TABLE 2 ASA Physical Status Classification

ASA Class	Description	Examples
I	A normal, healthy patient, without organic, physiologic, or psychiatric disturbances	Healthy with good exercise tolerance
II	A patient with controlled medical conditions without significant systemic effects	Controlled hypertension, controlled diabetes mellitus, cigarette smoking without evidence of COPD, anemia, mild obesity, age less than 1 or greater than 70 years, pregnancy
III	A patient having medical conditions and significant systemic effects intermittently associated with significant functional compromise	Controlled CHF, stable angina, poorly controlled hypertension, morbid obesity, bronchospastic disease with intermittent symptoms, chronic renal failure
IV	A patient with a medical condition that is poorly controlled, associated with significant dysfunction and is a potential threat to life	Unstable angina, symptomatic COPD, sympto- matic CHF, hepatorenal failure
v	A patient with a critical medical condition that is associated with little chance of survival with or without the surgical procedure	Multiorgan failure, sepsis syndrome with hemodynamic instability, hypothermia, poorly controlled coagulation

APPENDIX 1:

Additional Sources of Information

American Academy of Pediatric Dentists (AAPD). Guidelines for 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 http://www.aapd.org/media/policies.asp

American Academy of Periodontology (AAP). *Guidelines: In-Office Use of Conscious Sedation in Periodontics. Available* at <u>http://www.perio.org/resources-products/posppr3-1.html</u>

American Dental Association Policy Statement: The Use of Sedation and General Anesthesia by Dentists. <u>http://www.ada.org/prof/resources/positions/statements/statements_anesthesia.pdf</u>

American Dental Association Guidelines for the Use of Sedation and General Anesthesia by Dentists. <u>http://www.ada.org/prof/resources/positions/statements/</u> anesthesia_guidelines.pdf

American Dental Association Guidelines for the Teaching of Pain and Anxiety Control to Dentists and Dental Students. <u>http://www.ada.org/prof/resources/positions/</u>statements/anxiety_guidelines.pdf

American Dental Association Council on Scientific Affairs. Acceptance Program Guidelines: *Nitrous Oxide-Oxygen Conscious Sedation Systems, 2000.* Available at http://www.ada.org/prof/resources/positions/standards/denmat.asp#ada

American Association of Oral and Maxillofacial Surgeons (AAOMS). Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath o1) Anesthesia in Outpatient Facilities. Contact AAOMS at 1-847-678-6200 or visit http://www.aaoms.org/index.php

American Association of Oral and Maxillofacial Surgeons (AAOMS). Office Anesthesia Evaluation Manual 7th Edition. Contact AAOMS at 1-847-678-6200 or visit http://www.aaoms.org/index.php

American Society of Anesthesiologist (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 http://www2.asahq.org/publications/p-178-practice-guidelines-for-preoperative fasting.aspx.

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

Commission on Dental Accreditation (CODA). Accreditation Standards for Predoctoral and Advanced Dental Education Programs. Available at http://www.ada.org/prof/ed/accred/standards/index.asp

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 <u>http://www.cdc.gov/niosh/noxidalr.html</u>

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 http://jada.ada.org/cgi/content/full/137/4/502



General Anesthesia and Sedation by Dentists

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The opinions expressed in this white paper are those of the author and do not represent the official opinions of the American Dental Association.

In October 2007, the House of Delegates of the American Dental Association (ADA) overwhelmingly approved new Guidelines regarding the teaching and use of sedation and general anesthesia by dentists and also reiterated the policy statement endorsing the use of sedation and anesthesia by educationally qualified dentists. The Policy Statement affirms that the delivery of sedation and anesthesia care is an integral part of dentistry. These Guidelines provide guidance and direction to state boards of dental registration, malpractice and dental insurance carriers, the profession and the public, and offer a uniform standard for the practice of sedation/anesthesia in dentistry and set forth an educational framework for the teaching and use of sedation and anesthesia for all dentists.

The new Guidelines are a dramatic departure from previous guidelines that have evolved since 1972. The writing group (Committee H – Anesthesia) of the Council of Dental Education and Licensure was composed of experts representing the American Association of Oral and Maxillofacial Surgeons, the American Academy of Periodontology, the American Dental Association, the American Academy of Pediatric Dentistry, the American Society of Anesthesiologists, the American Dental Society of Anesthesiologists assisted by ADA staff members. After the receiving input from communities of interest and incorporating further suggestions, the Guidelines were presented at a reference committee hearing and at a unique town meeting prior to their adoption by the ADA House of Delegates.

MAJOR CHANGES

• Conceptually older versions did not comport with current dental practice, and significant changes in practice since the last revision, especially in the areas of minimal and moderate enteral sedation, were recognized and addressed.

• Reorganization of the documents based on the depth of sedation and anesthesia within the sedation-anesthesia continuum rather than the route of administration.

• The use of the American Society of Anesthesiologists' definitions in whole or part with these new definitions applicable to the practice of sedation and anesthesia in dentistry to unify medical/dental sedation providers.

• Additional resources and references appended to the end of the documents. (Appendix 1)

• Endorsement 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 for pediatric patients receiving sedation by dentists.

• Recommended development of a new emergency management course more relevant to the practice of sedation and anesthesia in the profession of dentistry.

DEFINITIONS

Sedation and anesthesia is a continuum and therefore it is not always possible to predict how an individual patient will respond. It is imperative to practice within one's educational qualifiers and state permitting. The most important concept of this continuum is that the ability to rescue a patient who enters a deeper level of sedation than initially intended is the key to safe practice. For all levels of sedation, the practitioner must have the training, skills, 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.

THE LEVELS OF THE CONTINUUM

• 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.

• Moderate Sedation - A drug-induced depression of consciousness during which patients respond purpose-fully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

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

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

	Minimal Sedation "Anxiolysis"	Moderate Sedation "Conscious Sedation"	Deep Sedation	General Anesthesia
Responsiveness	Normal* response to verbal and physical stimulation	Purposeful* response to verbal or physical stimulation	Purposeful response following repeated or painful stimuli	Unarousable-even with painful stimuli
Airway	Unaffected	Unaffected	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

TABLE 1 Continuum of Depth of Sedation–Definitions of Levels of Sedation and General Anesthesia

*In accord with these particular definitions, the drug(s) and/or techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, a patient, whose only response is reflex withdrawal from a painful stimulus, is not considered to be in a state of either minimal or moderate sedation.

Adapted from American Society of Anesthesiologists (ASA), *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists.*

MINIMAL SEDATION Adults

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.

Children (Aged 12 and under)

Children are at special risk for respiratory depression and airway obstruction during sedation. For that reason, the use of preoperative sedatives for children (aged 12 and under) 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.*

Dosing Guidelines for Minimal Sedation

Maximum Recommended Dose (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 1.5 times the MRD.

MINIMAL SEDATION – EDUCATIONAL REQUIREMENTS To administer minimal sedation the dentist must have successfully completed:

> • 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

• 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

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

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.

MINIMAL ENTERAL SEDATION

Education Requirements for training to competency in minimal enteral sedation:

• A minimum of 16 hours.

• Clinically-oriented experiences during which competency in enteral and/or combined inhalation-enteral minimal sedation techniques is demonstrated.

• May include group observations on patients undergoing enteral and/or combination inhalation-enteral minimal sedation.

• Clinical experience in managing a compromised airway is critical to the prevention of life-threatening emergencies.

THE USE OF MINIMAL ENTERAL SEDATION

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. 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 the level of consciousness, oxygenation, ventilation, and circulation are satisfactory prior to discharge.

CLINICAL GUIDELINES FOR MINIMAL SEDATION 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 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.

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.

Pre-operative 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.

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.

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 intra-operatively 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, detailing local anesthetics, dosages, and monitored physiological parameters.

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.

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, drugs, and protocols for patient rescue.

MODERATE ENTERAL SEDATION

The use of moderate enteral sedation for dentistry is a unique paradigm. These techniques rely upon either larger than maximum recommended doses or multiple doses titrated to effect. Titration is difficult due to inability to reliably predict absorption of these drugs from the GI system.

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.

Author's Note: The teaching guidelines contained in this section on moderate sedation differ slightly from documents in medicine to reflect the differences in delivery methodologies and practice environment in dentistry. For this reason, separate teaching guidelines have been developed for moderate enteral and moderate parenteral sedation.

EDUCATIONAL REQUIREMENTS FOR MODERATE ENTERAL SEDATION

To administer moderate sedation, the dentist must have successfully completed:

• 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

• 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

• A current certification in:

1) Basic Life Support for Healthcare Providers and

2) Advanced Cardiac Life Support (ACLS) or an appropriate dental sedation/anesthesia emergency management course.

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. These include:

• 24 hours of instruction

• At least 10 adult case experiences by the enteral and/or enteral-nitrous oxide/oxygen route are required to achieve competency.

These ten cases must include at least three live clinical dental experiences managed by participants in groups no larger than five. The remaining cases may include simulations and/or video presentations, but must include one experience in returning (rescuing) a patient from deep to moderate sedation.

Participants should be provided supervised opportunities for clinical experience to demonstrate competence in airway management with participant-faculty ratio of not more than five-to-one.

Courses in moderate sedation must be presented where adequate facilities are available for proper patient care, including drugs and equipment for the management of emergencies. These facilities may include dental and medical schools/offices, hospitals, and surgical centers.

CLINICAL GUIDELINES FOR MODERATE SEDATION

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. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

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 the level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge.

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.

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.

Pre-operative 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.

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 also be available.

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 CO2, 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 administered, including local anesthetics, dosages and monitored physiological parameters.

Pulse oximetry, heart rate, respiratory rate and blood pressure must be recorded continually.

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 reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.

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.

CONCLUSION

There are millions of Americans in need of dental care who cannot or will not access dental care without the use of minimal, moderate, deep sedation, or general anesthesia techniques. These patients include the mentally challenged, precooperative pediatric patients, patients with motor dysfunction, or other pre-existing medical conditions where stress levels are important to attenuate. The high incidence of fearful, anxious, and phobic dental patients make the use of sedation an important tool in assuring these patients comprehensive dental care.

Guidelines are dynamic and reflect best practices over time. Increased educational offerings at all dental educational levels, adherence to proper patient selection, the use of appropriate monitors, and an understanding of the pharmacology of these sedative drugs will all increase patient safety. Rescue from unintended deep levels of sedation for minimal/ moderate sedation providers and attention to the airway at all times will reduce the main causes of mortality and morbidity that center around hypoventilation, apnea, and airway obstruction.