Clinical Guideline on the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Dental Patients

Originating Council
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Purpose

Methodology

Background/Literature Review

Recommendations

The American Academy of Pediatric Dentistry's **Guidelines for the Elective Use of Pharmacological Conscious Sedation and Deep Sedation in Pediatric Dental Patients** were revised and published in 1996. At that time, no attempt was made to address the issue of general anesthesia for pediatric dental patients. However, some children and developmentally disabled patients require general anesthesia services in order to receive comprehensive dental care in a humane fashion. Access to hospital based general anesthesia may be limited for a variety of reasons including restriction of coverage by certain insurance companies. Many pediatric dentists (and others who treat children) have sought to provide general anesthesia in their office or other facilities (e.g., outpatient care clinics).

Therefore we have included general anesthesia in the guidelines to help facilitate safe anesthesia services for pediatric dental patients.

In 1985, the American Academy of Pediatric Dentistry established the **Guidelines for the Elective Use of Conscious Sedation, Deep Sedation and General Anesthesia in Pediatric Patients.** To be consistent with all aspects of delivery of care using pharmacologic interventions, it is appropriate and timely to expand and institute guidelines that address general anesthesia as well as sedation for those practitioners who provide care to pediatric dental patients. General anesthesia may be used when indicated for the delivery of oral health care to pediatric patients. It must be provided only by qualified and appropriately trained individuals and in accordance with state regulation. Such providers may include pediatric dentists who have completed advanced education in anesthesiology, dental or medical anesthesiologists, oral surgeons or certified registered nurse anesthetists.

The 1998 AAPD guidelines revision reflects the current understanding of appropriate monitoring needs and further, provides definitions and characteristics of five functional levels of sedation and general anesthesia involving pediatric patients in the context of recognized sedation terminology (i.e., "conscious" and "deep"). Appendix I provides a descriptive template for recognizing that sedation is a continuum; however, the practitioner's expected clinical outcomes in sedating the "average" patient can be targeted with the targeting being dependent on his/her training and experience in the use of sedative agents. The template shows five levels of sedation each with its own goals, characteristics, and requirements.

The pediatric dentist must be responsible for evaluating the qualifications of the general anesthesia provider and establishing a safe environment which complies with state rules and regulations as well as these guidelines for the protection of the patient. Educational qualifications for general anesthesia providers are outlined in these guidelines.

Educational preparation, while necessary, is only one aspect of safe general anesthesia care. As outlined in the Guidelines, the following are all essential in order to minimize the risk for the patient:

- facilities and equipment
- selection of pharmacologic agents and dosages
- monitoring and documentation
- patient selection utilizing physical status and indication for anesthetic management
- preoperative evaluation
- appropriately trained support personnel
- emergency medications, equipment and protocols.

The use of conscious sedation, deep sedation and general anesthesia will be affected by advances in pain and anxiety control, pharmacologic development, and monitoring and patient safety techniques. As research defines safer and more effective techniques, the Guidelines will be revised accordingly.

Definition of Terms

For the purpose of this document, the following definitions shall apply:

Guideline: Guidelines are systematically developed recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Guidelines are not intended as standards or absolute requirements and their use cannot guarantee any specific outcome.

Like a recommendation, it originates in an organization with acknowledged professional stature. Although it may be unsolicited, it usually is developed following a stated request or perceived need for such advice or instruction.

Pediatric dental patients: Includes all patients who are infants, children, and adolescents less than age of majority.

Must or shall: Indicates an imperative need and/or duty; as essential or indispensable; mandatory.

Should: Indicates the recommended need and/or duty; highly desirable.

May or could: Indicates freedom or liberty to follow a suggested or reasonable alternative.

Conscious sedation: Conscious sedation (Appendix I, levels 1, 2, and 3) is a controlled, pharmacologically induced, minimally depressed level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously and respond appropriately to physical stimulation and/or verbal command. The drugs, dosages, and techniques used should carry a margin of safety which is unlikely to render the child non-interactive and non-arousable (Appendix I, levels 4 and 5).

Deep sedation: Deep sedation (Appendix I, level 4) is a controlled, pharmacologically-induced state of depressed consciousness from which the patient is not easily aroused and which may be

accompanied by a partial loss of protective reflexes, including the ability to maintain a patent airway independently and/or respond purposefully to physical stimulation or verbal command.

General Anesthesia: General anesthesia (Appendix I, level 5) is an induced state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the ability to independently maintain an airway and respond purposefully to physical stimulation or verbal command.

General Considerations
Goals of Sedation and General Anesthesia

The sedation of children for the delivery of oral health care is recognized as and represents a unique clinical challenge. Consideration must be given to such factors as patient's age and corresponding levels of cognitive and coping skills. Because of patient extremes in responsiveness and acceptability of treatment modalities, the intended goals and outcome of sedations will vary depending on a host of factors. These guidelines should aid clinicians in achieving the benefits of sedation while minimizing associated risks and adverse outcomes for the patient.

The goals of sedation in the pediatric dental patient are to: (1) facilitate the provision of quality care; (2) minimize the extremes of disruptive behavior; (3) promote a positive psychologic response to treatment; (4) promote patient welfare and safety; (5) return the patient to a physiologic state in which safe discharge, as determined by recognized criteria, is possible (See Appendix II).

The goals of general anesthesia in the pediatric dental patient are to eliminate cognitive, sensory and skeletal motor activity in order to facilitate the delivery of quality comprehensive diagnostic and restorative dental services.

Indications for Sedation and General Anesthesia

The indications for conscious sedation include:

- Preschool children who cannot understand or cooperate for definitive treatment
- Patients requiring dental care who cannot cooperate due to lack of psychological or emotional maturity
- Patients requiring dental treatment who cannot cooperate due to a cognitive, physical or medical disability
- Patients who require dental care but are fearful and anxious and cannot cooperate for treatment

The indications for deep sedation and general anesthesia in pediatric dental patients include:

- Patients with certain physical, mental or medically compromising conditions
- Patients with dental restorative or surgical needs for whom local anesthesia is ineffective
- The extremely uncooperative, fearful, anxious or physically resistant child or adolescent with substantial dental needs and no expectation that the behavior will improve soon
- Patients who have sustained extensive orofacial or dental trauma
- Patients with dental needs who otherwise would not receive comprehensive dental care

Local Anesthesia Considerations During Sedation

All local anesthetic agents can become cardiac and CNS depressants when administered in excessive doses. There is a potential interaction between local anesthetic and sedatives used in pediatric dentistry which can result in enhanced sedative effects and/or untoward events; therefore, particular attention should be paid to doses used in children. For the patient who is going to be sedated, to avoid excessive doses, a maximum recommended dose in mg/kg or mg/lb should be calculated and the dose administered should be recorded for each patient prior to administration for all sedatives and local anesthetics.

Candidates

Patients who are ASA (American Society of Anesthesiologists) Class I or II (Appendix III) may be considered candidates for conscious sedation (Appendix I, levels 1, 2, or 3) or deep sedation (Appendix I, level 4) or general anesthesia (Appendix I, level 5). Patients in ASA Class III or IV present special problems and treatment in a hospital setting should be considered.

Responsible Adult

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian or other responsible adult who shall be required to remain at the facility for the entire treatment period.

Facilities and Equipment
Facilities

The practitioner who utilizes any type of sedative or local anesthetic in a pediatric patient shall possess appropriate training and skills and have available the proper facilities, personnel, and equipment to manage any reasonably foreseeable emergency situation that might be experienced. All newly installed facilities for delivering nitrous oxide and oxygen must be checked for proper gas delivery and fail-safe function prior to use. Where equipment and facilities are mandated by state law, such statutes shall supersede these guidelines.

Equipment

A positive-pressure oxygen delivery system that is capable of administering greater than 90% oxygen at a 10 L/min flow for at least 60 minutes (650 liter, "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. All equipment must be able to accommodate children of all ages and sizes. A functional suction apparatus with appropriate suction catheters must be immediately available. A sphygmomanometer with cuffs of appropriate size for pediatric patients shall be immediately available.

Inhalation sedation equipment must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate to the child's size, and must have a fail-safe system that is checked and calibrated annually. If nitrous oxide and oxygen delivery equipment capable of delivering more than 75% nitrous oxide and less than 25% oxygen is used, an in-line oxygen analyzer must be used. The equipment must have an appropriate scavenging system.

Equipment that is appropriate for the technique used and capable of monitoring the physiologic state of the patient before, during, and after the procedure must be present. Specific equipment monitoring and recommendations are listed in the sections on conscious sedation, deep sedation and general anesthesia and in the template of these guidelines (Appendix I).

An emergency cart or kit must be readily accessible and should include the necessary drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious pediatric patient and

provide continuous support while the patient is being transported to a medical facility. There should be documentation that all emergency equipment and drugs are checked and maintained on a regularly scheduled basis (e.g., monthly) (See Appendix IV for suggested drugs).

Back-up Emergency Services

Back-up emergency services should be identified. A protocol outlining necessary procedures for their immediate employment should be developed and operational for each facility. For non-hospital facilities, an emergency assist system should be established with the nearest hospital emergency facility and ready access to ambulance service must be assured.

Documentation

The practitioner must document each sedation or general anesthesia procedure in the patient's record. Documentation shall include the following:

Informed Consent. Each patient, parent, or other responsible individual is entitled to be informed regarding benefits, risks, and alternatives to sedation or general anesthesia and to give consent. The patient record shall document that appropriate informed consent was obtained according to the procedures outlined by individual state laws and/or institutional requirements.

Instructions to parents or responsible individual. The practitioner shall provide verbal and written instructions to the parents or responsible individual. Instructions should be explicit and include an explanation of pre- and post-sedation dietary precautions, potential or anticipated post-operative behavior, and limitation of activities. A 24-hr contact number for the practitioner should be provided to all patients.

Dietary precautions. The administration of sedative drugs or general anesthetic agents shall be preceded by an evaluation of the patient's food and liquid intake. Intake of food and liquids should be as follows: (a) no milk or solids for 6 hours for children 6-36 months and 6-8 hours for children 36 months and older; (b) clear liquids up to 3 hours before procedure for children ages 6 months and older.

Preoperative Health Evaluation. Prior to the administration of sedatives, the practitioner shall obtain and document information about the patient's current health status. The health status evaluation should include:

Health history including:

- Allergies and previous allergic or adverse drug reactions
- Current medications including dose, time, route, and site of administration
- Diseases, disorders, or physical abnormalities and pregnancy status
- Previous hospitalization to include the date, purpose, and hospital course
- History of general anesthesia or sedation and any associated complications
- Family history of diseases or disorders
- Review of systems
- Age in years and months and weight in kilograms or pounds

Physical evaluation including:

- Vital signs, including heart respiratory rates and blood pressure
- Evaluation of airway patency
- Risk assessment, e.g., ASA classification (see Appendix III)

Hospitalized Patients. The current hospital record may suffice for adequate documentation of pre-sedation health. A brief note shall be written documenting that the record was reviewed, positive findings were noted, and there were no contraindications to the planned procedure(s).

Child's Physician. Name, address, and telephone number of the child's physician or family physician should be recorded in the patient's record.

Rationale for Sedation or General Anesthesia. The practitioner shall briefly document the reason for the need for sedation or general anesthesia.

Baseline Vital Signs. Before administration of sedatives or general anesthesia, a baseline determination of vital signs (heart and respiratory rates and blood pressure) should be documented in the patient's record. If determination of baseline vital signs is prevented by the patient's physical resistance or emotional condition, the reason(s) should be documented.

Preprocedural Prescriptions. The only classification of drugs for sedation to be administered enterally by a responsible adult pre-procedurally outside the treatment facility is minor tranquilizers. Minor tranquilizers (e.g., hydroxyzine or diazepam) do not include chloral hydrate or narcotics. A copy or a note describing the content of the prescription should be documented in the patient's record, along with a description of the instructions given to the responsible individual.

Vital signs. The patient's record shall contain documentation of intermittent quantitative monitoring and recording of oxygen saturation (pulse oximetry) and heart and respiratory rates and blood pressure, as recommended for specific sedation techniques. It should be documented that the responsiveness of the patient was monitored at specific intervals before and during the procedure and until the patient was discharged.

Drugs. The patient's record shall document the name, dose and route, site, and time of administration of all drugs administered. The maximum recommended dose per kilogram or pound should be calculated and the actual dose given shall be documented in milligrams. The concentrations, flow rate, and duration of administration of oxygen and nitrous oxide shall be documented.

Recovery

The condition of the child and the time of discharge from the treatment facility should be documented in the record. Documentation shall include that appropriate discharge criteria have been met (See Appendix II). The record should also identify the responsible adult to whose care the patient was discharged.

Conscious Sedation (Levels 1, 2, 3)

Personnel

The practitioner responsible for the treatment of the patient and/or the administration of drugs for conscious sedation (levels 1, 2 and 3) shall be appropriately trained in the use of such drugs and techniques, and shall provide appropriate monitoring, and shall be capable of managing any reasonable foreseeable complications.

Drugs, other than minor tranquilizers, used for the purpose of conscious sedation (levels 1, 2, and 3) shall be administered in the treatment facility and shall be prescribed, dispensed, or administered only by appropriately licensed individuals, or under the direct supervision thereof, according to state law.

In addition to the operating practitioner, an individual trained to monitor appropriate physiologic parameters and to assist in any supportive or resuscitative measures required shall be present. Both individuals must have training in basic life support, shall have specific assignments, and shall have familiarity of the emergency cart (kit) inventory.

The practitioner and all treatment facility personnel should participate in periodic reviews of the office's emergency protocol, the emergency drug kit, and simulated exercises, to assure proper emergency management response.

Operating Facility and Equipment

The operating facility used for the administration of conscious sedation (levels 1, 2 or 3), shall have available all facilities and equipment previously recommended. With the possible exception of conscious sedation (level 1), mediated by minor tranquilizers administered enterally and/or nitrous oxide and oxygen inhalation sedation at 50% nitrous oxide concentration or less, minimum monitoring equipment for conscious sedation (levels 2, 3) shall be a pulse oximeter. Capnography is desirable for level 3. A sphygmomanometer shall be immediately available. A precordial/pretracheal stethoscope is required for level 3.

Monitoring Procedures
Before and during treatment

Whenever drugs for conscious sedation (levels 1, 2, or 3) are administered, the patient should be monitored continuously for patient responsiveness and airway patency. With the possible exception of conscious sedation (level 1), mediated by minor tranquilizers administered enterally and/or nitrous oxide and oxygen inhalation sedation at 50% nitrous oxide concentration or less, there shall be continual monitoring of oxygen saturation and heart and respiratory rates. Oxygen saturation and heart and respiratory rates shall be recorded at specific intervals throughout the procedure until the child has met documented discharge criteria. A precordial/pretracheal stethoscope shall be used for obtaining additional information on heart and respiratory rates and for monitoring airway patency during level 3 sedations. Clinical observation should accompany all levels of sedation. Treatment immobilization devices should be checked periodically to prevent airway obstruction or chest restriction and insure limb perfusion. The child's head position shall be checked frequently to ensure airway patency. A sedated patient shall be observed continuously by a trained individual.

Recovery

After completion of the treatment procedures, vital signs should be recorded at specific intervals. The practitioner shall assess the patient's responsiveness and discharge the patient only when the appropriate discharge criteria have been met (Appendix II).

Deep Sedation (Level 4)
Personnel

The techniques of deep sedation (level 4) require the following three individuals: 1) the treating practitioner who may direct the sedation; 2) a qualified individual to assist with observation and monitoring of the patient and who may administer drugs if appropriately licensed; and 3) other personnel to assist the operator as necessary. Of the three individuals, one shall be currently certified in Advanced Cardiac Life Support or Pediatric Advanced Life Support and the other two shall be currently certified in basic life support.

Operating Facility and Equipment

In addition to the facilities and equipment previously recommended for conscious sedation (levels 1, 2, 3), deep sedation requires an ECG and a capnograph in conjunction with pulse oximetry. The availability of a defibrillator for pediatric patients is desirable.

Intravenous Access

Patients receiving deep sedation (level 4) should have an intravenous line in place or have immediately available an individual skilled in establishing vascular access in pediatric patients.

Monitoring Procedures
Before and during treatment

The sedated patient shall be continuously monitored by an appropriately trained individual. There shall be continual monitoring of oxygen saturation by oximetry and expired carbon dioxide concentration via capnography, heart and respiratory rates, and blood pressure, all of which shall be recorded minimally every 5 minutes. A pulse oximeter and capnograph, precordial/pretracheal stethoscope, ECG, and blood pressure cuff are required. Temperature monitoring is desirable. The child's head position must be checked frequently to ensure airway patency. The operator should be observing the patient as well as the monitors and observing trends in the data obtained from the monitors. At no time shall a sedated patient be left unobserved by an appropriately trained individual.

Recovery

After treatment has been completed the patient must be observed in a suitably equipped recovery facility. This facility must have functioning suction apparatus and suction catheters of appropriate size, as well as the capacity to deliver greater than 90% oxygen and provide positive pressure ventilation for pediatric patients. An individual experienced in recovery care must be in attendance at all times in order to assess and record vital signs, observe the patient and ensure airway patency until the patient is stable. The patient must remain in the recovery facility until cardiovascular and respiratory stability are ensured and appropriate discharge criteria have been met (see Appendix II).

General Anesthesia (Level 5)
Personnel

The provision of general anesthesia requires the following three individuals: 1) a physician or dentist who has completed an advanced training program in anesthesia or oral and maxillofacial surgery and related subjects beyond the undergraduate medical or dental curriculum, who is responsible for anesthesia and monitoring of the patient, 2) a treating dentist, responsible for the provision of dental services, 3) other personnel to assist the operator as necessary. Of these individuals, the anesthetist shall be currently certified in Advanced Cardiac Life Support or Pediatric Advanced Life Support and the others shall be certified currently in basic life support. When a Certified Registered Nurse Anesthetist is permitted to function under the supervision of a dentist, the dentist is required to have completed training in general anesthesia, as specified above.

Operating Facility and Equipment

In addition to the facilities and equipment previously recommended for conscious sedation and deep sedation (level 4), i.e., pulse oximeter, capnograph, precordial stethoscope, blood pressure monitor and electrocardiograph, a temperature monitor and defibrillator are also required.

Monitoring Procedures

The anesthetized patient shall be continuously monitored by the anesthesia provider. There shall be continual monitoring of oxygen saturation by pulse oximetry and expired carbon dioxide concentration via capnography, heart and respiratory rates, and blood pressure, all of which shall be recorded minimally every 5 minutes. The anesthesia provider should be visualizing the patient as well as the monitors and observing trends in the data obtained from the monitors. At no time should the patient be unobserved by trained personnel until discharge criteria have been met.

Recovery

After treatment has been completed, the patient must be observed continuously and monitored appropriately in a suitably equipped recovery facility until the patient becomes stable. This facility must have functioning suction apparatus and suction catheters of appropriate size, as well as the capacity to deliver greater than 90% oxygen and provide positive pressure ventilation for pediatric patients. An individual experienced in recovery care must be in attendance at all times in order to assess and record vital signs, observe the patient, and ensure airway patency. The patient must remain in the recovery facility until cardiovascular and respiratory parameters and function are stable and appropriate discharge criteria have been met (see Appendix II).

Appendix II
Recommended Discharge Criteria

1. Cardiovascular function satisfactory and stable
2. Airway patency uncompromised and satisfactory
3. Patient easily arousable and protective reflexes intact
4. State of hydration adequate
5. Patient can talk, if applicable
6. Patient can sit unaided, if applicable
7. Patient can ambulate, if applicable, with minimal assistance
8. For the child who is very young or disabled, and incapable of the usually expected responses, the pre-sedation level of responsiveness or the level as close as possible for that child should be achieved.
9. Responsible individual is available.

Appendix III
American Society of Anesthesiologists Classification (Modified)

Class I. A normally healthy patient with no organic, physiologic, biochemical or psychiatric disturbance or disease.

Class II. A patient with mild-to-moderate systemic disturbance or disease.

Class III. A patient with severe systemic disturbance or disease.

Class IV. A patient with severe and life-threatening systemic disease or disorder.

Class V. A moribund patient who is unlikely to survive without the planned procedure.

Appendix IV

Appropriate emergency equipment should be available whenever sedative drugs, capable of causing cardiorespiratory and central nervous system depression, are administered. The list below should be used as a guide, which should be modified depending upon the individual practice circumstances.

Emergency Medications:

Oxygen
Ammonia spirits
Glucose (50%)
Atropine
Diazepam
Epinephrine
Lidocaine (cardiac)
Diphenhydramine hydrochloride
Hydrocortisone
Pharmacologic Antagonists
Naloxone hydrochloride
Flumazenil

Basic airway management equipment

Nasal and Oral Airways of different sizes

Portable oxygen delivery system capable of delivering bag and mask ventilation greater than 90% at 10 L/min flow for at least 60 minutes (e.g., "E" cylinder) and resuscitation bag with masks that will accommodate children of all sizes.

Intravenous Equipment (Level 4 sedations)

Gloves
Alcohol wipes
Tourniquets
Sterile gauze pads
Tape

Intravenous solutions and equipment for administration appropriate to the patient population being treated.

References

Appendix I

Template of Definitions and Characteristics For Levels Of Sedation And General Anesthesia.

		Conscious Sedation		Deep Sedation	General Anesthesia
Functional Level of Sedation	Mild Sedation (Anxiolysis)	Interactive	Non-Interactive/Arousable With Mild/Moderate Stimulus	Non-Interactive/Non-Arousable Except With Intense Stimulus	General Anesthesia
	(Level 1)	**(Level 2)**	**(Level 3)**	**(Level 4)**	**(Level 5)**
Goal	Decrease anxiety; facilitate coping skills	Decrease or eliminate anxiety; facilitate coping skills	Decrease or eliminate anxiety; facilitate coping skills; promote non-interaction sleep	Eliminate anxiety; coping skills over-ridden	Eliminate cognitive, sensory and skeletal motor activity; some autonomic activity depressed
Responsiveness	Uninterrupted interactive ability; totally awake	Minimally depressed level of consciousness; eyes open or temporarily closed; responds appropriately to verbal commands	Moderately depressed level of consciousness; mimics physiologic sleep (vitals not different from that of sleep); eyes closed most of time; may or may not respond to verbal prompts alone; responds to mild /moderate stimuli (e.g., repeated trapezius pinching or needle insertion in oral tissues elicits reflex withdrawal and appropriate verbalization [complaint, moan, crying]); airway only occasionally may require re-adjustment via chin thrust	Deeply depressed level of consciousness; sleep-like state, but vitals may be slightly depressed compared to physiologic sleep; eyes closed; does not respond to verbal prompts alone; reflex withdrawal with no verbalization when intense stimuli occurs (e.g., repeated, prolonged and intense pinching of the trapezius); airway expected to require constant monitoring and frequent management	Unconscious and unresponsive to surgical stimuli. Partial or complete loss of protective reflexes including the airway; does not respond purposefully to physical and verbal command
Personnel	2	2	2	3	3
Monitoring Equipment	Clinical observation•	PO; precordial recommended*	PO, precordial, BP; capno desirable†	PO & Capno, ECG; precordial, BP, defibrillator desirable	PO, Capno, precordial, BP, ECG, temperature & defibrillator required
Monitoring Info	None	HR, RR, O_2 Pre-; During (q 15 min); Post, as needed	HR, RR, O_2, BP; [CO_2] if available Pre-; During (q 10 min); Post till stable/Discharge Criteria	HR, RR, O_2 & C [CO_2], BP, ECG Pre-; During (q 5 min); Post till stable/Discharge Criteria	HR, RR, O_2 CO_2, BP, EKG, Temperature Pre-; During (q 5 min minimum); post till stable/Discharge Criteria

Monitors: PO (Pulse Oximetry); Capno (Capnography); BP (Blood Pressure Cuff); ECG (Electrocardiogram)

• It should be noted that clinical observation should accompany any level of sedation and general anesthesia.

† "Recommended" and "Desirable" should be interpreted as not a necessity, but as an adjunct in assessing patient status.