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

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

Committee on Drugs

In the last 5 years there has been an increase in invasive diagnostic, radiologic, and minor surgical procedures on pediatric patients outside the traditional operating room setting. As a consequence, there has been a marked increase in the use of sedatives and general anesthetic agents in physician offices, dental offices, subspecialty procedure suites, imaging facilities, emergency departments, and ambulatory surgery centers.¹⁻¹⁷ In recognition of the expanding need for both the elective and emergency use of these agents in nontraditional settings, the American Academy of Pediatrics guidelines for the use of depressant agents in children, first presented in 1985 under the title "Guidelines for the Elective Use of Conscious Sedation, Deep Sedation, and General Anesthesia in Pediatric Patients,"¹⁸ have been revised.

This revised statement reflects our current understanding of appropriate monitoring needs, both during and after a procedure, for children receiving sedatives and general anesthetic agents.¹⁹⁻²⁹ The monitoring and care outlined in these guidelines may be exceeded at any time, based on the judgment of the responsible physician. Although they are intended to encourage high-quality patient care, observing these guidelines cannot guarantee a specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice.

These guidelines are proffered with the awareness that regardless of the intended level of sedation or route of administration, the sedation of a patient represents a continuum, and may result in the loss of the patient's protective reflexes;³⁰ a patient may move easily from a light level of sedation to obtundation.^{1-6,8,12,14,15,26,29} The distinction between conscious sedation and deep sedation is made for the purpose of describing the appropriate levels of physiologic monitoring. Deep sedation and general anesthesia are virtually inseparable for purposes of monitoring.³⁰ Sedation of pediatric patients has serious associated risks such as hypoventilation, apnea, airway obstruction, and cardiopulmonary impairment; these risks should be avoided or accurately and rapidly diagnosed and appropriately treated.^{3,6,19-29} Appropriate management may include ventilation by mask and cardiopulmonary resuscitation, which require special training and skills.

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 the department of anesthesia, are specifically addressed by policies developed by the American Society of Anesthesiologists (ASA) and by individual departments of anesthesia, and they are beyond the scope of this document.³¹ Guidelines for the sedation of patients undergoing mechanical ventilation in a critical care environment are also beyond the scope of this document.

The goals of sedation in the pediatric patient are (1) to guard the patient's safety and welfare; (2) to minimize physical discomfort or pain; (3) to minimize negative psychological responses to treatment by providing analgesia, and to maximize the potential for amnesia; (4) to control behavior; and (5) to return the patient to a state in which safe discharge, as determined by recognized criteria, is possible (see Appendix 1).

DEFINITION OF TERMS

- *Pediatric patients*: all patients through 21 years of age, as defined by the American Academy of Pediatrics.
- *Must or shall*: indicates an imperative need or duty that is essential, indispensable, or mandatory.
- *May or could*: indicates freedom or liberty to follow a suggested or reasonable alternative.
- *ASA Physical Status Classification*: guidelines for classifying the physical status according to the American Society of Anesthesiologists (see Appendix 2).
- *Conscious sedation*: a medically controlled state of depressed consciousness that (1) allows protective reflexes to be maintained; (2) retains the patient's ability to maintain a patent airway independently and continuously; and (3) permits appropriate response by the patient to physical stimulation or verbal command, eg, "open your eyes."
- *Deep sedation*: a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. It may be accompanied by a partial or complete loss of protective reflexes, and includes the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.
- *General anesthesia*: a medically controlled state of unconsciousness accompanied by a loss of protective reflexes, including the inability to maintain a

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

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patent airway independently and respond purposefully to physical stimulation or verbal command.

GENERAL GUIDELINES

Candidates

Patients who are ASA class I and II are frequently considered appropriate candidates for conscious or deep sedation (Appendix 2). Patients in ASA class III or IV present special problems that require additional and individual consideration.

Responsible Person

The pediatric patient shall be accompanied to and from the treatment facility by a parent, legal guardian, or other responsible person.

Facilities

The practitioner who uses sedation must have immediately available the facilities, personnel, and equipment to manage emergency situations. Possible complications include, but are not limited to, vomiting, seizures, anaphylaxis or anaphylactoid reactions, and cardiorespiratory impairment, which may lead to a cardiopulmonary arrest.

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, an emergency assist system should be established, and ready access to ambulance service must be assured.

On-Site Equipment

Equipment must be suitable for children of all ages and sizes being treated. A positive-pressure oxygen delivery system, capable of administering greater than 90% oxygen for at least 60 minutes, and a functional suction apparatus with appropriate suction catheters must be immediately available. Note that if a self-inflating type bag is used, 15 L/min flow is required.³²⁻³⁵ Equipment for noninvasive measurement of blood pressure (sphygmomanometer and blood pressure cuffs) and oxygen saturation monitoring (pulse oximetry) must be available. Airway management and breathing equipment must be checked for appropriate function before each sedation.

An emergency cart or kit must be immediately accessible. This cart or kit must contain equipment to provide the necessary age-appropriate drugs and equipment to resuscitate a nonbreathing and unconscious patient. 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 Appendix 3 for suggested drugs and Appendix 4 for emergency life support equipment.)

Inhalation sedation equipment must (1) have the capacity of delivering 100% and never less than 25% oxygen concentration at a flow rate appropriate to the

size of the patient, and (2) be used in conjunction with a calibrated and functional oxygen analyzer.

Consideration should be given to the National Institute of Occupational Safety and Health Standards for the scavenging of waste gases.³⁶

Documentation

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

Before Sedation

1. *Informed consent.* The patient record shall document that appropriate informed consent was obtained according to local, state, and institutional requirements.

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. A 24-hour telephone number for the practitioner or his/her associates should be provided to all patients and their families. Instructions shall include limitations of activities and appropriate dietary precautions.

Dietary Precautions

The use of sedation must be preceded by an evaluation of food and fluid intake (see Appendix 5).

Documentation at the Time of Sedation

1. *Health evaluation.* Before conscious or deep sedation, a health evaluation shall be performed by an appropriately licensed practitioner and reviewed at the time of treatment. This health evaluation should include:

- Age and weight;
- Health history, including (1) allergies and previous allergic or adverse drug reactions; (2) drug use including dosage, time, route, and site of administration for prescription, over-the-counter, or illicit drugs; (3) relevant diseases, physical abnormalities, and pregnancy status; (4) a summary of previous relevant hospitalizations, (5) history of sedation or general anesthesia, and any complications; and (6) relevant family history;
- Review of systems;
- Vital signs, including heart rate, blood pressure, respiratory rate, and temperature;
- Physical examination, including an evaluation of the airway
- Physical status evaluation (ASA classification, see Appendix 2);
- Name, address, and telephone number of the child's or family's physician.

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, 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.

Documentation during Treatment

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 satisfied predetermined discharge criteria (see Appendix 1). The patient's chart shall also contain a time-based record that includes the name, route, site, time, dosage, and patient effect of administered drugs. During administration, the inspired concentrations of oxygen and inhalation sedation agents and the duration of their administration shall be documented. Adverse events shall be documented. Special attention must be paid to calculation of dosage, ie, mg/kg or mg/lb.

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 has returned to a state that is safe for discharge by recognized criteria (see Appendix 1).

SPECIFIC GUIDELINES FOR LEVEL OF SEDATION

Conscious Sedation

Conscious sedation is a medically controlled state of depressed consciousness that (1) allows protective reflexes to be maintained; (2) retains the patient's ability to maintain a patent airway independently and continuously; and (3) permits appropriate response by the patient to physical stimulation and/or verbal command, eg, "open your eyes." A minimally depressed level of consciousness should be used for the very young or handicapped child incapable of the usually expected verbal responses.

The caveat that loss of consciousness should be unlikely is a particularly important aspect 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 highly unlikely. Since the patient who receives conscious sedation may progress into a state of deep sedation and obtundation, the practitioner should be prepared to increase the level of vigilance corresponding to that necessary for deep sedation. Sedatives should only be administered at the health care facility where appropriate monitoring can be instituted.

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 these guidelines, and to manage complica-

tions of these techniques. The practitioner must be trained in, and capable of providing, at the minimum, pediatric basic life support; training in pediatric advanced life support is strongly encouraged.

Support personnel. The use of conscious 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, as required. It is strongly encouraged that this individual be trained in pediatric basic life support. The support person shall have specific assignments in the event of an emergency and, thus, current knowledge of the emergency cart inventory.

The practitioner and all ancillary personnel should participate in periodic reviews of the facility's emergency protocol, to ensure proper function of the equipment and staff interaction.

Monitoring and Documentation

Baseline. Before administration of sedative medications, a baseline determination of vital signs shall be documented.

During the procedure. The practitioner shall document the name, route, site, time of administration, and dosage of all drugs administered. There shall be continuous quantitative monitoring of oxygen saturation (eg, pulse oximetry) and heart rate, and intermittent recording of respiratory rate and blood pressure; these should be monitored and recorded in a time-based record. Restraining devices should be checked to prevent airway obstruction or chest restriction. The child's head position should be checked frequently to ensure airway patency. If a restraint device is used, a hand or foot should be kept exposed. A functioning suction apparatus must be present.

After the procedure. The child who has received conscious sedation must be observed in a suitably equipped facility; ie, the facility must have functioning suction apparatus, as well as the capacity to deliver more than 90% oxygen and positive-pressure ventilation, eg, bag and mask. The patient's vital signs should be recorded at specific intervals. If the patient is not fully alert, oxygen saturation (pulse oximetry) and heart rate monitoring shall be used continuously until appropriate discharge criteria are met (see Appendix 1).

The Use of Nitrous Oxide for Conscious Sedation

The use of nitrous oxide for conscious sedation is defined as the administration of nitrous oxide—50% 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 ASA class I or II patient. The patient is able to maintain verbal communication throughout. A second individual whose responsibility is to monitor the patient may also assist with the procedure. While pulse oximetry is not required under this specific method of sedation, it is strongly encouraged.

Deep Sedation

Deep sedation is a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. Deep sedation may be accompanied by a partial or complete loss of protective reflexes, including the inability to maintain a patent airway independently and to respond purposefully to physical stimulation or to verbal command. The state and risks of deep sedation may be indistinguishable from those of general anesthesia.

Personnel

The state of deep sedation, regardless of how it is achieved, requires that 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 pediatric basic life support, and who is skilled in airway management and cardiopulmonary resuscitation; training in pediatric advanced life support is strongly encouraged.

Equipment

In addition to the equipment previously cited for conscious sedation, an electrocardiograph monitor and a defibrillator for use in pediatric patients should be readily available.

Vascular Access

Patients receiving deep sedation should have an intravenous line in place or have immediately available a person skilled in establishing vascular access in pediatric patients.

Monitoring

The patient shall be observed continuously by a competent individual, and monitoring shall include all parameters described for conscious sedation. Vital signs, including oxygen saturation and heart rate, must be documented at least every 5 minutes in a time-based record. The use of a precordial stethoscope or capnograph to aid in monitoring adequacy of ventilation is encouraged. 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 "Conscious 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. To ensure that the patient will not receive an excessive dose, the maximum allowable safe dosage (eg, mg/kg

or mg/lb) should be calculated prior to administration. There may be enhanced sedative effects when local anesthetic drugs are used with other sedatives or narcotics.^{24,25,37-39}

Inhalation sedation. The use of nitrous oxide poses special risks. Except under the direction of an anesthesiologist or anesthetist, nitrous oxide should not be used in patients of ASA physical status 3 and 4, in patients with an altered level of consciousness, or in patients for whom sequential assessment of level of consciousness is critical. Using inhalation sedation with nitrous oxide in conjunction with sedatives, narcotics, or other depressant medications may rapidly produce a state of deep sedation or general anesthesia and requires the level of monitoring described under "Deep Sedation."

Special Considerations for Monitoring during Magnetic Resonance Imaging

The special technologic problems associated with monitoring patients in a magnetic resonance imaging scanner—specifically, the powerful magnetic field and the generation of radiofrequency—necessitate the use of special equipment to provide continuous patient monitoring throughout the scanning procedure. Pulse oximeters capable of continuous function even during scanning are now available and 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, and it should be used with caution in this setting.⁴⁰⁻⁴³

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Appendix 1. 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 premedication 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 2. ASA Physical Status Classification

- Class I A normally healthy patient.
 Class II A patient with mild systemic disease.
 Class III A patient with severe systemic disease.
 Class IV A patient with severe systemic disease that is a constant threat to life.
 Class V A moribund patient who is not expected to survive without the operation.

Appendix 3. Suggested Emergency Drugs⁴⁴

Oxygen
 Glucose (50%)
 Atropine
 Epinephrine (1:1 000; 1:10 000)
 Phenylephrine
 Dopamine
 Diazepam
 Isoproterenol
 Calcium chloride or calcium gluconate
 Sodium bicarbonate
 Lidocaine (cardiac lidocaine, local infiltration)
 Naloxone hydrochloride
 Diphenhydramine hydrochloride
 Hydrocortisone
 Methylprednisolone
 Succinylcholine
 Aminophylline
 Racemic epinephrine
 Albuterol by inhalation
 Ammonia spirits

Note: The choice of emergency drugs may vary according to individual need.

Appendix 4. Suggested Emergency Equipment

Intravenous Equipment
 Intravenous catheters
 24-, 22-, 20-, 18-, and 16-gauge
 Tourniquets
 Alcohol wipes
 Adhesive tape
 Assorted syringes
 1 mL, 3 mL, 6 mL, and 12 mL
 Intravenous tubing
 Pediatric drip (60 drops/mL)
 Pediatric burette type
 Adult drip (10 drops/mL)
 Extension tubing

Intravenous fluid
 Lactated Ringer's solution
 Normal saline
 Three-way stopcocks
 Pediatric intravenous (IV) boards
 Assorted IV needles
 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
 Oral airways
 Infant, child, small adult, medium adult, large adult
 Nasal airways
 Small, medium, large
 Laryngoscope handles
 Laryngoscope blades
 Straight (Miller) No. 1, 2, 3
 Curved (Macintosh) No. 2, 3
 Endotracheal tubes
 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 uncuffed
 6.0, 7.0, 8.0 cuffed
 Stylettes (appropriate sizes for endotracheal tubes)
 Surgical lubricant
 Suction catheters (appropriate sizes for endotracheal tubes)
 Nasogastric tubes
 Yankauer-type suction
 Nebulizer with medication kits
 Gloves

Appendix 5. Recommended Dietary Precautions

1. *Before elective sedation.* The use of sedation must be preceded by an evaluation of food and fluid intake. Intake of food and liquids should be as follows: (1) infants 0 to 5 months, no milk or solids for 4 hours before scheduled procedure; (2) infants 6 to 36 months, no milk or solids for 6 hours before scheduled procedure; and (3) children older than 36 months, no milk or solids for 8 hours before scheduled procedure. Oral intake of clear liquids may continue, but in no instance should oral intake occur less than 2 hours before sedation. Patients known to be at risk for pulmonary aspiration of gastric contents (eg, those with a history of gastroesophageal reflux, extreme obesity, pregnancy, a history of previous esophageal dysfunction) may benefit from appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH.

2. *For the emergency patient.* The use of sedation must be preceded by an evaluation of food and fluid intake. 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. If possible, such patients may benefit from delaying the procedure and administering appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH. When proper fasting has not been assured, the increased risks of sedation must be carefully weighed against its benefits, and the lightest effective sedation should be used. An emergency patient may require protection of the airway before sedation.

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