Committee on Drugs
Section on Anesthesiology

Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Patients

The goals of sedation and general anesthesia in the ambulatory patient are: (1) patient welfare; (2) control of patient behavior; (3) production of positive psychological response to treatment; and (4) return to pretreatment level of consciousness by time of discharge.

DEFINITION OF TERMS

Terms used in this document are defined as follows:

Pediatric 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 manner of obtaining the standard; highly desirable.

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

Conscious sedation: Conscious sedation is a 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, eg, “Open your eyes.” For the very young or handicapped individual, incapable of the usually expected verbal responses, a minimally depressed level of consciousness for that individual should be maintained. The caveat that loss of consciousness should be unlikely is a particularly important part of the definition of conscious sedation, and the drugs and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.

Deep sedation: Deep sedation is a controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused, which may be accompanied by a partial or complete loss of protective reflexes, including the ability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.

General anesthesia: General anesthesia is a controlled state of unconsciousness accompanied by a loss of protective reflexes, including the ability to maintain an airway independently and respond purposefully to physical stimulation or verbal command.

LOCAL ANESTHESIA CONSIDERATIONS

All local anesthetic agents are CNS depressants. Their use is particularly hazardous in smaller children. There is a potential interaction between local anesthetic drugs and other sedatives.

CANDIDATES

Patients who are ASA (American Society of Anesthesiologists) Class I or II are candidates for conscious sedation, deep sedation, or ambulatory general anesthesia (Appendix I). Patients in ASA Class III or IV require special considerations and should be dealt with on an individual basis, probably in a hospital setting.

FACILITIES AND EQUIPMENT

Facilities

The practitioner who utilizes any type of sedation medication or general anesthetic agent must have available the proper facilities, personnel, and equipment to manage any reasonably foreseeable emergency situation experienced by the patient and as mandated by state law.
Back-up Emergency Services

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

Equipment

A positive-pressure oxygen delivery system that is capable of administering greater than 90% oxygen at a 5 L/min flow for at least 60 minutes must be available. All equipment must be able to accommodate children of all ages and sizes.

Inhalation sedation equipment must: (1) provide a maximum of 100% and never less than 20% oxygen concentration at a flow rate appropriate to the child’s size, and (2) have a fail-safe system that is checked and calibrated annually.

Equipment that is appropriate for the technique being used and that can monitor the physiologic state of the patient before, during, and after the procedure must be present. (See Sections I, II, and III for specific monitoring guidelines.)

An emergency cart or kit must be readily accessible and should include the necessary drugs and equipment to resuscitate a nonbreathing and unconscious patient, and provide continuous support while that patient is being transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a scheduled basis. (See Appendix II for recommended drugs.)

INFORMED CONSENT

Each family is entitled to be informed and to give consent regarding risks of conscious sedation, deep sedation, and general anesthesia. Written consent should be obtained according to the procedure outlined by individual state laws.

RESPONSIBLE ADULT

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

DOCUMENTATION

Prior to Treatment

The practitioner must document each sedation and general anesthetic procedure in the patient’s chart. Documentation shall include the following:

1. Instructions to Parents. The practitioner shall provide verbal and written instructions to the parents. The instructions must be explicit and shall include an explanation of potential or anticipated postoperative behavior and limitation of activities together with dietary precautions. A 24-hour contact number for the practitioner should be provided to all patients.

2. Dietary Precautions. Intake of food and liquids should be as follows: (a) no milk or solids after midnight prior to scheduled procedure; (b) clear liquids up to four hours before procedure, ages 0 to 3 years; clear liquids up to six hours before procedure, aged 3 to 6 years; clear liquids up to 8 hours before procedure, age 7 years or greater.

3. Vital Statistics. Weigh (in pounds or kilograms) and age (in years and months) shall be recorded.

4. Preoperative Health Evaluation. Prior to the administration of sedative or general anesthetic drugs, a health evaluation shall be performed.

In the case of conscious sedation, such evaluation should have been accomplished within the past year; for deep sedation or general anesthesia, it shall be accomplished within two weeks prior to the procedure, to be reviewed at time of treatment. Such health evaluation should include: (a) risk assessment (ASA classification, see Appendix I); (b) health history including: (1) allergies and previous allergic reactions; (2) current medications including dose, time, route, and site of administration; (3) diseases, disorders, or abnormalities; (4) previous hospitalization to include the date and for what purpose, together with any history of general anesthesia and hospital courses; and (5) family history of diseases or disorders; (c) review of systems, with a statement as to airway patency; (d) vital signs, including pulse and blood pressure; and (e) physical examination.

5. Child’s Physician. Name and address of the child’s physician or a family physician should be provided.

6. Rationale for Sedation. The practitioner shall briefly state the reason for the need for sedation or general anesthesia.

During Treatment

Vital Signs. The patient’s chart shall contain documentation that heart rate, respiratory rate, and the responsiveness of the patient were checked and observations of the patient’s color, eg, nailbeds, mucosa, etc, were made at specific intervals before and during the procedure, and until the patient was discharged.

Medications Given. The practitioner shall list the route, site, and time of administration together with
the type of drug and the dose. The maximum recommended dose per kilogram (or pound) should be calculated, and the actual dose given shall be documented (in milligrams).

When prescriptions are used, a copy or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions given to the parent.

**After Treatment**

The time and condition of the child upon discharge should be documented in the chart.

**SECTION I: CONSCIOUS SEDATION**

**Personnel**

The practitioner responsible for the treatment of the patient and/or the administration of drugs for conscious sedation shall be appropriately trained in the use of such techniques.

For conscious sedation, the minimum number of personnel shall be two; i.e., the operator and an assistant trained to monitor appropriate physiologic parameters and to assist in any support or resuscitation measures required. These individuals must have training in basic life support, shall have specific assignments, and shall have current knowledge of the emergency cart inventory. The practitioner and all office personnel should participate in periodic reviews of the office's emergency protocol, including simulated exercises, to assure proper equipment function and staff interaction.

**Monitoring Procedures**

1. **Operative Monitoring.** Whenever drugs for conscious sedation are administered, a trained individual should continuously monitor the patient. With the possible exception of very light sedation, the heart and respiratory rates should be continuously monitored and recorded at specific intervals. A precordial stethoscope is considered to be minimum equipment for obtaining continuous information on heart rate and respiratory rate.

   The child's color, eg, nailbeds, mucosa, etc, shall be visually monitored on a continuous basis. If a restraint device is used and it covers the patient, a hand or a foot should be kept exposed. Restraining devices should be checked to prevent chest restriction. The child's head position should be checked frequently to ensure a patent airway. At no time shall a sedated person be left unobserved by a trained person.

2. **Postoperative Monitoring.** When the treatment procedures have been completed and the patient is being readied for discharge, the vital signs should be recorded at specific intervals. The practitioner shall assess the patient's responsiveness and discharge the patient only when the following criteria are met: (a) cardiovascular and airway stability are assured; (b) patient is alert; (c) patient can talk; (d) patient can sit up unaided; and (e) patient can ambulate with minimal assistance. For the very young or handicapped individual, incapable of the usually expected responses, the presedation level of responsiveness that is as close as possible to the normal level for that individual should be achieved.

**SECTION II: DEEP SEDATION**

**Personnel**

The technique of deep sedation requires at least three individuals; each must be appropriately licensed: (1) a qualified person to direct the sedation; (2) a qualified person whose only responsibilities are observation and monitoring of the patient, and who may administer drugs; and (3) other personnel to assist the operator, if necessary. A person other than the operator may direct and/or administer the drugs and monitor the patient.

**Operating Facility**

In addition to the facilities and equipment previously cited, the operating facility used for the administration of deep sedation must have the capability of monitoring temperature and blood pressure and have a functioning suction apparatus. An ECG and a defibrillator are desirable. Airway management and breathing equipment must be checked prior to each patient use.

**Intravenous Access**

Patients receiving deep sedation should have an intravenous line in place.

**Monitoring Procedures**

1. **Operative Monitoring.** Continuous monitoring of the heart rate, respiratory rate, and blood pressure, and visual monitoring of the patient's color must be carried out and recorded at five-minute intervals. A precordial stethoscope and blood pressure cuff are minimum monitoring devices; ECG and temperature monitoring are desirable. The child's head position must be checked frequently to ensure a patent airway. At no time shall a sedated person be left unobserved by a trained person. A time-based or anesthetic-type record shall be maintained. The practitioner shall list the route, site, and time of administration together with the type of drug and the dose. The maximum recommended dose per kilogram (or pound) should be calculated.
and the actual dose given shall be documented (in milligrams). When prescriptions are used, a copy or a note describing the content of the prescription should be in the patient’s chart along with a description of the instructions given to the parent.

Recovery Care

Following deep sedation, the patient must be observed in a suitably equipped recovery facility. This facility must have functioning suction apparatus, as well as the capacity to deliver greater than 90% oxygen and positive-pressure ventilation. 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 assure a patent airway. The patient must remain in the recovery area until cardiovascular and respiratory stability are assured and the patient is awake and oriented.

SECTION III: GENERAL ANESTHESIA

Personnel

The technique of general anesthesia requires at least three individuals each of whom should be appropriately licensed: (1) a qualified person to direct the anesthesia; (2) a qualified person whose only responsibilities are observation and monitoring of the patient, and who may administer drugs; and (3) Other personnel to assist the operator; if necessary. A person other than the operator may direct and/or administer the drugs and monitor the patient.

Operating Facility

In addition to the facilities and equipment previously cited, the operating facility used for the administration of general anesthesia must have the capability of monitoring temperature and blood pressure, and have an ECG device and a functioning suction apparatus. A defibrillator is desirable. Airway management and breathing equipment must be checked prior to each patient use. When general anesthesia is being administered, drugs necessary for the treatment of malignant hyperthermia must be readily available. This must include sodium dantrolene.

Intravenous Access

Patients receiving ambulatory general anesthesia shall have an intravenous line in place.

Monitoring Procedures

1. Operative Monitoring. Continuous monitoring of the heart rate, respiratory rate, and blood pressure, and visual monitoring of the patient’s color must be carried out and recorded at five minute intervals. A precordial stethoscope and blood pressure cuff are minimum monitoring devices; ECG and temperature monitoring are desirable. The child’s head position must be checked frequently to ensure a patent airway. At no time shall an anesthetized person be left unobserved by a trained person. A time-based or anesthetic-type record shall be maintained. The practitioner shall list the route, rate, site, and time of administration together with the type of drug and the dose. The maximum recommended dose per kilogram (or pound) should be calculated and the actual dose given shall be documented (in milligrams).

Recovery Care

Following general anesthesia, the patient must be observed in a suitably equipped recovery facility. This facility must have functioning suction apparatus, as well as the capacity to deliver greater than 90% oxygen and positive-pressure ventilation. 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 assure a patent airway. The patient must remain in the recovery area until cardiovascular and respiratory stability are assured and the patient is awake and oriented.

APPENDIX I

American Society of Anesthesiologists Classification

Class I—There is no organic, physiologic, biochemical, or psychiatric disturbance. The pathologic process for which operation is to be performed is localized and is not a systemic disturbance.

Class II—Mild-to-moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes.

Class III—Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality.

Class IV—Indicative of the patient with severe systemic disorder already life-threatening, not always correctable by the operative procedure.

Class V—The moribund patient who has little chance of survival but is submitted to operation in desperation.

APPENDIX II

Recommended Emergency Drugs

Glucose (50%)
Atropine
Epinephrine
Calcium chloride
Sodium bicarbonate
Lidocaine
Naloxone hydrochloride
Diphenhydramine hydrochloride
Hydrocortisone

Intravenous solutions and equipment for administration appropriate to the patient population being treated.
Portable oxygen capable of delivering bag and mask ventilation greater than 90% at 5 L/min flow for at least 60 minutes (eg, “E” cylinder and resuscitation bag with masks that will accommodate children of all ages and sizes)

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