.....

If it turns out that there is a common thread such that for instance, the majority of these cases are occurring in the single-practitioner model, with an unproteced airway (no LMA and not intubated) and no separate

anesthesiologist, then bringing in a qualified anesthesia provider for all pediatric sedation cases, may be a decision some practitioners decide to make.

Thank you again for your time.

Sincerely,

Dr. Diana Belli, DDS Anesthesiologist 855-773-7363

From: Dr. David Crippen [mailto:drcrippen@capitalpd.com]
Sent: Tuesday, July 26, 2016 9:49 AM
To: Fischer, Karen@DCA
Subject: 2016 anesthesia study

Hello Ms. Fischer,

My name is David Crippen and I am a board certified, practicing pediatric dentist in Sacramento. I maintain both an oral conscious sedation for minors certificate as well as a conscious sedation permit. I am also a current subject matter expert in the field of pediatric dentistry for the Dental Board of California.

This email is regarding the DBC 2016 Anesthesia Study. I understand there is a meeting this Thursday with the subcommittee to discuss the recently released working document. I have emailed Ms. Linda Byers to set up a call-in line because I am unable to reschedule patients on that day and thus cannot attend the meeting in person. In addition to being involved in the working document discussion, I am very interested in participating in any additional meetings or committees that the board deems appropriate. I believe my experience and expertise in the field of Pediatric Dentistry and sedation would prove valuable to the board and the public and I would welcome the opportunity to serve in this capacity.

Thank you in advance for your consideration.

David

David J. Crippen, DDS
920 29th Street
Sacramento, CA 95816
916.476.3972

From: Dr. Skip Harris [mailto:dr.harris@HighDesertOralSurgery.com]
Sent: Friday, July 22, 2016 10:14 AM
To: Wallace, Sarah@DCA
Subject: Pediatric Anesthesia Study and Arizona

Hello,

My name is Brown "Skip" Harris. I am a private practice Oral and Maxillofacial Surgeon in AZ.

I am also an official consultant to the Dental Board and an unofficial subject matter expert and tracker of anesthesia related adverse events and fatalities in the state of Arizona.

I would very much like to offer the data I have collected to your panel creating this study and as you might imagine, I have some things I would like to discuss with your panel.

Would it be possible for you to give them my email address so that I could correspond with the authors and aid them in adding data they don't appear to have. I would also be willing to contact them directly if they are willing and you would provide me with their contact information.

Of course this is all unofficial and I am not speaking on behalf the Arizona Board or any of it staff.

I just want to be helpful and I am interested.

Thank you

Skip Harris, DDS, OMFS
dr.harris@highdesertoralsurgery.com
480-575-0844(o)
602-509-5356(c)

Fischer, Karen@DCA

From:	Annie Kaplan <anna987@gmail.com>
Sent:	Wednesday, June 15, 2016 12:05 PM
To:	Fischer, Karen@DCA
Cc:	Kolakosky, Bridget
Subject:	Fwd: propofol safety
Attachments:	Response to Citizen Petition.pdf

Dear Ms. Fischer,

I'd like to formally submit this email from the FDA to the Dental Board's subcommittee for use in their evaluation. Their explanation/ summary in the body of the email, as well as the attached letter with references is very pertinent to their investigation. Can you make sure they get it?

Thank you so much,

Annie
---------- Forwarded message ----------
From: **CDER DRUG INFO** <DRUGINFO@fda.hhs.gov>
Date: Tue, Jun 14, 2016 at 1:52 PM
Subject: RE: propofol safety
To: Annie Kaplan <anna987@gmail.com>

Dear Dr. Annie Kaplan,

Thank you for your inquiry. Please accept our deepest condolences on the loss of your nephew Caleb. FDA has no comment on California bill AB2235. Regarding the need for a separate anesthesia provider to monitor propofol administration, however, we evaluated this issue in connection with a 2005 citizen petition from the American College of Gastroenterology. The petition asked FDA to remove the warning from the labeling of Diprivan (propofol) stating that "[F]or general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." We denied this petition in 2010, explaining as follows:

> In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary. This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure. [...]
>
> Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur. Others not so trained, or whose attention is

divided between administering propofol and conducting other tasks associated with the procedure, may not be.

A copy of our response to the 2005 petition is attached.

Best Regards,

HT | Pharmacist
Drug Information Specialist

Division of Drug Information | Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter at http://twitter.com/fda_drug_info

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 11 2010

Rec'd 8/11/2010

Richard M. Cooper, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005

Re: Docket No. FDA-2005-P-0059

Dear Mr. Cooper:

This responds to your citizen petition dated June 27, 2005 (Petition), submitted on behalf of the American College of Gastroenterology.[1] You ask the Food and Drug Administration (FDA or Agency) to remove the following warning from the labeling for Diprivan (propofol) (Petition at 1-2):[2]

> For general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.

After carefully considering your request, we deny it for the reasons given below. This decision is based on a review of the Petition including the scientific and medical literature accompanying the Petition, the comments submitted on the petition,[3] and the experience and judgment of the Agency.

---

[1] This citizen petition was originally assigned docket number 2005P-0267/CP1. The number was changed to FDA-2005-P-0059 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] The labeling for a generic drug product approved under an abbreviated new drug application (ANDA) is required to be the same as the labeling for the reference listed drug, with certain permissible differences not relevant here. See 21 U.S.C. 355(j)(2)(A)(v), 21 CFR 314.94(a)(8)(iv); see also 21 CFR 314.127(a)(7). Therefore, removal of the warning quoted above from the labeling for Diprivan would require removal of the warning from the labeling for all generic versions of the drug approved under an ANDA as well.

[3] More than 300 comments were submitted on this Petition. A majority of the comments came from members of the anesthesiology community asking that we maintain the warning as it is currently written. However, we received a few comments from gastroenterologists, anesthesiologists, and other health care practitioners who believe that the warning should be removed.

FDA-2005-P-0059

PDN

I. BACKGROUND

A. Diprivan

FDA approved a new drug application (NDA) for Diprivan (propofol) injectable emulsion submitted by Zeneca Inc., now AstraZeneca Pharmaceuticals LP (AstraZeneca), on October 2, 1989.[4] Diprivan is a sterile, nonpyrogenic emulsion containing 10 milligrams (mg)/milliliter (mL) of propofol suitable for intravenous administration.

Diprivan is a sedative-hypnotic agent for use in the induction and maintenance of anesthesia or sedation. Intravenous injection of a therapeutic dose of propofol induces hypnosis, with minimal excitation, usually within 40 seconds from the start of injection. Diprivan is indicated for use in initiation and maintenance of monitored anesthesia care sedation, combined sedation and regional anesthesia, induction and maintenance of general anesthesia, and intensive care unit sedation of intubated, mechanically ventilated patients.[5] Diprivan is often used to sedate patients undergoing endoscopic procedures, such as colonoscopy and esophagogastroduodenoscopy procedures.

FDA has also approved a number of ANDAs for generic versions of Diprivan. The labeling for both Diprivan and the generic propofol products includes the warning at issue in the Petition (see footnote 2).

B. Levels of Sedation and Anesthesia

The Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Comprehensive Accreditation Manual for Ambulatory Care defines the four levels of sedation and anesthesia as follows:

- *Minimal sedation (anxiolysis)*—A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

- *Moderate sedation/analgesia (conscious sedation)*—A drug-induced depression of consciousness during which patients respond purposefully to

[4] APP Pharmaceuticals, LLC is the current holder of the approved NDA (19-627) for Diprivan.

[5] Diprivan is indicated for use in adults only, except for the induction of general anesthesia (indicated for use in patients three years of age and older only) and maintenance of general anesthesia (indicated for use in patients two months of age and older only).

verbal commands,[6] 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.

- *Deep sedation/analgesia*—A drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually impaired.

- *Anesthesia*—Consists of general anesthesia and spinal or major regional anesthesia. It does *not* include local anesthesia. General anesthesia is a drug-induced consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Based on these definitions, patients undergoing endoscopic procedures, particularly colonoscopies, generally require light to moderate sedation, although deep sedation may be required during certain stages of these procedures. It is possible that doses of sedative medications required to induce or maintain a state of deep sedation could inadvertently result in the induction of general anesthesia. Also, studies submitted with your Petition show that the dosing range of propofol required to achieve and maintain sedation during endoscopic procedures overlaps with the range required to achieve and maintain general anesthesia.

C. Relevant Regulations on Warnings and Precautions in Prescription Drug Product Labeling

FDA regulations state that the WARNINGS AND PRECAUTIONS section of prescription drug product labeling must describe clinically significant adverse reactions, other potential safety hazards, limitations in use imposed by them, and steps that should be taken if these situations occur (21 CFR 201.57(c)(6)(i); 21 CFR 201.80(e)). This section must also contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (21 CFR 201.57(c)(6)(ii); 21 CFR 201.80(f)(1)).

[6] A reflex withdrawal from a painful stimulus is not considered a purposeful response.

II. DISCUSSION

You request that FDA remove the warning from the propofol labeling stating that propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.[7] You state that propofol has several advantages over alternative sedation agents for endoscopic procedures but has a similar "risk profile" (Petition at 2). You claim the warning is no longer warranted because studies have established that propofol can be administered safely and effectively by medical professionals other than anesthesiologists and nurse anesthetists (Petition at 3-8). You believe that the requested labeling change will promote efficiency and reduce costs to payors by eliminating the need for an anesthesiologist or nurse anesthetist to be present to administer propofol during an endoscopic procedure (Petition at 1). You also suggest that the current warning places an unwarranted restriction on the ability of gastroenterologists to practice medicine (Petition at 1).

After considering your claims and the literature you provided for our review, we conclude that you have not shown that the warning is no longer warranted or appropriate. In fact, we conclude that the warning is warranted and appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. Accordingly, we will not seek to have the warning removed, reduced, or otherwise amended.

A. The Warning Is Warranted and Appropriate in Light of the Risks Associated with the Use of Propofol as a Sedation Agent for Endoscopic Procedures

You state that while propofol has several advantages over alternative sedation agents for endoscopic procedures, "the risk profile of propofol appears to be no worse than" these alternative agents. (Petition at 3). We disagree. As explained below, we believe the risks associated with propofol are significantly different from — and, in some critical respects, greater than — the risks associated with the alternative sedation agents you

[7] The warning at issue has two components: that propofol should be administered only by persons trained in the administration of general anesthesia and that the person administering propofol should not be otherwise engaged in the conduct of the procedure. While you request that the entire warning be removed (Petition at 2, *passim*), your petition only addresses the first component of the warning. Specifically, while you contend that "[a] number of controlled and uncontrolled clinical studies have established that propofol can be administered safely and effectively by medical professionals other than anesthesiologists or nurse anesthetists" (Petition at 2), you do not appear to contend that any studies support the position that propofol could be administered safely and effectively by medical professionals — whatever their training — whose attention is divided between administering propofol and conducting the procedure itself. Nevertheless, we discuss both components of the warning in this response.

mention. We further conclude that the warning you seek to have removed is warranted and appropriate in light of the unique risks posed by propofol.

You claim that propofol is superior to alternative agents such as Versed (midazolam) and Demerol (meperidine) because it induces sedation more rapidly than a midazolam-meperidine or midazolam-fentanyl combination, results in faster recovery times than midazolam with meperidine or midozalam with fentanyl, and is associated with better post-procedure functioning than alternative sedation drugs (Petition at 2).[8] We agree that because of the quick onset and offset of sedation associated with propofol, along with a clear sensorium following its use, practitioners might choose propofol over the routinely used alternative sedation agents for short endoscopic procedures. The issue, however, is not propofol's therapeutic advantages over alternative agents, but the safety of propofol as a sedation agent relative to the administrator's level of training in the administration of general anesthesia and relative to whether the administrator is taking part in the procedure apart from administering propofol.

You acknowledge that propofol has risks that make it unique and uniquely demanding to administer among agents used for procedural sedation (Petition at 2).[9] We agree. Propofol has a narrow therapeutic window, that is, a narrow dosage range that produces the desired effect while staying within the safety range. The additional dosing required to deepen sedation from one level to the next is small. This means that propofol poses a significant risk that a level of sedation greater (or lesser) than that intended may be induced.

Over-sedation with propofol poses especially serious risks. Propofol is a cardiovascular depressant that causes a drop in blood pressure as well as a respiratory depressant that can cause partial airway obstruction. In particular, the possibility of apnea with arterial oxygen desaturation and hemodynamic changes, most notably hypotension, increases

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[8] We note that propofol and the alternative sedation agents you mention are in different drug classes. Fentanyl and meperidine are narcotics and not indicated for sedation. Their analgesic properties and sedative side effects allow for a significant reduction in the amount of other medications required to produce a desired level of sedation. The side effects of narcotics, particularly their respiratory depressive effects, may be enhanced when they are co-administered with benzodiazepines, like midazolam, or sedative-hypnotics, such as propofol.

Midazolam is a short-acting benzodiazepine that is indicated for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic, or endoscopic procedures, such as bronchoscopy, gastroscopy, and cystoscopy, among others. Midazolam, which was approved after meperidine and fentanyl, contains both a boxed warning and a partially bold warning providing detailed information on the risks involved with its use, the equipment and drugs that should be readily available when it is used, and the types of monitoring that should be used.

[9] While the risks associated with propofol use are dose dependent, the risks pertain to patients receiving propofol for sedation as well as for general anesthesia. As the studies you submit in support of your Petition show, the propofol dose ranging used to sedate patients for endoscopic procedures, particularly colonoscopies, overlaps with propofol dose ranging used to achieve and maintain general anesthesia.

with deepening levels of sedation. These side effects tend to occur suddenly and can be of life-threatening magnitude if appropriate intervention is not instituted immediately. Furthermore, as you acknowledge, there is no reversal agent for propofol (Petition at 2), whereas there are reversal agents for the other routinely used sedation agents. A propofol dose which exceeds that needed to maintain moderate-to-deep sedation may require treatment including assisted ventilation and hemodynamic support until the patient's own spontaneous ventilation resumes.

For endoscopic procedures, particularly colonoscopies, a light-to-moderate level of sedation is needed for less stimulating parts of the procedure. However, the anesthetic requirements often increase substantially during the more painful portions of the procedure (for example, when negotiating the colonoscope through the splenic and hepatic flexures). Hence, a state of deep sedation is likely to be induced during the more painful parts of the procedure to manage pain and minimize patient movement and the concomitant risk of bowel perforation. Dosing of propofol to achieve such states of sedation has been associated with unintended induction of general anesthesia and the attendant respiratory and hemodynamic risks just described.

Under-sedation also poses risks. For example, as just noted, the risk of unnecessary patient pain or even bowel perforation during a colonoscopy may increase if an insufficient amount of propofol is administered. An inexperienced or insufficiently trained medical professional not confident in his or her ability to intervene in response to over-sedation may err on the side of administering an insufficient dose of propofol, increasing the risk of adverse events associated with under-sedation.

Furthermore, many patients presenting for endoscopic procedures are older, frequently have multiple co-morbidities, and are generally on multiple medications. Each of these factors increases the risks associated with using propofol as a sedation agent, particularly the risks of oxygen desaturation and wide swings in blood pressure.

In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary.[10] This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure.

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[10] This is especially true for endoscopic procedures, where the level of stimulation varies greatly and frequently.

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur.[11] Others not so trained, or whose attention is divided between administering propofol and conducting other tasks associated with the procedure, may not be.

We note that the warning is consistent with the findings and policies of JCAHO, the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, Inc., and the American Society of Anesthesiologists. According to the JCAHO's revised standard, *Moderate and Deep Sedation and Anesthesia Standards*, individuals administering moderate or deep sedation and anesthesia must be qualified and have the appropriate credentials to manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. Those practitioners must be qualified to rescue patients from general anesthesia and be competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation. A sufficient number of qualified personnel (in addition to the licensed independent practitioner performing the procedure) must also be present during the procedure to provide moderate or deep sedation.

Accordingly, we disagree with your assertion that the risk profile of propofol when used in endoscopic procedures appears to be comparable to that of alternative sedation agents. More importantly, we believe both components of the warning you seek to have removed are, in fact, appropriate and well warranted in light of the risks posed by the use of propofol — which you seem to acknowledge are both significant and materially different from those posed by the routinely used alternative sedation agents (Petition at 2). Thus, we believe that the warning should help ensure that propofol is used safely.

B. The Studies Submitted Fail to Show that the Warning is Unwarranted

You submitted 31 publications with your Petition. You assert that studies reported in these publications show that gastroenterologists and nurses supervised by them can safely and effectively administer propofol to patients for endoscopic procedures even without training in the administration of general anesthesia (Petition at 3). As previously noted (see footnote 7), your contentions concerning these studies appear to be limited to the first component of the warning (training in general anesthesia), but you seek to have the second component of the warning (involvement in the conduct of the procedure) removed as well. We address both components below.

Among the publications you submitted were 13 papers reporting on studies involving propofol administration by non-anesthesia trained personnel, 10 abstracts, a review

[11] The warning does not specify what constitutes sufficient training.

article, 4 opinion papers, a historical review, a case report, and a paper discussing cardiovascular complications occurring in the gastrointestinal clinic setting. While the Agency respectfully considers the opinions proffered by experts, it places greater weight on the findings of studies that are prospective, randomized, and controlled by design, adequately powered to discern outcome differences between study arms for the primary endpoint(s), and appropriately executed according to the protocol. Because the opinion papers indicate there are proponents on both sides of this issue, and the historical perspective and review articles provide no substantial data for consideration, we only evaluated the abstracts, study reports, and safety information from the case report and cardiovascular complications report.

We have reached the following conclusions based on our analysis of the articles you submitted in connection with your Petition:

- There is a significant risk of adverse events due to over-sedation when using propofol for procedural sedation, including oxygen desaturation, hypoxemia, hypotension, and bradycardia. These events can result in serious injury or death if appropriate intervention is not instituted immediately.
- Vulnerable populations, like the elderly, who often require endoscopic procedures for diagnostic and therapeutic purposes, are especially at risk of adverse events associated with propofol sedation.
- The only study comparing the safety of administration of propofol by anesthesiologists with administration of propofol by a GI (gastrointestinal) provider (i.e., a gastroenterologist or a nurse supervised by a gastroenterologist) suggests that the risk of cardiopulmonary complications is significantly reduced when propofol is administered by anesthesiologists.[12]
- In several studies assessing the relative safety of propofol versus other sedation agents administered by a GI provider, the frequency and extent of adverse events were quite significant for *both* sedation methods.[13]
- In several studies assessing the safety of administration of propofol by a GI provider with no comparator arm (i.e., no alternative sedation agent), the frequency and extent of adverse events were quite significant.[14]

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- In several studies assessing the safety of administration of propofol by non-anesthesiologists, the GI providers received training — sometimes several months of training — from anesthesiologists.[15] This included elements of training associated with the administration of general anesthesia (e.g., airway management techniques, advanced respiratory monitoring). Furthermore, several authors emphasized the need for adequate training before GI providers could administer propofol safely and effectively.[16]
- Several authors concluded that administration of propofol by GI providers was sufficiently safe despite the occurrence of significant sedation-related adverse events and despite the lack of any comparator arm in the studies on which they based their conclusions.[17]

Having carefully reviewed the studies you submitted, we first conclude that there are no data from prospective, randomized, adequately-powered,[18] well-controlled clinical trials that demonstrate that gastroenterologists or nurses supervised by them who are not trained in the administration of general anesthesia can administer propofol safely and effectively. Furthermore, we conclude that the studies you submitted do not support your contention that the first component of the warning is unwarranted or inappropriate. In fact, we believe the studies, taken as a whole, support the opposite conclusion. Specifically, the studies tend to show that the risks posed by the use of propofol to sedate patients for endoscopic procedures are significant, and that substantial training, experience, and professional judgment are necessary to sufficiently mitigate those risks. Accordingly, we consider the first component of the warning wholly appropriate and warranted.

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specialists in 9152 endoscopic cases in an ambulatory surgery center. Am J. Gastroentero. 2003;98: 1744-50.

[15] Yusoff IF et al. Endoscopist administered propofol for upper-GI EUS is safe and effective: a prospective study in 500 patients. Gastrointest. Endosc. 2004;60:356-60. Walker JA et al. 2003 (see supra footnote 14). Heuss LT et al. Conscious sedation with propofol in elderly patients: a prospective evaluation. Aliment. Pharmacol. Ther. 2003;17:1493-1501. Heuss et al. Risk stratification and safe administration of propofol by registered nurses supervised by the gastroenterologist: a prospective observational study of more than 2000 cases. Gastrointest. Endosc. 2003;57:664-71. Heuss LT et al. Safety of propofol for conscious sedation during endoscopic procedures in high-risk patients: a prospective, controlled study. Am. J. Gastroenterol. 2003;98:1751-57.

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[18] We note that, as there are low rates of morbidity and mortality associated with sedation, adequately powering a study purporting to show that GI providers can safely and effectively administer propofol for endoscopic procedures is likely to require enrollment of large numbers of patients.

Furthermore, we believe your specific contention that GI providers administering propofol for sedation for endoscopic procedures poses no greater risks than GI providers administering benzodiazepine (together with a narcotic) is not sufficiently supported by the literature you submitted. Shortcomings in the relevant studies include differing findings for the cardiovascular versus respiratory outcomes, evaluation of oxygen saturation but not the hemodynamic changes during sedation, and reporting of findings in a manner that precluded further analysis or interpretation of the data. Also, as noted above, we are concerned with the frequency and extent of adverse events reported for *both* treatment arms in several of those comparison studies.

Accordingly, the contention that the incidence of adverse events was similar gives us no comfort.[19] Finally, we are skeptical that the studies in question — even if the flaws just discussed were not present — could reliably predict real-world outcomes. GI providers participating in the studies you submitted may well have greater levels of training, experience, or proficiency administering propofol than the average GI provider.

We also conclude that none of the studies you have presented support your position that the second component of the warning is unwarranted and should be removed. As discussed in the previous section, we believe the warning's admonition that the person administering propofol should not be otherwise involved in the conduct of the procedure is appropriate and warranted because adverse events associated with propofol can occur suddenly and must be addressed immediately.

Accordingly, we do not find the studies you submitted persuasive, and we continue to believe, for the reasons expressed here and in the previous section, that the warning that propofol should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure is appropriate and warranted in light of the risks associated with the administration of the drug.

C. Increased Procedural Costs Do Not Support Removal of the Warning

You assert that, in accordance with the warning you seek to have removed, as many as 12 states and many hospitals require that propofol be administered only by anesthesiologists or nurse anesthetists (Petition at 2). This increases the costs of using propofol for

[19] We further note that it appears that the amount of the alternative sedation agent administered in several of these studies was higher than may be indicated on the relevant drug labeling for the procedures studied. Vargo JJ et al 2002 (see supra footnote 13); Ulmer BJ, et al. Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. Clin. Gastroenterol. Hepatol. 2003;1:425-32. To the extent the risks associated with these alternative agents are dose dependent, higher-than-normal dosing would tend to increase the incidence of complications associated with the alternative sedation agent, making propofol look safer by comparison.

endoscopic procedures because an anesthesiologist or nurse anesthetist must be present to administer propofol during an endoscopy, resulting in higher costs than if the drug were administered by the gastroenterologist or nurse working under his or her direction. (Petition at 2-3).

We first note that the warning does not state that only anesthesiologists or registered nurse anesthetists may administer propofol – it simply warns that only those "trained in the administration of general anesthesia" should administer the drug.

Hospitals and state credentialing authorities set their own rules and policies regarding the administration of drugs; FDA is not involved in that process.[20]

You represent that the services of an anesthesiologist add about $100 to $400 to the cost of an endoscopic procedure (Petition at 3).[21] But as discussed in Part II, the risks associated with propofol are significant and may result in serious injury or death. Accordingly, we continue to think the warning at issue is warranted and appropriate in light of the significant risks posed by propofol, despite any increased costs that may be associated with this warning.

D. The Warning Does Not Unduly Restrict the Practice of Gastroenterologists

You state that the requested labeling change would eliminate an unwarranted restriction on the practice of gastroenterologists (Petition at 1, 8). We disagree.

We first note that the warning simply provides guidance as to the nature of the clinical skills that allow for the safe use of propofol, and neither prohibits the use of propofol by any group of health care providers nor limits its use to a particular medical specialty.

Next, to the extent that some hospitals and state credentialing authorities have determined that only anesthesiologists or registered nurse anesthetists may administer propofol, we note again that these institutions set their own rules regarding the administration of drugs, and, in the case of propofol, they may have done so for reasons other than (or in addition to) the warning on the approved labeling (see footnote 20).

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[20] As previously noted (see section II.A), the warning is consistent with the findings and policies of JCAHO, the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, Inc., and the American Society of Anesthesiologists. Hospitals and states that restrict those who may administer propofol may be influenced by these institutions' positions quite apart from (or in addition to) the warning in the approved labeling. For that matter, they may simply be following their own judgments about the risks attending propofol use.

[21] You make no representations concerning the costs associated with using a registered nurse anesthetist to administer propofol for an endoscopic procedure.

Finally, regardless of whether the warning can be said to restrict the practice of gastroenterologists, we continue to believe it is appropriate and warranted in light of the significant risks associated with propofol.

III. CONCLUSION

For the reasons described, we conclude that you have not demonstrated that the warning is inappropriate or unwarranted. In fact, we conclude that both components of the warning are appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. We therefore will not seek to have the warning removed, reduced, or otherwise amended.

For the reasons stated above, your Petition is denied.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Fischer, Karen@DCA

From: Annie Kaplan <anna987@gmail.com>
Sent: Monday, July 18, 2016 1:46 PM
To: Fischer, Karen@DCA
Cc: Kolakosky, Bridget
Subject: Re: propofol safety
Attachments: Caleb'sLawWhitePaper2016.pdf

Hi Ms. Fischer,

In addition to the FDA information, I would love to formally submit the research and references we have put together regarding AB2235 for use by the Sub-committee to evaluate dental anesthesia safety. Can you make sure they get this information?

Thank you!

Annie Kaplan, MD

On Wed, Jun 15, 2016 at 12:04 PM, Annie Kaplan <anna987@gmail.com> wrote:
Dear Ms. Fischer,

I'd like to formally submit this email from the FDA to the Dental Board's subcommittee for use in their evaluation. Their explanation/ summary in the body of the email, as well as the attached letter with references is very pertinent to their investigation. Can you make sure they get it?

Thank you so much,

Annie
---------- Forwarded message ----------
From: **CDER DRUG INFO** <DRUGINFO@fda.hhs.gov>
Date: Tue, Jun 14, 2016 at 1:52 PM
Subject: RE: propofol safety
To: Annie Kaplan <anna987@gmail.com>

Dear Dr. Annie Kaplan,

Thank you for your inquiry. Please accept our deepest condolences on the loss of your nephew Caleb. FDA has no comment on California bill AB2235. Regarding the need for a separate anesthesia provider to monitor propofol administration, however, we evaluated this issue in connection with a 2005 citizen petition from the American College of Gastroenterology. The petition asked FDA to remove the warning from the labeling of Diprivan (propofol) stating that "[F]or general anesthesia or monitored anesthesia care (MAC) sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." We denied this petition in 2010, explaining as follows:

> In sum, the medical professional administering propofol should have the requisite experience, training, judgment, and undivided focus to achieve and maintain the various levels of sedation appropriate for

the procedure and to monitor the patient continuously throughout the procedure and intervene quickly and appropriately as necessary. This means the individual in question must be qualified to detect and manage the airway, cardiovascular, and hemodynamic changes that occur when a patient enters a state of general anesthesia, and to quickly detect and respond to any complications that may arise. The warning at issue appropriately describes the clinical expertise needed to manage the risk associated with propofol as well as the need for that expertise to be dedicated solely to administering and monitoring effects of the anesthetic throughout the procedure. [...]

Individuals trained in the administration of general anesthesia and not otherwise involved in the conduct of the procedure should be capable both of minimizing the incidence of these complications and handling them appropriately should they occur. Others not so trained, or whose attention is divided between administering propofol and conducting other tasks associated with the procedure, may not be.

A copy of our response to the 2005 petition is attached.

Best Regards,

HT | Pharmacist
Drug Information Specialist

Division of Drug Information | Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter at http://twitter.com/fda_drug_info

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Annie Kaplan
anna987@gmail.com
(510) 846-7847

CALEB'S LAW - WHITE PAPER
A.B. 2235

A.B.2235 seeks to increase the safety of administering general anesthesia to children during dental procedures.

SUMMARY

Following the death last year of Caleb Sears, a healthy six year-old child, a team of family and friends made up of medical, legal and policy professionals were motivated to find out why it happened and could it have been prevented. The findings were alarming. The most disconcerting discovery was that some oral surgeons are the only healthcare professionals who operate and administer anesthesia on children simultaneously, without a separate anesthesia provider,[1,2] and many do not use modern monitoring technologies. Additionally, data collection regarding adverse events during dental anesthesia has been unscientific, unreliable, and inaccessible.[3 4 5 6] A.B. 2235, authored by Assemblymember Tony Thurmond (D15), seeks to address these issues and close any gaps in dental anesthesia safety measures.

BACKGROUND

The question sometimes arises, *'Why now?'* The short answer is that the proposed legislation is long overdue. Guidelines and warnings have been in place for decades advising against the operator-anesthetist model outlined above, as there are high risks associated with general anesthesia and deep sedation that can lead to death or injury.[7 8 9 10]

The model in which the surgical operator is different from the person administering and monitoring anesthesia is supported by the American Society of Anesthesiologists (ASA) and the American Association of Nurse Anesthetists (AANA). The American Academy of Pediatric Dentists (AAPD) also supports having a separate anesthesia provider/monitor in addition to the operating dentist and support staff trained in emergency procedures.[11] To be clear, many dentists and oral surgeons choose to adhere to the model put forth by the ASA but in all the cases where they are not, there are additional risks to undergoing dental anesthesia, particularly for children.

In fact, in 2005, gastroenterologists unsuccessfully petitioned the FDA to remove the warning language from the Propofol label, the most commonly used drug for anesthesia/deep sedation.[12] The warning states that it "should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure." The FDA argued that the safety of the drug is only relative to the administrator's level of training in general anesthesia administration and if someone else is conducting the procedure. As there is a narrow window to achieve the desired effect of the anesthetic within a safe range, the FDA clarified that along with experience, training and judgment, *undivided focus* is critical in safely maintaining sedation.

Undivided focus is vital in a surgical setting and neuroscience studies show that performing more than one task at the same time drastically interferes with the other task, no matter how simple they may be.[13] A complement to focus, vigilance is also an essential component of performing efficiently in medical settings (i.e., monitoring anesthesia levels and an EKG during surgical procedures).[14] A high level task, such as a dental procedure, requires a high level of mental effort, which in turn leads to high stress and a faster decline in vigilance, no matter someone's training or experience.[15]

Training in general anesthesia administration varies greatly across professional specialties.[16] Lower levels of training combined with the dual role of anesthesia administration and surgical practitioner lead to an increased likelihood of adverse events given the small window to recognize danger and respond.

- Anesthesiologist: 4 years anesthesia residency, 2 months pediatrics[17]
- Pediatric Anesthesiologist: 4 years anesthesia residency, 1 year pediatrics[18 19]
- CRNA: 2-3 years of anesthesia training[20]
- Dentist Anesthesiologist: 3 years anesthesia residency[21]

- Oral Surgeons: 5 months, 1 month pediatrics[22]
- Pediatric dentists: 2 months of training[23]
- Veterinarian: 3 years anesthesia residency[24]

Studies show that there are a disproportionate number of recent deaths stemming from anesthesia or sedation given by a dentist, which is echoed by multiple media reports.[25 26 27 28 29 30] There is also a rise in office-based anesthesia administration in the dental field, despite a lack of reliable data collected in a scientific manner that indicates that this is a safe model of operation.[31] There were 55 deaths in California (2008-2011),[32] including at least 20 deaths of children reported by the media since 2005. In contrast, there have been very low numbers and, a large multi-center study of outpatient medical anesthesia care had 0 deaths in the parallel setting with a separate anesthesia provider.[33]

Adverse events during anesthesia are more common in children and seniors. Serious sedation risks of pediatric patients include hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment,[34] which can lead to long-term injury and death. Given the higher doses of medication that are often required to sedate children,[35] it is not uncommon for children to reach a higher level of sedation than is intended, which can lead to the aforementioned risks.[36 37]

Despite sufficient data showing a higher level of risk by having the same person administer general anesthesia/deep sedation and perform the surgical procedure, to date, evidence-based data regarding safety in the administration of anesthesia while performing dental operations is lacking. [38 39 40 41]

Upon review of the references used in the 2013 American Association of Oral and Maxillofacial Surgeons' white paper (AAOMS) about office-based anesthesia provided by oral surgeons, they were determined to be out of date, even 'historical' (i.e., 1947), and used a skewed volunteer survey model. The major study referenced was never actually published by the insurance company, OMSNIC (which is part of AAOMS)[42], and the company has refused to issue the report externally.[43]

Hard data is also unavailable from the CA Dental Board. For example, in 2011 the President of American Society of Dentist Anesthesiologists (ASDA) formally requested hard data from the CA Dental Board multiple times so that he could perform a scientific study to evaluate what he saw as an alarming number of patient deaths. His requests were denied and he was never provided any data.[44] Recent requests for data from the Dental Board have also indicated that there is a lack of consistent, available data.[45]

SOLUTIONS

A.B.2235 outlines the first steps toward increasing the safety of administering and monitoring general anesthesia, and deep sedation to children during dental procedures. Notably, it encourages dentists to contribute sedation data to a national pediatric sedation database. There is already the Pediatric Sedation Research Consortium Database that logs data from each sedation encounter that could be set up to incorporate California dental sedation data for almost no cost since it is already set up and running and used by the outpatient medical community for the past 16 years.

Another extremely important part of the bill increases the data found within adverse event reports and sets up an enforceable time frame for dentists to report to the board after an adverse event happens. These adverse event reports are both the starting points of investigations and are the only transparent part of the investigatory file available for outside study. The bill also lays forth language to be included in the consent to be given to parents regarding the existence of these different anesthesia practices. The bill requires dental sedation providers to give parents more information with regard to the existence of differences in anesthesia practices within different settings and providers. Finally, the law will also require that the California Dental Board establish a committee to study the safety of pediatric anesthesia in dental offices and whether additional safety measures would reduce the potential for injury or death in minors. This committee will act in addition to the important primary steps that the law is immediately taking to improve both data collection and distribution of information to parents of minors undergoing dental anesthesia.

The proposed collection, study, and dissemination of epidemiological data on adverse dental anesthesia events is critical to ensure that there are no gaps in the safety measures.

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