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ACR PRACTICE GUIDELINE FOR PEDIATRIC SEDATION/ANALGESIA

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed to assist radiologists in the safe and effective use of sedation and analgesia for children undergoing diagnostic imaging and therapeutic procedures. The goal of this guideline is to allow radiologists to provide their patients with the benefits of sedation/analgesia while minimizing the associated risks. Sedation/analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain. It facilitates and optimizes imaging and interventional procedures that require patient cooperation.

II. DEFINITIONS

Light sedation or anxiolysis is defined by the Joint Commission and the American Society of Anesthesiologists (ASA) as “the administration of oral medications for the reduction of anxiety” and “a drug-induced state during which the patient responds normally to verbal commands.” The ASA states further that “although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.” Examples of drugs administered orally that might be considered for this use are sedative-hypnotics, anxiolytics, benzodiazepines, antihistamines, and narcotics.

Moderate or “conscious” sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains continuous and independent ability to maintain protective reflexes and a patent airway and to be aroused by physical or verbal stimulation.

Deep sedation/analgesia is a 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, including the ability to maintain a patent airway independently and to respond purposefully to repeated or painful stimulation.

General anesthesia is a controlled state of unconsciousness in which there is a complete loss of protective reflexes, including the ability to maintain a patent airway independently and to respond appropriately to painful stimulation.

Regardless of the intended level of sedation or route of drug administration, the sedation of a patient represents a continuum and may result in the loss of the patient’s protective reflexes. All sedated patients should be monitored and treated appropriately regardless of the intended level of sedation. The personnel and equipment considered appropriate for monitoring depend on the patient’s acuity level and potential response to the procedure or intervention proposed.

III. SCOPE

The monitoring guidelines in this document apply only to pediatric patients who receive sedation for any diagnostic, therapeutic, or interventional procedure.

Pediatric patients receiving sedation, regardless of the depth or degree, should be monitored. General anesthesia should be performed by an anesthesiologist or nurse anesthetist.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia should be performed under the supervision of a licensed physician. Appropriately trained medical personnel should be available to treat any adverse event. All persons administering and monitoring sedation are responsible for maintaining proficient skills necessary to provide quality patient care.

Personnel are required to:

1. Be familiar with: a) proper drug dosages on a patient weight basis (kilograms or pounds), and b) administration of sedating drugs.
2. Be familiar with methods of preventing adverse reactions and overdoses.

3. Be able to assess total patient care requirements or parameters, including but not limited to respiratory rate, oxygen saturation, blood pressure, cardiac rate, and level of consciousness.
4. Know how to recognize and treat adverse reactions and overdoses, including recognition of airway obstruction.
5. Demonstrate the skills in basic life support and have the knowledge and skills to intervene in the event of complications. The physician, nurse, or other licensed healthcare provider caring for the patient in the imaging/interventional suite should meet credentialing requirements of the facility.

A designated individual, other than the practitioner performing the imaging procedure, must be present to monitor the patient throughout procedures performed with sedation/analgesia. This individual may assist with minor, interruptible tasks.

V. PATIENT SELECTION

Infants and young children who are in American Society of Anesthesiologists (ASA) class I or II qualify for sedation/analgesia when imaging procedures are required (see Appendix A).

These guidelines specifically exclude the following:

1. Patients who are not undergoing a diagnostic imaging or therapeutic procedure.
2. Perioperative management of patients undergoing general anesthesia.
3. Patients undergoing mechanical ventilation in a critical care environment.
4. Patients who are ASA class III or IV (see Appendix A). Such patients require individual consideration and are not considered in these guidelines.
5. Patients who are ASA class V. Such patients should not be sedated by nonanesthesiologists.

VI. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, physician’s assistant, or other appropriately trained individual for the presence of risk factors that may increase the likelihood of an adverse effect. If risk factors are present, alternatives such as supervision by an anesthesiologist may be considered.

Risk factors include, but are not limited to, congenital or acquired abnormalities of the airway, liver failure, underlying lung disease, congestive heart failure, clinical brain stem dysfunction, apnea or hypotonia, prematurity, history of adverse reaction to sedating medications, and

severe gastroesophageal reflux. Positive pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with atypical airway anatomy, and some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation (see Appendix B).

VII. PATIENT EVALUATION AND MANAGEMENT

A. Pre-sedation Counseling and Information

Parents or legal guardians and, when appropriate, minor patients should be informed of, and agree to, the administration of sedation/analgesia before the procedure begins. If a parent or legal guardian is not present to give informed consent, he or she must be contacted to give consent by telephone. The need for written informed consent shall follow institutional policies and procedures and state requirements.

For outpatients, a parent, legal guardian, or other designated responsible adult must accompany the patient to the procedure and resume care of the patient after recovery from sedation and analgesia.

B. Preprocedure Patient Evaluation

Clinicians administering sedation/analgesia shall be familiar with relevant aspects of the patient's medical history including, but not limited to, abnormalities of the major organ systems; previous adverse experience with sedation, analgesia, or regional and general anesthesia; current medications; drug allergies; and time and nature of last oral intake. Patients presenting for sedation/analgesia shall undergo a focused physical examination including auscultation of the heart and lungs and evaluation of the airway. The patient's weight and resting vital signs (including blood pressure, temperature, pulse rate, percentage of oxygen saturation, and respiration rate) shall be recorded. Preprocedure laboratory testing should be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia. Routine laboratory studies are not recommended. Instead preprocedure laboratory testing should be performed on an as needed basis guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia or the procedure being performed.

Patients undergoing sedation/analgesia for elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying. In some situations, the oral administration of contrast (e.g.,

as needed for abdominal computed tomography) may be an advantage. In these cases, the benefits of the oral contrast must be balanced against the possible risk of aspiration. Gastric emptying may be influenced by many factors, including anxiety, pain, abnormal autonomic function (e.g., diabetes), and mechanical obstruction. Therefore, the suggestions listed do not guarantee that complete gastric emptying has occurred. Unless contraindicated, pediatric patients can be offered clear liquids until 2 to 4 hours before sedation, depending on the age and medical status of the child and hospital policy. For small infants (<10 kg) only a single feeding may be withheld to minimize the risk of dehydration. A suggested fasting protocol is given in Appendix C.

C. Requirements during Sedation Procedure

1. Sedative and analgesic agents

a. Choice

The appropriate choice of agents and techniques for sedation/analgesia depends on institutional policies, the experience and preference of the individual practitioner, and requirements or constraints imposed by the patient or procedure. Physicians and their institutions have ultimate responsibility for selecting medications. It is recommended that each institution develop and regularly review a list of acceptable sedation/analgesia agents for itself. Each institution shall also develop a protocol for administration of each agent including dose, route, specific contraindications, and specific reversal agents (if available).

b. Administration of medications

A physician, registered nurse, nurse practitioner, physician's assistant, or other healthcare worker permitted by state law must administer the medications for sedation and analgesia. Intravenous sedative/analgesic drugs shall be given on a patient weight basis (kilograms or pounds) in incremental doses that are titrated to the desired endpoints of sedation and analgesia. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (e.g., oral, rectal, intramuscular), allowance shall be made for the time required for drug absorption before supplementation is considered.

Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the

condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (e.g., additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to potentiate respiratory depression emphasizes the need to reduce the dose of each component appropriately, as well as the need to monitor respiratory function continually.

2. Reversal agents

Specific antagonists should be available whenever opioid analgesics or benzodiazepines are administered for sedation/analgesia. Naloxone (Narcan) and/or flumazenil (Romazicon) may be administered to improve spontaneous ventilatory efforts in patients who have received opioids or benzodiazepines. This may be especially helpful in cases in which airway control and positive pressure ventilation are difficult. Before or concomitant with pharmacologic reversal, patients who become hypoxemic or apneic during sedation/analgesia should be encouraged or stimulated to breathe deeply, given blow by oxygen and if necessary receive positive pressure bag and mask ventilation if spontaneous ventilation is inadequate or if oxygen saturation below 92% persists. After pharmacologic reversal, patients shall be observed long enough to ensure that cardiorespiratory depression does not recur. Acute reversal of opioid-induced analgesia may result in pain, hypertension, tachycardia, or pulmonary edema.

3. Supplemental oxygen

Equipment to administer supplemental oxygen shall be present when sedation/analgesia is administered. Supplemental oxygen can be administered routinely and must be administered to treat low oxygen saturation.

4. Intravenous access

In patients receiving intravenous medications for sedation and analgesia, vascular access, preferably using a dedicated IV site, shall be maintained whenever possible throughout the procedure and until the patient is no longer at risk for cardiorespiratory depression. In patients who have received sedation and analgesia by nonintravenous routes or whose intravenous line has become dislodged, obstructed, or infiltrated, the clinician shall determine the advisability of establishing or re-establishing intravenous access on a case-by-case basis. In all instances, an

individual with the skills to establish intravenous access shall be immediately available.

5. Patient monitoring

Vital signs are taken and recorded on the chart prior to initiation of sedation and at the end of the procedure.

Monitoring of the patient shall be continuous throughout the procedure and shall include documentation of:

- a. Pulse rate, respiration rate, and oxygen saturation at regular intervals during the procedure, at a minimum of every 5 minutes.
- b. Blood pressure taken as needed during the procedure or as ordered by the physician. It is recognized that taking blood pressure may awaken a sedated child.

Electrocardiographic monitoring must be used in patients with significant cardiovascular disease, as well as during procedures in which dysrhythmias are anticipated.

D. Patient Recovery and Discharge

Each patient-care facility in which sedation/analgesia is administered should develop recovery and discharge criteria that are suitable for its specific patients and procedures.

All patients receiving sedation/analgesia shall be monitored until appropriate discharge criteria are satisfied. The duration of monitoring must be individualized depending on the level of sedation achieved, overall condition of the patient, and nature of the intervention for which sedation/analgesia was administered. The recovery area must be equipped with appropriate monitoring, suction, supplemental oxygen, and resuscitation equipment. A nurse or other qualified individual should be available until discharge criteria are fulfilled. An individual capable of establishing a patent airway and providing positive pressure ventilation should be immediately available. Level of consciousness and vital signs shall be recorded at regular intervals during recovery. The responsible practitioner should be notified if vital signs fall outside of the limits previously established for each patient. A postprocedure evaluation of the patient will be performed and documented by the physician or registered nurse.

VIII. DISCHARGE CRITERIA

Guidelines for discharge

1. Vital signs shall be stable and within acceptable limits.

2. Children are usually responsive or alert before discharge but may not be back to their baseline. However, patients should be responsive to stimuli. Infants and patients whose mental status was initially abnormal shall have returned to their pre sedation status.
3. The patient should demonstrate the ability to swallow fluids at the pre sedation level.
4. Sufficient time (up to 2 hours) shall have elapsed after the last administration of reversal agents (e.g., naloxone or flumazenil) to ensure that patients do not become re sedated after reversal effects have abated.
5. Outpatients shall be discharged to the care of a parent, legal guardian, or other designated responsible adult who will accompany them home and be able to report any post-procedure complications.
6. Written post-discharge instructions shall be given to the patient's responsible accompanying adult. Discharge instructions should be signed by the parent(s) or guardian(s). A copy will be kept in the patient's chart, and a copy will be given to the parent, legal guardian, or other designated responsible adult. These instructions will contain dietary restrictions and instructions to the parent(s) or guardian(s). Instructions for recognizing complications of the procedure, their treatment and after effects of sedation will be included. Instructions for handling the child will include advice not to let the child walk unaided and a warning that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat. Telephone numbers where help can be obtained will be provided, including an after-hours number. The name of a specific person to contact will be given. This information will be reviewed with the patient, parent, legal guardian, or other designated responsible adult.

IX. DOCUMENTATION

Adequate documentation of all aspects of patient evaluation and monitoring is essential for high-quality patient care. This documentation shall include, but is not limited to:

1. Dosage, route, site, and time of administered drugs.
2. Patient's response to medication and the procedure.
3. Inspired concentrations of oxygen, its rate and duration, and method of administration.
4. Physiological data from monitoring.
5. Any interventions such as oxygen or intravenous therapy and the patient's response.
6. Any untoward reactions and their resolution.

Reporting should be in accordance with the [Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures](#).

X. EQUIPMENT

There must be documented policies for monitoring and evaluating the function of all equipment. Any location in which sedation is performed must have ready access to equipment and drugs for emergency resuscitation. It is critical that a complete range of sizes of emergency and monitoring equipment be available for children of all ages and sizes. The equipment should include:

1. Oxygen supply from a portable or permanent source.
2. Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannulas, masks, oral airways and resuscitation equipment (e.g., AMBU bag, laryngoscopes, ventilating masks, and endotracheal tubes). A nonrebreather mask capable of delivering 100% oxygen is necessary.
3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mm Hg and checked for adequacy just prior to sedation. Suction catheters appropriate for patient's airway.
4. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and/or sizes in the patient population.
5. Monitors
 - a. Pulse oximetry with appropriate probes for the child's size. Pulse oximeter should have both digital and auditory display.
 - b. Blood pressure measuring device with cuffs appropriate for the child's size.
 - c. EKG as appropriate for medical history.
 - d. A means of monitoring ventilation, either visually or mechanically.
6. A stethoscope.
7. A defibrillator should be available in close proximity.

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety should be

developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

A record shall be kept for all patients receiving sedation, indicating sedation failure and adverse effects (e.g., vomiting, hypoxic events, resuscitation, and 24-hour follow-up) and possible explanations for adverse outcomes. Patient care areas using sedation and analgesia should have policies and procedures for reporting complications encountered during sedation and analgesia to the quality-assurance committee.

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Suggested Reading

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APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification

Class I	A normal 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.
Class VI	A declared brain-dead patient whose organs are being removed for donor purposes.

APPENDIX B

Factors that may be associated with difficulty in airway management include, but are not limited to:

- Previous problems with anesthesia or sedation.
- Stridor.
- Snoring or apnea.
- Dysmorphic facial features (e.g., Pierre Robin syndrome, trisomy 21).
- Craniocervical abnormalities.
- Significant obesity (especially involving the neck and facial structures).
- Short neck, limited neck extension, neck mass.
- Tracheal deviation.
- Small mouth, protruding incisors, loose or capped teeth, high arched palate.
- Macroglossia.
- Tonsillar hypertrophy.
- Nonvisible uvula.
- Micrognathia.
- Retrognathia.
- Trismus.

APPENDIX C

Suggested Fasting Protocol

	Solids and Nonclear Liquids*	Clear Liquids
Children < 6 mos	4 to 6 hr	2 hr
Children 6 to 36 mos	6 hr	2 to 4 hr
Children > 36 mos	6 to 8 hr	2 to 4 hr

*This includes milk, formula, and breast milk (high fat content may delay gastric emptying).

*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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