VIRGINIA BOARD OF DENTISTRY

Nitrous Subcommittee

AGENDA

April 27, 2016

Department of Health Professions
Perimeter Center - 9960 Mayland Drive, 2nd Floor Conference Center, Hearing Room 5
Henrico, Virginia 23233

TIME		PAGE
2:00 p.m.	**Call to Order – Charles E. Gaskins, DDS, President**	
	Evacuation Announcement – Ms. Reen	
	Public Comment	
	Recommendation on the Monitoring Requirements of Nitrous Oxide and Minimal Sedation	**P1-P34**
	Next meetings	
Adjourn		

Virginia Administrative Code
Title 18. Professional and Occupational Licensing
Agency 60. Board of Dentistry
Chapter 21. Regulations Governing the Practice of Dentistry

18VAC60-21-280. Administration of Minimal Sedation (Anxiolysis or Inhalation Analgesia).

A. Education and training requirements. A dentist who utilizes minimal sedation shall have training in and knowledge of:

1. Medications used, the appropriate dosages, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. Physiological effects of nitrous oxide, potential complications of administration, the indicators for complications, and the interventions to address the complications.

3. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to arrival at the dental office or treatment facility.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer minimal sedation:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist under his medical direction and indirect supervision;

d. A dental hygienist with the training required by 18VAC60-25-90 B or C only for administration of nitrous oxide/oxygen and under indirect supervision; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of minimal sedation, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-90 C to parenterally administer Schedule V local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule ' topical oral anesthetics.

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the denta office or treatment facility, the dentist may only use the personnel listed in subdivision 1 of this subsection to administer local anesthesia.

D. Equipment requirements. A dentist who utilizes minimal sedation or who directs the administration by anothe licensed health professional as permitted in subsection C of this section shall maintain the following equipment working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag;

4. Suction apparatus; and

5. Pulse oximeter.

E. Required staffing.

1. The treatment team for minimal sedation other than just inhalation of nitrous oxide/oxygen shall consist of dentist and a second person in the operatory with the patient to assist the dentist and monitor the patient. The second person shall be a licensed health care professional or a person qualified in accordance with 18VAC60-2 260 I; or

2. When only nitrous oxide/oxygen is administered for minimal sedation, a second person is not required. Eith the dentist or qualified dental hygienist under the indirect supervision of a dentist may administer the nitrous oxide/oxygen and treat and monitor the patient.

F. Monitoring requirements.

1. Baseline vital signs to include blood pressure, respiratory rate, and heart rate shall be taken and recorded pri to administration of sedation and prior to discharge.

2. Blood pressure, oxygen saturation, respiratory rate, and pulse shall be monitored intraoperatively.

3. Once the administration of minimal sedation has begun by any route of administration, the dentist shall ens that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors th patient at all times until discharged as required in subsection G of this section.

4. If nitrous oxide/oxygen is used, monitoring shall include making the proper adjustments of nitrous oxide/ox machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. If any other pharmacological agent is used in addition to nitrous oxide/oxygen and a local anesthetic, requirements for the induced level of sedation must be met.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation the level of consciousness. Vital signs, to include blood pressure, respiratory rate, and heart rate shall be taken recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24 hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to th patient's care.

Statutory Authority

§ 54.1-2400 of the Code of Virginia.

Historical Notes

Derived from Volume 32, Issue 05, eff. December 2, 2015.

4/15/

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.

Guideline on Use of Nitrous Oxide for Pediatric Dental Patients

Originating Council
Council on Clinical Affairs

Review Council
Council on Clinical Affairs

Adopted
2005

Revised
2009, 2013

Purpose

The American Academy of Pediatric Dentistry (AAPD) recognizes nitrous oxide/oxygen inhalation as a safe and effective technique to reduce anxiety, produce analgesia, and enhance effective communication between a patient and health care provider. The need to diagnose and treat, as well as the safety of the patient and practitioner, should be considered before using nitrous oxide. By producing this guideline, the AAPD intends to assist the dental profession in developing appropriate practices in the use of nitrous oxide/oxygen analgesia/anxiolysis for pediatric patients.

Methods

This document is an update of the previous guideline revised in 2009. The revision is based on a review of the current dental and medical literature related to nitrous oxide use. An electronic search was conducted using PubMed® with the following parameters: Terms: nitrous oxide, analgesia, anxiolysis, behavior management, and dental treatment; Fields: all; Limits: within the last 10 years, humans, English, and clinical trials. Forty articles met these criteria, and papers were added to the references from the previous document. When data did not appear sufficient or were inconclusive, recommendations were based upon expert and/or consensus opinion by experienced researchers and clinicians.

Background

Dentists have expertise in providing anxiety and pain control for their patients. While anxiety and pain can be modified by psychological techniques, in many instances pharmacological approaches are required.[1] Analgesia/anxiolysis is defined as diminution or elimination of pain and anxiety in a conscious patient.[2] The patient responds normally to verbal commands. All vital signs are stable, there is no significant risk of losing protective reflexes, and the patient is able to return to preprocedure mobility. In children, analgesia/anxiolysis may expedite the delivery of procedures that are not particularly uncomfortable, but require that the patient not move.[2] It also may allow the patient to tolerate unpleasant procedures by reducing or relieving anxiety, discomfort, or pain. The outcome of pharmacological approaches is variable and depends upon each patient's response to various drugs. The clinical effect of nitrous oxide/oxygen inhalation, however, is more predictable among the majority of the population.

Nitrous oxide is a colorless and virtually odorless gas with a faint, sweet smell. It is an effective analgesic/anxiolytic agent causing central nervous system (CNS) depression and euphoria with little effect on the respiratory system.[3,4] Nitrous oxide has multiple mechanisms of action. The analgesic effect of nitrous oxide appears to be initiated by neuronal release of endogeneous opioid peptides with subsequent activation of opioid receptors and descending Gamma-aminobutyric acid type A (GABAA) receptors and noradrenergic pathways that modulate nociceptive processing at the spinal level. The anxiolytic effect involves activation of the GABAA receptor either directly or indirectly through the benzodiazepine binding site.[5,6] Nitrous oxide has rapid uptake, being absorbed quickly from the alveoli and held in a simple solution in the serum. It is relatively insoluble, passing down a gradient into other tissues and cells in the body, such as the CNS. It is excreted quickly from the lungs. As nitrous oxide is 34 times more soluble than nitrogen in blood, diffusion hypoxia may occur. Studies[7-9] have shown that children desaturate more rapidly than adolescents, and administering 100 percent oxygen to the patient once the nitrous oxide in a closed system has been terminated is important.[7] Nitrous oxide causes minor depression in cardiac output while peripheral resistance is slightly increased, thereby maintaining the blood pressure.[3] This is of particular advantage in treating patients with cerebrovascular system disorders.

Nitrous oxide is absorbed rapidly, allowing for both rapid onset and recovery (two to three minutes). It causes minimal impairment of any reflexes, thus protecting the cough reflex.[3] It exhibits a superior safety profile with no recorded fatalities or cases of serious morbidity when used within recommended

concentrations.[10-13] Studies have reported negative outcomes associated with use of nitrous oxide greater than 50 percent and as an anesthetic during major surgery. [14,15] Although rare, silent regurgitation and subsequent aspiration need to be considered with nitrous oxide/oxygen sedation. The concern lies in whether pharyneal-laryngeal reflexes remain intact. This problem can be avoided by not allowing the patient to go into an unconscious state.[16]

The decision to use nitrous oxide/oxygen analgesia/anxiolysis must take into consideration alternative behavioral guidance modalities, the patient's dental needs, the effect on the quality of dental care, the patient's emotional development, and the patient's physical considerations. Nitrous oxide generally is acceptable to children and can be titrated easily. Most children are enthusiastic about the administration of nitrous oxide/oxygen; many children report dreaming or being on a "space-ride".[16] For some patients, however, the feeling of "losing control" may be troubling and claustrophobic patients may find the nasal hood confining and unpleasant.[17]

Nitrous oxide has been associated with bioenvironmental concerns because of its contribution to the greenhouse effect. Nitrous oxide is emitted naturally by bacteria in soils and oceans; it is produced by humans through the burning of fossil fuels and forests and the agricultural practices of soil cultivation and nitrogen fertilization. Altogether, nitrous oxide contributes about five percent to the greenhouse effect.[18,19] Only a small fraction of this five percent (0.35 to two percent), however, is actually the result of combined medical and dental applications of nitrous oxide gas.[19]

The objectives of nitrous oxide/oxygen inhalation include:

1. Reduce or eliminate anxiety.
2. Reduce untoward movement and reaction to dental treatment.
3. Enhance communication and patient cooperation.
4. Raise the pain reaction threshold.
5. Increase tolerance for longer appointments.
6. Aid in treatment of the mentally/physically disabled or medically compromised patient.
7. Reduce gagging.
8. Potentiate the effect of sedatives.

Disadvantages of nitrous oxide/oxygen inhalation may include:[3]

1. Lack of potency.
2. Dependant largely on psychological reassurance.
3. Interference of the nasal hood with injection to anterior maxillary region.
4. Patient must be able to breathe through the nose.
5. Nitrous oxide pollution and potential occupational exposure health hazards.

Recommendations

Indications for use of nitrous oxide/oxygen analgesia/anxiolysis include:

1. A fearful, anxious, or obstreperous patient.
2. Certain patients with special health care needs.
3. A patient whose gag reflex interferes with dental care.
4. A patient for whom profound local anesthesia cannot be obtained.
5. A cooperative child undergoing a lengthy dental procedure.

Review of the patient's medical history should be performed prior to the decision to use nitrous oxide/oxygen analgesia/anxiolysis. This assessment should include:

1. Allergies and previous allergic or adverse drug reactions.
2. Current medications including dose, time, route, and site of administration.
3. Diseases, disorders, or physical abnormalities and pregnancy status.
4. Previous hospitalization to include the date and purpose.
5. Recent illnesses (eg, cold or congestion) that may compromise the airway.

Contraindications for use of nitrous oxide/oxygen inhalation may include:

1. Some chronic obstructive pulmonary diseases.[20]
2. Severe emotional disturbances or drug-related dependencies.[21]
3. First trimester of pregnancy.[22]
4. Treatment with bleomycin sulfate.[23]
5. Methylenetetrahydrofolate reductase deficiency.[24]
6. Cobalamin deficiency.[6]

Whenever possible, appropriate medical specialists should be consulted before administering analgesic/anxiolytic agents to patients with significant underlying medical conditions (eg, severe obstructive pulmonary disease, congestive heart failure, sickle cell disease[25], acute otitis media, recent tympanic membrane graft[26], acute severe head injury[27]).

Technique of nitrous oxide/oxygen administration

Nitrous oxide/oxygen must be administered only by appropriately licensed individuals, or under the direct supervision thereof, according to state law. The practitioner responsible for the treatment of the patient and/or the administration of analgesic/anxiolytic agents must be trained in the use of such agents and techniques and appropriate emergency response.

Selection of an appropriately sized nasal hood should be made. A flow rate of five to six L/min generally is acceptable to most patients. The flow rate can be adjusted after observation of the reservoir bag. The bag should pulsate gently with each breath and should not be either over- or underinflated. Introduction of 100 percent oxygen for one to two minutes followed

by titration of nitrous oxide in 10 percent intervals is recommended. During nitrous oxide/oxygen analgesia/anxiolysis, the concentration of nitrous oxide should not routinely exceed 50 percent. Studies have demonstrated that gas concentrations dispensed by the flow meter vary significantly from the end-expired alveolar gas concentrations; it is the later that is responsible for the clinical effects.[28,29] To achieve sedation, the scavenging vacuum should not be so strong as to prevent adequate ventilation of the lungs with nitrous oxide.[30] A review of records of patients undergoing nitrous oxide-oxygen inhalation sedation demonstrate that the typical patient requires from 30 to 40 percent nitrous oxide to achieve ideal sedation.[31] Nitrous oxide concentration may be decreased during easier procedures (eg, restorations) and increased during more stimulating ones (eg, extraction, injection of local anesthetic). Side effects such as nausea and vomiting are more likely to be observed when titration is not employed.[31] During treatment, it is important to continue the visual monitoring of the patient's respiratory rate and level of consciousness. The effects of nitrous oxide largely are dependent on psychological reassurance. Therefore, it is important to continue traditional behavior guidance techniques during treatment. Once the nitrous oxide flow is terminated, 100 percent oxygen should be delivered for five minutes.[21] The patient must return to pretreatment responsiveness before discharge.

Monitoring

The response of patients to commands during procedures performed with analgesia/anxiolysis serves as a guide to their level of consciousness. Clinical observation of the patient must be performed during any dental procedure. During nitrous oxide/oxygen analgesia/anxiolysis, continual clinical observation of the patient's responsiveness, color, and respiratory rate and rhythm must be performed. Spoken responses provide an indication that the patient is breathing.[2] If any other pharmacologic agent is used in addition to nitrous oxide/oxygen and a local anesthetic, monitoring guidelines for the appropriate level of sedation must be followed.[32]

Adverse effects of nitrous oxide/oxygen inhalation

Nitrous oxide/oxygen analgesia/anxiolysis has an excellent safety record. When administered by trained personnel on carefully selected patients with appropriate equipment and technique, nitrous oxide is a safe and effective agent for providing pharmacological guidance of behavior in children. Acute and chronic adverse effects of nitrous oxide on the patient are rare.[33] Nausea and vomiting are the most common adverse effects, occurring in 0.5 percent of patients.[34] A higher incidence is noted with longer administration of nitrous oxide/oxygen, fluctuations in nitrous oxide levels, and increased concentrations of nitrous oxide.[3] Fasting is not required for patients undergoing nitrous oxide analgesia/anxiolysis. The practitioner, however, may recommend that only a light meal be consumed in the two hours prior to the administration of nitrous oxide.[35] Diffusion hypoxia can occur as a result of rapid release of nitrous oxide from the blood stream into the alveoli, thereby diluting the concentration of oxygen. This may lead to headache and disorientation and can be avoided by administering 100 percent oxygen after nitrous oxide has been discontinued.[3]

Documentation

Informed consent must be obtained from the parent and documented in the patient's record prior to administration of nitrous oxide/oxygen. The practitioner should provide instructions to the parent regarding pretreatment dietary precautions, if indicated. In addition, the patient's record should include indication for use of nitrous oxide/oxygen inhalation, nitrous oxide dosage (ie, percent nitrous oxide/oxygen and/or flow rate), duration of the procedure, and post treatment oxygenation procedure.

Facilities/personnel/equipment

All newly installed facilities for delivering nitrous oxide/oxygen must be checked for proper gas delivery and fail-safe function prior to use. Inhalation equipment must have the capacity for delivering 100 percent, and never less than 30 percent, oxygen concentration at a flow rate appropriate to the child's size. Additionally, inhalation equipment must have a fail-safe system that is checked and calibrated regularly according to the practitioner's state laws and regulations.[15] If nitrous oxide/oxygen delivery equipment capable of delivering more than 70 percent nitrous oxide and less than 30 percent oxygen is used, an inline oxygen analyzer must be used. The equipment must have an appropriate scavenging system to minimize room air contamination and occupational risk.

The practitioner who utilizes nitrous oxide/oxygen analgesia/anxiolysis for a pediatric dental patient shall possess appropriate training and skills and have available the proper facilities, personnel, and equipment to manage any reasonably foreseeable emergency. Training and certification in basic life support are required for all clinical personnel. These individuals should participate in periodic review of the office's emergency protocol, the emergency drug cart, and simulated exercises to assure proper emergency management response.

An emergency cart (kit) must be readily accessible. Emergency equipment must be able to accommodate children of all ages and sizes. It should include equipment to resuscitate a nonbreathing, unconscious patient and provide continuous support until trained emergency personnel arrive. A positive-pressure oxygen delivery system capable of administering greater than 90 percent oxygen at a 10 L/min flow for at least 60 minutes (650 L, "E" cylinder) must be available. When a self-inflating bag valve mask device is used for delivering positive pressure oxygen, a 15 L/min flow is recommended. There should be documentation that all emergency equipment and drugs are checked and maintained on a regularly scheduled basis.[32] Where state law mandates equipment and facilities, such statutes should supersede this guideline.[32]

Occupational safety

In the medical literature, long-term exposure to nitrous oxide used as a general anesthetic has been linked to bone marrow suppression and reproductive system disturbances.[6,36-38] In an effort to reduce occupational health hazards associated with nitrous oxide, the AAPD recommends exposure to ambient nitrous oxide be minimized through the use of effective scavenging systems and periodic evaluation and maintenance of the delivery and scavenging systems.[39,40]

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Guideline for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures

Developed and Endorsed by
American Academy of Pediatrics and the American Academy of Pediatric Dentistry

Adopted
2006

Reaffirmed
2011

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 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 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 tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction, a clear understanding of the pharmacokinetic and pharmacodynamic effects of the medications used for sedation as well as an appreciation for 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 people 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 presedation level of consciousness before discharge from medical supervision, and appropriate discharge instructions.

Introduction
Invasive diagnostic and minor surgical procedures on pediatric patients outside the traditional operating room setting have increased in the last decade. 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 physician offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, and ambulatory surgery centers also has markedly increased.[1-37] In recognition of this need for both elective and emergency use of sedation in nontraditional settings, the American Academy of Pediatrics (AAP) and 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.[38-42] The purpose of this updated statement is to unify the guidelines for sedation used by medical and dental practitioners, add clarifications regarding monitoring modalities, provide new information from medical and dental literature, and suggest methods for further improvement in safety and outcomes. With the revision of this document, the Joint Commission on Accreditation of Healthcare Organizations, the American Society of Anesthesiologists (ASA), the AAP, and the AAPD will use similar language to define sedation categories and the expected physiologic responses.[41-44]

This revised statement reflects the current understanding of appropriate monitoring needs both during and after sedation for a procedure.[4,5,12,19,21,22,26,45-53] The monitoring and care out-lined in this guideline may be exceeded at any time, based on the judgment of the responsible practitioner. Although intended to encourage high-quality patient care, adherence to this guideline cannot guarantee a specific patient outcome. However, structured sedation protocols designed to incorporate the principles in this document have been widely implemented and shown to reduce morbidity.[29,32-34,37,54,55] This guideline is proffered with the awareness that, regardless of the intended level of sedation or route of administration, the sedation of a pediatric patient represents a continuum and may result in respiratory depression and the loss of the patient's protective reflexes.[43,57-60]

Sedation of pediatric patients has serious associated risks, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment.[2,6,22,45,46,54,60-69] 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.[54] Appropriate drug selection for the intended procedure as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are essential.

Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.[46,51,54]

The sedation of children is different from the sedation of adults. Sedation in children often is administered to control behavior 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 and developmental age. Often, children younger than six years and those with developmental delay require deep levels of sedation to gain control of their behavior.[57] Therefore, the need for deep sedation should be anticipated. Children in this age group are particularly vulnerable to the sedating medication's effects on respiratory drive, patency of the airway, and protective reflexes.[46] Studies have shown that it is common for children to pass from the intended level of sedation to a deeper, unintended level of sedation.[56,59,70] For older and cooperative children, other modalities, such as parental presence, hypnosis, distraction, topical local anesthetics, and guided imagery, may reduce the need for or the needed depth of pharmacologic sedation.[31,71-81]

The concept of rescue is 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 necessary to provide appropriate cardiopulmonary support if needed. Sedation and anesthesia in a nonhospital environment (private physician or dental office or freestanding imaging facility) may be associated with an increased incidence of "failure to rescue" the patient should an adverse event occur, because the only backup in this venue may be to activate emergency medical services (EMS).[46,82] Rescue therapies require specific training and skills.[46,54,83,84] Maintenance of the skills needed to perform successful bag-valve-mask ventilation is essential to successfully rescue a child who has become apneic or developed airway obstruction. Familiarity with emergency airway management procedure algorithms is essential.[83-87] Practitioners should have an in-depth knowledge of the agents they intend to use and their potential complications. A number of reviews and hand-books for sedating pediatric patients are available.[32,48,55,88-93] This guideline is intended for all venues in which sedation for a procedure might be performed (hospital, surgical center, freestanding imaging facility, dental facility, or private office).

There are other guidelines for specific situations and personnel 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.[94] Also, 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 hospice care are beyond the scope of this document.

Definitions of terms for this report

- *Pediatric patients*: all patients through 21 years of age, as defined by the AAP.
- *Must* or *shall*: an imperative need or duty that is essential, indispensable, or mandatory.
- *Should*: the recommended need and/or duty.
- *May* or *could*: freedom or liberty to follow a suggested or reasonable alternative.
- *Medical supervision* or *medical personnel*: a current, licensed practitioner in medicine, surgery, or dentistry trained in the administration of medications used for procedural sedation and the management of complications associated with these medications.
- *Are encouraged*: a suggested or reasonable action to be taken.
- *ASA Physical Status Classification*: guidelines for classifying the baseline health status according to the ASA (see Appendix B).
- *Minimal sedation* (old terminology *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* (old terminology conscious sedation or sedation/analgesia): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (eg, *open your eyes* either alone or accompanied by light tactile stimulation—a light tap on the shoulder or face, not a sternal rub). For older patients, this level of sedation implies an interactive state; for younger patients, age-appropriate behaviors (eg, crying) occur and are expected. Reflex withdrawal, although a normal response to a painful stimulus, is not considered as the only age-appropriate purposeful response (eg, it must be accompanied by another response, such as pushing away the painful stimulus so as to confirm a higher cognitive function). With moderate sedation, no intervention is required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. However, in the case of procedures that may themselves cause airway obstruction (eg, dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway. If the patient is not making spontaneous efforts to open his/her airway so as to relieve the obstruction, then the patient should be considered to be deeply sedated.
- *Deep sedation* (deep sedation/analgesia): a drug-induced depression of consciousness during which patients cannot be

easily aroused but respond purposefully (see discussion of reflex withdrawal above) after repeated verbal or painful stimulation (eg, purposefully pushing away the noxious stimuli). 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.

- *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.

Goals of sedation

The goals of sedation in the pediatric patient for diagnostic and therapeutic procedures are: 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 control 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 safe discharge from medical supervision, as determined by recognized criteria, is possible (Appendix A).

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 goal of the procedure are essential for safe practice.[53,88,91-93,95-97] For example, analgesic medications such as opioids 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 commonly are used. Anxiolysis and amnesia are additional goals that should be considered in selection of agents for particular patients. However, the potential for an adverse outcome may be increased when three or more sedating medications are administered.[44,98] Knowledge of each drug's time of onset, peak response, and duration of action is essential. Although the concept of titration of drug to effect is critical, one must know whether the previous dose has taken full effect before administering additional drug. Such management will improve safety and outcomes. Drugs with long durations of action (eg, chloral hydrate, intramuscular pentobarbital, phenothiazines) will require longer periods of observation even after the child achieves currently used recovery and discharge criteria.[45,99,100] This concept is particularly important for infants and toddlers transported in car safety seats who are at risk of resedation after discharge because of residual prolonged drug effects with the potential for airway obstruction.[45,46]

General guidelines

Candidates

Patients who are in ASA classes I and II are frequently considered appropriate candidates for minimal, moderate, or deep sedation (Appendix B). Children in ASA classes III and IV, children with special needs, and those with anatomic airway abnormalities or extreme tonsillar hypertrophy present issues that require additional and individual consideration, particularly for moderate and deep sedation.[51] 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 two or more adults accompany children who are still in car safety seats if transportation to and from a treatment facility is provided by one of the adults.[101]

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, hypoxemia, and apnea. Hypotension and cardiopulmonary arrest may occur, usually from inadequate recognition and treatment of respiratory compromise. Other rare complications may also include seizures and allergic reactions. Facilities providing pediatric sedation should monitor for, and be prepared to treat, such complications.

Back-up emergency services

A protocol for access to back-up emergency services shall be clearly identified, with an outline of the procedures necessary for immediate use. For nonhospital facilities, a protocol for ready access to ambulance service and immediate activation of the EMS system for life-threatening complications must be established and maintained. It should be understood that the availability of EMS services does not replace the practitioner's responsibility to provide initial rescue in managing life-threatening complications.

On-site monitoring and rescue equipment

An emergency cart or kit must be immediately accessible. This cart or kit must contain equipment to provide the necessary age- and size-appropriate drugs and equipment 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 facility or to another area within a medical facility. All equipment and drugs must be checked and maintained on a scheduled basis (see Appendices C and D 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 oximeter probes), end-tidal carbon dioxide monitors, and defibrillators (with size-appropriate defibrillator paddles), must have a safety and function check on a regular basis as required by local or state regulation.

Documentation before sedation

Documentation shall include, but not be limited to, the guidelines that follow:

1. Informed consent. The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.[102]
2. Instructions and information provided to the responsible 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. 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 so as to avoid airway obstruction. Transportation by 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.[45,46,100,103] Consideration for a longer period of observation shall be given if the responsible person's ability to observe the child is limited (eg, only one adult who also has to drive). Another indication for prolonged observation would be a child with an anatomic airway problem or a severe underlying medical condition. 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. Therefore, it is prudent that before sedation, the practitioner evaluate preceding food and fluid intake. It is likely that the risk of aspiration during procedural sedation differs from that during general anesthesia involving tracheal intubation or other airway manipulation.[104,105] However, because the absolute risk of aspiration during procedural sedation is not yet known, guidelines for fasting periods before elective sedation generally should follow those used for elective general anesthesia. For emergency procedures in children who have not fasted, the risks of sedation and the possibility of aspiration must be balanced against the benefits of performing the procedure promptly (see next column). Further research is needed to better elucidate the relationships between various fasting intervals and sedation complications.

Before Elective Sedation

Children receiving sedation for elective procedures should generally follow the same fasting guidelines as before general anesthesia (Table 1). It is permissible for routine necessary medications to be taken with a sip of 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 and necessity for completing the procedure. In this circumstance, the use of sedation must be preceded by an evaluation of food and fluid intake. There are few published studies with adequate statistical power to provide guidance to the practitioner regarding safety or risk of pulmonary aspiration of gastric contents during procedural sedation.[104-109] When protective airway reflexes are lost, gastric contents may be regurgitated into the airway. Therefore, patients with a history of recent oral intake or with other known risk factors, such as trauma, decreased level of consciousness, extreme obesity, pregnancy, or bowel motility dysfunction, require careful evaluation before administration of sedatives. When proper fasting has not been ensured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. The use of agents with less risk of depressing protective airway reflexes may be preferred.[110] Some emergency patients requiring deep sedation may require protection of the airway before sedation.

Use of immobilization devices

Immobilization devices, such as papoose boards, must be applied in such a way as to avoid airway obstruction or chest restriction. 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. The purpose of this evaluation is not only to document baseline status but also to determine whether patients present specific risk factors that may warrant additional consultation before sedation. This evaluation will also screen out patients

whose sedation will require more advanced airway or cardiovascular management skills or alterations in the doses or types of medications used for procedural sedation.

A new 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, echinacea) may alter drug pharmacokinetics through inhibition of the cytochrome P450 system, resulting in prolonged drug effect and altered (increased or decreased) blood drug concentrations.[111-116] Kava may increase the effects of sedatives by potentiating gamma-aminobutyric acid inhibitory neurotransmission, and valerian may itself produce sedation that apparently is mediated through modulation of gamma-aminobutyric acid neurotransmission and receptor function.[117,118] Drugs such as erythromycin, cimetidine, and others also may inhibit the cytochrome P450 system, resulting in prolonged sedation with midazolam as well as other medications competing for the same enzyme systems.[119-122] Medications used to treat human immunodeficiency virus infection, some anticonvulsants, and some psychotropic medications also may produce clinically important drug-drug interactions.[123-125] Therefore, a careful drug history is a vital part of the safe sedation of children. The clinician should consult various sources (a pharmacist, textbooks, online services, or handheld databases) for specific information on drug interactions.[126]

The health evaluation should include:

- Age and weight.
- Health history, including: 1) 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, and neurologic impairment that might increase the potential for airway obstruction, such as a history of snoring or obstructive sleep apnea,[127,128] 4) pregnancy status, 5) a summary of previous relevant hospitalizations, 6) history of sedation or general anesthesia and any complications or unexpected responses, and 7) relevant family history, particularly related to anesthesia.
- Review of systems with a special focus on abnormalities of cardiac, pulmonary, renal, or hepatic function that might alter the child's expected responses to sedating/analgesic medications.
- Vital signs, including heart rate, blood pressure, respiratory rate, 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 occurrence).
- Physical examination, including a focused evaluation of the airway (tonsillar hypertrophy, abnormal anatomy—eg, mandibular hypoplasia) to determine whether there is an increased risk of airway obstruction.[54,129,130]
- Physical status evaluation [ASA classification (see Appendix B)].
- Name, address, and telephone number of the child's medical home.

For hospitalized patients, the current hospital record may suffice for adequate documentation of presedation health; however, a brief 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 benefit of direct supervision by trained medical personnel.** Administration of sedating medications at home poses an unacceptable risk, particularly for infants and preschool-aged children traveling in car safety seats.[46]

Documentation during treatment

The patient's chart shall contain a time-based record that includes the name, route, site, time, dosage, 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 site of the procedure.[43] During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Before drug administrations, special attention must be paid to calculation of dosage (ie, mg/kg). 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, and oxygen saturation were monitored until the patient attained predetermined discharge criteria (see Appendix A). A variety of sedation scoring systems are available and may aid this process.[70,100] Adverse events and their treatment shall be documented.

Documentation after treatment

The time and condition of the child at discharge from the treatment area or facility shall be documented; this 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 A). 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 resedation,[45,103,131,132] some patients might benefit from a longer period of less-intense observation (eg, a step-down observation area) before discharge from medical supervision.[133] Several scales to evaluate recovery have been devised and validated.[70,134,135] A recently described and 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.[100]

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.[137-141] Therefore, each facility should maintain records that track adverse events, such as desaturation, apnea, laryngospasm, the need for airway interventions including jaw thrust, positive pressure ventilation, prolonged sedation, unanticipated use of reversal agents, unintended or prolonged hospital admission, and unsatisfactory sedation/analgesia/anxiolysis. Such events can then be examined for assessment of risk reduction and improvement in patient satisfaction.

Preparation and setting up for sedation procedures

Part of the safety net of sedation is to use 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:

- **S** = Size-appropriate **suction** catheters and a functioning **suction** apparatus (eg, Yankauer-type suction)
- **O** = An adequate **oxygen** supply and functioning flow meters/other devices to allow its delivery
- **A** = **Airway:** size-appropriate airway equipment [nasopharyngeal and oropharyngeal airways, laryngoscope blades (checked and functioning), endotracheal tubes, stylets, face mask, bag-valve-mask or equivalent device (functioning)]
- **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[141,142] and other monitors as appropriate for the procedure (eg, noninvasive blood pressure, end-tidal carbon dioxide, 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.[57]

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 following light tactile stimulation (see Definition of Terms for This Report). No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function usually is maintained. The caveat that loss of consciousness should be unlikely is a particularly important aspect of the definition of moderate sedation. The drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness highly unlikely. Because the patient who 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.[57]

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 provided in this guideline, 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 provide rescue should the child progress to a level of deep sedation. The practitioner must be trained in, and capable of providing, at the minimum, bag-valve-mask ventilation so as to be able to oxygenate a child who develops airway obstruction or apnea. Training in, and maintenance of, advanced pediatric airway skills is required; regular skills reinforcement is strongly encouraged.

Support personnel. The use of moderate sedation shall include 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.[44] This individual must be trained in and capable of providing pediatric basic life support. 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 and practice drills of the facility's emergency protocol to ensure proper function of the equipment and coordination of staff roles in such emergencies.

Monitoring and Documentation

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

During the procedure. The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. There shall be continuous monitoring of oxygen saturation and heart rate and intermittent recording of respiratory rate and blood pressure; these should be recorded in a time-based record. Restraining devices 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 checked frequently to ensure airway patency. A functioning suction apparatus must be present.

After the procedure. The child who has received moderate sedation must be observed in a suitably equipped recovery facility [eg, the facility must have functioning suction apparatus as well as the capacity to deliver more than 90 percent oxygen and positive-pressure ventilation (eg, bag and mask with oxygen capacity as described previously)]. The patient's vital signs should be recorded at specific intervals. 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 A). Because sedation medications with a long half-life may delay the patient's complete return to baseline or pose the risk of resedation, 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 supervision (see also Documentation Before Sedation for instructions to families).[45,103,131,132] A recently described and 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.[100] Patients who have received reversal agents, such as flumazenil or naloxone, will also require a longer period of observation, because the duration of the drugs administered may exceed the duration of the antagonist, which can lead to resedation.

Deep sedation

Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated verbal or painful stimulation (see Definition of Terms for this report). The state and risks of deep sedation may be indistinguishable from those of general anesthesia.

Personnel

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.

Equipment

In addition to the equipment previously cited for moderate sedation, an electrocardiographic 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 and Documentation

A competent individual shall observe the patient continuously. The monitoring shall include all parameters described for moderate sedation. Vital signs, including oxygen saturation and heart rate, must be documented at least every five minutes in a time-based record. The use of a precordial stethoscope or capnograph for patients difficult to observe (eg, during MRI, in a darkened room) to aid in monitoring adequacy of ventilation is encouraged.[143] The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. The inspired 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.

Special considerations

Local anesthetic agents

All local anesthetic agents are cardiac depressants and may cause central nervous system excitation or depression. Particular attention should be paid to dosage in small children.[64,66] To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (ie, 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 narcotics (see Tables two and three for limits and conversion tables of commonly used local anesthetics).[64,144-157] In general, when administering local anesthetic drugs, the practitioner should aspirate frequently so as to minimize the likelihood that the needle is in a blood vessel; lower doses should be used when injecting into vascular tissues.[158]

Pulse oximetry

The new generation of pulse oximeters is less susceptible to motion artifacts and may be more useful than older oximeters

that do not contain the updated software.[159-163] Oximeters that change tone with changes in hemoglobin saturation provide immediate aural warning to everyone within hearing distance. It is essential that any oximeter probe is positioned properly; clip-on devices are prone to easy displacement, which may produce artifactual data (eg, under- or overestimation of oxygen saturation).[141,142]

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 magnetic resonance imaging or computerized axial tomography devices or darkened rooms.[47,49,50,143,164-173] The use of expired carbon dioxide monitoring devices is encouraged for sedated children, particularly in situations where 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.[164,165] 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.[166,168,173]

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, and bag-mask-valve ventilation. Occasionally, endotracheal intubation is required for more prolonged ventilatory support. In addition to standard endotracheal intubation techniques, a number of new devices are available for the management of patients with abnormal airway anatomy or airway obstruction. Examples include the laryngeal mask airway (LMA), the cuffed oropharyngeal airway, and a variety of kits to perform an emergency cricothyrotomy.

The largest clinical experience in pediatrics is with the LMA, which is available in a variety of sizes and can even be used in neonates. Use of the LMA is now being introduced into advanced airway training courses, and familiarity with insertion techniques can be life saving.[174,175] The LMA also can serve as a bridge to secure airway management in children with anatomic airway abnormalities.[176,177] Practitioners are encouraged to gain experience with these techniques as they become incorporated into pediatric advanced life support courses.

An additional emergency device with which to become familiar is the intraosseous needle. Intraosseous needles also are available in several sizes and can be life saving in the rare situation when rapid establishment of intravenous access is not possible. Familiarity with the use of these adjuncts for the management of emergencies can be obtained by keeping current with resuscitation courses, such as Pediatric Advanced Life Support and Advanced Pediatric Life Support or other approved programs.

Patient simulators

Advances in technology, particularly patient simulators that allow a variety of programmed adverse events (eg, apnea, bronchospasm, laryngospasm), response to medical interventions, and printouts of physiologic parameters, are now available. The use of such devices is encouraged to better train medical professionals to respond more appropriately and effectively to rare events.[178-180]

Monitoring during MRI

The powerful magnetic field and the generation of radiofrequency emissions necessitate the use of special equipment to provide continuous patient monitoring throughout the MRI scanning procedure. Pulse oximeters 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; avoid coiling the oximeter wire and place the probe as far from the magnetic coil as possible to diminish the possibility of injury. Electrocardiogram monitoring during magnetic resonance imaging has been associated with thermal injury; special MRI-compatible ECG pads are essential to allow safe monitoring.[181-184] Expired carbon dioxide monitoring is strongly encouraged in this setting.

Nitrous oxide

Inhalation sedation/analgesia equipment that delivers nitrous oxide must have the capacity of delivering 100 percent and never less than 25 percent oxygen concentration at a flow rate appropriate to the size of the patient. Equipment that delivers variable ratios of nitrous oxide to oxygen and that has a delivery system 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.[185] 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.[15,186-210] The use of nitrous oxide for minimal sedation is defined as the administration of nitrous oxide (50 percent or less) with the balance as oxygen, without any other sedative, narcotic, 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 greater than 50 percent, the likelihood for moderate or deep sedation increases.[211,212] In this situation, the clinician must be prepared to institute the guidelines for moderate or deep sedation as indicated by the patient's response.[213]

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
Breast 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

* 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. A Report of the American Society of Anesthesiologists. Available at: "http://www.asahq.org/publicationsAndServices/npoguide.html"

Table 2. COMMONLY USED LOCAL ANESTHETIC AGENTS: DOSES, DURATION, AND CALCULATIONS*

Local anesthetic	Maximum dose with Epinephrine (mg/kg)†		Duration of action (min) ‡
	Medical	Dental	
Esters			
Procaine	10.0	6	60-90
Chloroprocaine	20.0	12	30-60
Tetracaine	1.5	1	180-600
Amides			
Lidocaine	7.0	4.4	90-200
Mepivacaine	7.0	4.4	120-240
Bupivacaine	3.0	1.3	180-600
Levobupivacaine	3.0	2	180-600
Ropivacaine	3.0	2	180-600
Articaine		7	60-230

* Maximum recommended doses and duration of action. Note that lower doses should be used in very vascular areas.

† 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 percent in infants younger than six months. When lidocaine is being administered intravascularly (eg, during intravenous regional anesthesia), the dose should be decreased to three to five mg/kg; long-acting local anesthetic agents should not be used for intravenous regional anesthesia.

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

Table 3. LOCAL ANESTHETIC PERCENT CONCENTRATION CONVERSION TO mg/mL

Concentration (%)	mg/mL
3.0	30.0
2.5	25.0
2.0	20.0
1.0	10.0
0.5	5.0
025	2.5
0.125	1.25

Appendix A. Recommended Discharge Criteria

1. Cardiovascular function and airway patency are satisfactory and stable.
2. The patient is easily arousable, and protective reflexes are intact.
3. The patient can talk (if age appropriate).
4. The patient can sit up unaided (if age appropriate).
5. For a very young or handicapped child incapable of the usually expected responses, the presedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved.
6. The state of hydration is adequate.

Appendix B. ASA Physical Status Classification

Class I	A normally healthy patient.
Class II	A patient with mild systemic disease (eg, controlled reactive airway disease).
Class III	A patient with severe systemic disease (eg, a child who is actively wheezing).
Class IV	A patient with severe systemic disease that is a constant threat to life (eg, a child with status asthmaticus).
Class V	A moribund patient who is not expected to survive without the operation (eg, a patient with severe cardiomyopathy requiring heart transplantation).

Appendix C. Drugs* That May Be Needed to Rescue a Sedated Patient[44]

Albuterol for inhalation
Ammonia spirits
Atropine
Diphenhydramine
Diazepam
Epinephrine (1:1000, 1:10 000)
Flumazenil
Glucose (25 percent or 50 percent)
Lidocaine (cardiac lidocaine, local infiltration)
Lorazepam
Methylprednisolone
Naloxone
Oxygen
Fosphenytoin
Racemic epinephrine
Rocuronium
Sodium bicarbonate
Succinylcholine

* The choice of emergency drugs may vary according to individual or procedural needs.

Appendix D. Emergency Equipment† That May Be Needed to Rescue a Sedated Patient‡

Intravenous Equipment

- Assorted IV catheters (eg, 24-, 22-, 20-, 18-, 16-gauge)
- Tourniquets
- Alcohol wipes
- Adhesive tape
- Assorted syringes (eg, 1-, 3-, 5-, 10-mL)
- IV tubing
  - Pediatric drip (60 drops/mL)
  - Pediatric burette
  - Adult drip (10 drops/mL)
  - Extension tubing
  - 3-way stopcocks
- IV fluid
  - Lactated Ringer solution
  - Normal saline solution
  - D_5 0.25 normal saline solution
- Pediatric IV boards
- Assorted IV needles (eg, 25-, 22-, 20-, and 18-gauge)
- Intraosseous bone marrow needle
- Sterile gauze pads

Airway Management Equipment

- Face masks (infant, child, small adult, medium adult, large adult)
- Breathing bag and valve set
- Oropharyngeal airways (infant, child, small adult, medium adult, large adult)
- Nasopharyngeal airways (small, medium, large)
- Laryngeal mask airways (1, 1.5, 2, 2.5, 3, 4, and 5)
- Laryngoscope handles (with extra batteries)
- Laryngoscope blades (with extra light bulbs)
  - Straight (Miller) No. 1, 2, and 3
  - Curved (Macintosh) No. 2 and 3
- Endotracheal tubes (2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0 uncuffed and 6.0, 7.0, and 8.0 cuffed)
- Stylettes (appropriate sizes for endotracheal tubes)
- Surgical lubricant
- Suction catheters (appropriate sizes for endotracheal tubes)
- Yankauer-type suction
- Nasogastric tubes
- Nebulizer with medication kits
- Gloves (sterile and nonsterile, latex free)

† The choice of emergency equipment may vary according to individual or procedural needs.

‡ The practitioner is referred to the SOAPME acronym described in the text in preparation for sedating a child for a procedure.

Guidelines for the Use of Sedation and General Anesthesia by Dentists

I. INTRODUCTION

The administration of local anesthesia, sedation and general anesthesia is an integral part of dental practice. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists. The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia.

Dentists providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document are not subject to *Section III, Educational Requirements.*

II. DEFINITIONS

Methods of Anxiety and Pain Control

analgesia — the diminution or elimination of pain.

conscious sedation[1] — a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and that is produced by a pharmacological or non-pharmacological method or a combination thereof.

In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of conscious sedation.

combination inhalation-enteral conscious sedation (combined conscious sedation) — conscious sedation using inhalation and enteral agents.

When the intent is anxiolysis only, and the appropriate dosage of agents is administered, then the definition of enteral and/or combination inhalation-enteral conscious sedation (combined conscious sedation) does not apply.

local anesthesia — the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

minimal sedation — a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.[2]

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1 Parenteral conscious sedation may be achieved with the administration of a single agent or by the administration of more than one agent.

2 Portions excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, 2004, of the American Society of Anesthesiologists (ASA). A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. Further, patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

When the intent is minimal sedation for adults, the appropriate initial dosing of a single enteral drug is no more than the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use.

The use of preoperative sedatives for children (aged 12 and under) prior to arrival in the dental office, except in extraordinary situations, must be avoided due to the risk of unobserved respiratory obstruction during transport by untrained individuals.

Children (aged 12 and under) can become moderately sedated despite the intended level of minimal sedation; should this occur, the guidelines for moderate sedation apply.

For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.*

Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

The following definitions apply to administration of minimal sedation:

maximum recommended (MRD) — maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

incremental dosing — administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD).

supplemental dosing — during minimal sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures. The supplemental dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed. The total aggregate dose must not exceed 1.5x the MRD on the day of treatment.

moderate 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.[3]

Note: In accord with this particular definition, the drugs and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

titration — administration of incremental doses of a drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

deep sedation — 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.[3]

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 and general anesthesia are 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 diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.[3]

For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

3 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, 2004, of the American Society of Anesthesiologists (ASA). A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

Routes of Administration

enteral — any technique of administration in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa [i.e., oral, rectal, sublingual].

parenteral — a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].

transdermal — a technique of administration in which the drug is administered by patch or iontophoresis through skin.

transmucosal — a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

inhalation — a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Terms

qualified dentist — meets the educational requirements for the appropriate level of sedation in accordance with Section III of these *Guidelines*, or a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document.

must/shall — indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should — indicates the recommended manner to obtain the standard; highly desirable.

may — indicates freedom or liberty to follow a reasonable alternative.

continual — repeated regularly and frequently in a steady succession.

continuous — prolonged without any interruption at any time.

time-oriented anesthesia record — documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available — on site in the facility and available for immediate use.

American Society of Anesthesiologists (ASA) Patient Physical Status Classification[4]

ASA I — A normal healthy patient.

ASA II — A patient with mild systemic disease.

ASA III — A patient with severe systemic disease.

ASA IV — A patient with severe systemic disease that is a constant threat to life.

ASA V — A moribund patient who is not expected to survive without the operation.

4 ASA Physical Status Classification System is reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, IL 60068-2573.

ASA VI — A declared brain-dead patient whose organs are being removed for donor purposes.

E — Emergency operation of any variety (used to modify one of the above classifications, i.e., ASA III-E).

III. EDUCATIONAL REQUIREMENTS

A. Minimal Sedation

1. To administer minimal sedation the dentist must have successfully completed:

   a. Training to the level of competency in minimal sedation consistent with that prescribed in the ADA *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*, or 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 minimal sedation commensurate with these guidelines;

   and

   c. A current certification in Basic Life Support for Healthcare Providers.

2. Administration of minimal sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

B. Moderate Sedation

1. To administer moderate sedation, the dentist must 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;

   and

   c. 1) A current certification in Basic Life Support for Healthcare Providers and
   2) Either current certification in Advanced Cardiac Life Support (ACLS) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

2. Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must have completed:

   a. An advanced education program accredited by the ADA Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with *Part IV.C* of these guidelines;

   and

   b. 1) A current certification in Basic Life Support for Healthcare Providers and
   2) Either current certification in Advanced Cardiac Life Support (ACLS) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS.

2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.

For all levels of sedation and anesthesia, dentists, who are currently providing sedation and anesthesia in compliance with their state rules and/or regulations prior to adoption of this document, are not subject to these educational requirements. However, all dentists providing sedation and general anesthesia in their offices or the offices of other dentists should comply with the Clinical Guidelines in this document.

IV. CLINICAL GUIDELINES

A. Minimal sedation

1. Patient Evaluation

   Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this may consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Preparation

   - The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
   - Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
   - Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.

- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.

4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

- **Oxygenation:**
  - Color of mucosa, skin or blood must be evaluated continually.
  - Oxygen saturation by pulse oximetry may be clinically useful and should be considered.
- **Ventilation:**
  - The dentist and/or appropriately trained individual must observe chest excursions continually.
  - The dentist and/or appropriately trained individual must verify respirations continually.
- **Circulation:**
  - Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.

7. Management of Children

For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.*

B. Moderate Sedation

1. Patient Evaluation

Patients considered for moderate sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this should consist of at least a review of their current medical history and medication use. However, patients with significant medical considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-operative Preparation

- The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.

- Pre-operative verbal or written instructions must be given to the patient, parent, escort, guardian or care giver.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

- **Consciousness:**
  - Level of consciousness (e.g., responsiveness to verbal command) must be continually assessed.
- **Oxygenation:**
  - Color of mucosa, skin or blood must be evaluated continually.
  - Oxygen saturation must be evaluated by pulse oximetry continuously.
- **Ventilation:**
  - The dentist must observe chest excursions continually.
  - The dentist must monitor ventilation. This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO_2 or by verbal communication with the patient.
- **Circulation:**
  - The dentist must continually evaluate blood pressure and heart rate (unless the patient is unable to tolerate and this is noted in the time-oriented anesthesia record).

- Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters. (See *Additional Sources of Information* for sample of a time-oriented anesthetic record).
- Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.

7. Management of Children

For children 12 years of age and under, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry *Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.*

C. Deep Sedation or General Anesthesia

1. Patient Evaluation

Patients considered for deep sedation or general anesthesia must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this must consist of at least a review of their current medical history and medication use and NPO status. However, patients with significant medical

considerations (e.g., ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-operative Preparation

- The patient, parent, guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- Baseline vital signs must be obtained unless the patient's behavior prohibits such determination.
- A focused physical evaluation must be performed as deemed appropriate.
- Preoperative dietary restrictions must be considered based on the sedative/anesthetic technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.
- An intravenous line, which is secured throughout the procedure, must be established except as provided in *Part IV. C.6. Pediatric and Special Needs Patients.*

3. Personnel and Equipment Requirements

Personnel: A minimum of three (3) individuals must be present.

- A dentist qualified in accordance with *Part III. C.* of these *Guidelines* to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.
- Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
- If volatile anesthetic agents are utilized, a capnograph must be utilized and an inspired agent analysis monitor should be considered.
- Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

- **Oxygenation:**
  - Color of mucosa, skin or blood must be continually evaluated.
  - Oxygenation saturation must be evaluated continuously by pulse oximetry.
- **Ventilation:**
  - Intubated patient: end-tidal CO_2 must be continuously monitored and evaluated.
  - Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO_2 must be continually monitored and evaluated.
  - Respiration rate must be continually monitored and evaluated.
- **Circulation:**
  - The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
  - The dentist must continually evaluate blood pressure.
- **Temperature:**
  - A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
  - The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters. (See *Additional Sources of Information* for sample of a time-oriented anesthetic record)
- Pulse oximetry and end-tidal CO_2 measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, guardian or care giver.

6. Pediatric Patients and Those with Special Needs

Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some pediatric patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management

The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.

V. ADDITIONAL SOURCES OF INFORMATION

American Dental Association. Example of a time oriented anesthesia record at ADA.org.

American Academy of Pediatric Dentistry (AAPD). *Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update.* Developed through a collaborative effort between the American Academy of Pediatrics and the AAPD. Available at www.aapd.org/policies.

~~American Academy of Periodontology (AAP). *Guidelines: In-Office Use of Conscious Sedation in Periodontics.* Available at www.perio.org/resources-products/posppr3-1.html.~~ **The AAP rescinded this policy in 2008.**

American Association of Oral and Maxillofacial Surgeons (AAOMS). *Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath 01) Anesthesia in Outpatient Facilities.* Contact AAOMS at 847.678.6200 or visit www.aaoms.org/index.php.

American Association of Oral and Maxillofacial Surgeons (AAOMS). *Office Anesthesia Evaluation Manual 7th Edition.* Contact AAOMS at 847.678.6200 or visit www.aaoms.org/index.php.

American Society of Anesthesiologists (ASA). *Practice Guidelines for Preoperative Fasting and the Use of Pharmacological Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures.* Available at https://ecommerce.asahq.org/p-178-practice-guidelines-for-preoperative-fasting.aspx.

American Society of Anesthesiologists (ASA). *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists.* Available at www.asahq.org/publicationsAndServices/practiceparam.htm#sedation. The ASA has other anesthesia resources that might be of interest to dentists. For more information, go to www.asahq.org/publicationsAndServices/sgstoc.htm.

Commission on Dental Accreditation (CODA). *Accreditation Standards for Predoctoral and Advanced Dental Education Programs.* Available at ADA.org/115.aspx.

National Institute for Occupational Safety and Health (NIOSH). *Controlling Exposures to Nitrous Oxide During Anesthetic Administration* (NIOSH Alert: 1994 Publication No. 94-100). Available at www.cdc.gov/niosh/docs/94-100/.

Dionne, Raymond A.; Yagiela, John A., et al. Balancing efficacy and safety in the use of oral sedation in dental outpatients. *JADA* 2006;137(4):502-13. ADA members can access this article online at jada.ada.org/cgi/content/full/137/4/502.