



**Pediatric Anesthesia
& Pain Management**

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Guidelines for Surgery Outside the Operating Rooms

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Introduction

Sedation, analgesia, and general anesthesia in pediatric patients for procedures outside the operating room is becoming increasingly commonplace. Anesthesiologists are increasingly involved with these procedures, which is appropriate given the expert skills of anesthesiologists in airway evaluation and support, monitoring, pharmacology, and the physiologic effects of sedatives, hypnotics, opiates, and anesthetics. Furthermore, in consideration of these facts, in instances in which there are no anesthesiologists involved with sedation of children outside the operating room, the JCAHO has given hospitals' departments of anesthesia broad oversight responsibility to assure that the sedation practices of hospitals' non-anesthesiologist practitioners are safe and consistent with our standards of care. The purpose of this lecture is to familiarize the practicing anesthesiologist with the types of procedures that are commonly performed in children outside the operating room, safe protocols for conscious sedation, deep sedation, and general anesthesia and their attendant risks, and the existing guidelines for sedation of children published by specialty societies for their members.

Guidelines for Sedation Outside the Operating Room:

Definitions: There is an unfortunate tendency to use the term "conscious sedation" to encompass all forms of sedation. This tendency trivializes the concept of sedation. Conscious sedation refers to the medically controlled state of depressed anxiety and consciousness that *allows protective reflexes to be maintained, retains the ability of the patient to maintain a patent airway independently and continuously, and permits appropriate response by the patient to physical or verbal commands.* Deep sedation refers to that medically controlled state in which *consciousness is lost, protective reflexes are obtunded, the airway may become obstructed, and in which respiratory depression may occur.*

A degree of safety is implied by conscious sedation over deep sedation, therefore one might assume that the degree of care provided to patients under conscious sedation could be less intense or less compulsive, however moving from a state of consciousness to conscious sedation, to deep sedation, and indeed to general anesthesia, is a dose-related continuum. This continuum can be extremely variable and depends on individual response, age, health status, and drug combinations used. The state of sedation originally intended may not be the one ultimately attained. Therefore, because of the ease with which one moves along this continuum, guidelines should be applicable to all levels of sedation in a hospital or clinic by all clinicians, not just deep sedation.

The following are the guidelines in place at the Packard Children's Hospital at Stanford, which are a direct extrapolation from the American Academy of Pediatrics (AAP) guidelines for sedation.(1) Most of these provisions below are second nature to anesthesiologists, whose standards of practice already incorporate most if not all the safety elements outlined. However, these provisions are not intuitive to our medical and surgical colleagues, who have and continue to embark upon courses of sedation without adequate patient preparation, monitoring, or emergency equipment. These guidelines are being provided to you as a template for pediatric sedation guidelines at your institution, if none exist now; other guidelines exist and are excellent templates for hospital guidelines.(2-4)

General Sedation Guidelines:

- I. Patients who are American Society of Anesthesiologists (ASA) Physical Class I and II may be candidates for conscious or deep sedation. Patients in ASA Class III or IV present special problems that require additional and individual

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- consideration outside the guidelines provided by this document, and may require consultation with or care by a member of the Department of Anesthesia.
- II. **Responsible Person:** Patients undergoing conscious sedation in an outpatient setting must have designated responsible adult(s) accompanying them to and from the treatment facility. Hospital inpatients transported from treatment facilities need to be continuously accompanied by a qualified hospital personnel during transport from the nursing unit to the procedure facility and subsequently from the procedure back to the unit.
 - III. **Responsible Physician:** Each patient undergoing conscious sedation must have a physician who is responsible for its administration. That physician must be trained and experienced in the administration of conscious sedation and must be immediately available to the patient and the practitioner.
 - IV. **Support Personnel:** The use of conscious sedation shall include provision of a person whose responsibility is to monitor appropriate physiologic parameters and to assist in any supportive or resuscitative measures as required. It is strongly encouraged that this individual be trained in pediatric advanced life support. The support person shall have specific assignments in the event of an emergency, and shall have current knowledge of the emergency cart inventory.
 - V. **Facilities:** Practitioners utilizing conscious and deep sedation for performance of diagnostic and therapeutic procedures must have immediately available the personnel and equipment to manage emergency situations. Possible complications include, but are not limited to apnea, vomiting, seizures, anaphylaxis or anaphylactoid reactions, cardiorespiratory impairment, and cardiopulmonary arrest.
 - VI. **Backup Emergency Services:** The protocol for access to backup emergency services shall be clearly identified and ready access to a transportation system must be assured. Follow-up care in the PACU will be available for patients who need prolonged monitoring after conscious sedation. The protocol will need to be specified in each area where conscious sedation is administered.
 - VII. **On-Site Equipment:** Size-specific equipment for pediatric or adult patients must be available on site for securing and maintaining a patent airway and providing cardiorespiratory assistance. A positive pressure oxygen delivery system that is capable of administering greater than 90 percent oxygen at a five liter flow rate for at least 60 minutes, and a functional suction apparatus with appropriate suction catheters must be immediately available. This equipment is found on the Lucile Packard Children's Hospital code cart (crash cart). This code cart must be maintained in accordance with pre-existing policies of LSPCH.

Equipment to be utilized for conscious sedation, including non-invasive blood pressure measuring devices and pulse oximeters, must be available and checked prior to each sedation.

An emergency cart or kit must be immediately accessible. This cart or kit must include the necessary age-appropriate drugs and equipment to resuscitate a non-breathing or unconscious patient. This kit includes at least the following: defibrillator, suction device, oxygen, airways, emergency drugs, (including Naloxone, Flumazenil), intubation equipment, and ECG monitor that must be capable of providing continuous life support while the patient is being transported to another area within the medical facility. All equipment and drugs must be checked and maintained on a scheduled basis, according to the policies of Lucile Salter Packard Children's Hospital.

- VIII. Intravenous access is recommended with conscious sedation and is required for deep sedation.

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- IX. Health evaluation and consent must be obtained on each patient, with appropriate documentation of such in the medical record.
- A. Prior to conscious sedation, a general health evaluation shall be performed by an appropriate licensed practitioner. Such an evaluation should include a current health history and physical examination with particular emphasis on:
1. Allergies and adverse drug reactions.
 2. Drug use, including prescription, over-the-counter, and illicit drugs.
 3. Relevant diseases, physical abnormalities, hospitalizations, and pregnancy.
 4. History of prior sedation or general anesthesia, and if so, any complications.
- B. Informed Consent. Patient's record shall document that appropriate informed consent was obtained according to local, state and institutional requirements. Patients and parents shall be informed about the reasons for sedation, benefits, alternatives and risks associated either in written form or by discussion.
- C. Dietary precaution: the use of sedation must be preceded by an evaluation of recent food and fluid intake and an appropriate period of fasting (see appendix).
- D. Discharge Instructions and information shall be provided to the responsible person. The physician and/or his designated practitioner shall provide verbal and/or written instructions to the responsible person. Instructions shall include objectives of the sedation, anticipated changes, and behavior during and after sedation.
- E. The presence of cyanotic heart disease, congestive heart failure, airway anomalies, an active history of apnea, gastroesophageal reflux, or poorly controlled seizures should lead to consultation with and/or care by the Department of Anesthesia.
- X. Monitoring of the patient is to be continuous throughout the procedure and will include documentation of:
- Appropriate selected vital signs, including blood pressure, pulse rate, percent of oxygen saturation, and respiration's taken and recorded on the chart at the end of the procedure;
 - Pulse rate, respiration's and oxygen saturation must be documented at regular intervals during the procedure, at a minimum of every 15 minutes. Blood pressure shall be taken as needed during the procedure or as ordered by physician;
 - Continuous pulse oximetry with both digital and auditory displays;
 - Level of consciousness documented every 15 minutes;
 - All medications administered and any adverse drug reactions.
 - Post-procedure documentation of level of consciousness, vital signs including oxygen saturation, blood pressure, pulse rate, respirations, maintenance on room air, and unit and name of person receiving the patient.

Safety and Efficacy of Drugs and Combinations of Drugs for Sedation of Children

The goals for sedation outside the operating room are to provide anxiolysis and sedation, with or without analgesia as indicated, perhaps to the point of general anesthesia. All of these drugs are effective, but all carry significant risk of respiratory depression and/or airway obstruction; even agents formerly thought to be benign in children, such as chloral hydrate, have been associated with pediatric deaths. It is especially important to recognize that combinations of drugs cause

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toxicity that is at least additive. For example, in a study of GI endoscopy, 94% of the cardiorespiratory events were associated with the administration of a benzodiazepine *and* an opioid.

Whatever drugs are chosen, an important principle is that the drug should be titrated to the desired therapeutic effect rather than used in single large doses. For this reason it is advantageous to secure intravenous access after the administration of the initial sedative dose. The most common drugs administered to children fall into the following classes:

Anxiolytics:

Midazolam (5): Provides amnesia, short duration of effect, ease of administration either p.o. or i.v., and reversibility. Sedative doses infrequently result in clinical respiratory depression, but severe depression may occur in combination with opioids. Midazolam usually renders children very cooperative and amenable to invasive procedures that otherwise they would refuse. Dose: p.o. 0.5-0.75 mg/kg, i.v. 0.1 mg/kg.

Sedatives/Hypnotics:

Pentobarbital (Nembutal®): Long acting barbiturate with little respiratory effect. The duration of effect may be excessive. Dose: p.r. 4-5 mg/kg, i.v. 2-5 mg/kg.

Chloral Hydrate (6-8): By far the most common agent administered to infants and small children, but far from an ideal agent. Onset is slow (30-60 min), duration is excessive (1-3 hours), and there are many treatment failures from incomplete sedation. Children with abnormal airways and sleep apnea may develop airway obstruction. It should be given in a medical facility rather than at home, and the sedated child should be kept under observation for the duration of effect. Dose: p.o. or p.r. 25-50 mg/kg.

Ketamine (9,10): Dissociative hypnotic with excellent analgesic properties. Causes catecholamine release resulting in elevation of HR and BP. In hypnotic doses causes salivation necessitating an antisialagogue such as atropine. Airway reflexes are obtunded. Visual hallucinations may occur during awakening, which is usually more distressing to parents than the patients. Dose: p.o. 5-10 mg/kg (sedative), i.m. 1-2 mg/kg (sedative), i.v. 0.5-1 mg/kg (sedative), i.m. 3-5 mg/kg (anesthetic), i.v. 2-3 mg/kg (anesthetic); by continuous infusion 50-150 µg/kg/min.

Propofol (11,12): Fast and short lasting hypnotic, no analgesic property. Allows very rapid arousal, often obviating the need for PACU recovery after short procedures. Anti-emetic. Produces profound airway reflex suppression, therefore use should be confined to anesthesiologists. Dose: 0.25-1 mg/kg (sedative), 2-4 mg/kg (anesthetic), 50-150 µg/kg (continuous infusion).

Analgesics:

Nitrous Oxide (5): Often used as "Nitrox," mixed 50:50 with oxygen. Causes sedation and analgesia usually without loss of consciousness. In combination with other agents, however, may lead to loss of consciousness, airway obstruction, and/or respiratory depression.

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Fentanyl (13): Opioid, approximately 50-100X the potency of morphine. When used as single dose, has a short offset due to drug redistribution. When used as multiple doses or infusion has an offset similar to morphine (beta-half life is about 200 minutes, the same as morphine). Useful, therefore, for short painful procedures such as biopsies. Causes profound respiratory depression that may become unmasked after the procedure and attendant stimulation is over. Infants experience more severe respiratory effects than older children. Dose 0.5-1 µg/kg/dose. Oral transmucosal fentanyl citrate (OTFC, Fentanyl Oralet®) is an alternate route for delivering a potent opiate. Usually given in doses of 10-20 µg/kg, with a bioavailability of about 50%, the OTFC produces excellent analgesia, but has a significant incidence (85%) of side effects including pruritus, vomiting, and respiratory depression.

Local Anesthetics: Excellent adjunctive agents for infiltration at biopsy sites, wound edges, etc. Transdermal anesthesia may be obtained using EMLA Cream (Eutectic Mixture of Local Anesthetics). EMLA requires 30-60 min to achieve efficacy. Maximum doses: lidocaine 5 mg/kg (e.g. 0.5 cc/kg of 1%), bupivacaine 2.5 mg/kg (e.g. 0.5 cc/kg of 0.5%).

Combination Agents

DPT: Demerol®, Phenergan, Thorazine® combination has been popular for many years for both painful and other procedures, but it is time to abandon this combination. It causes deep sedation with loss of airway reflexes, has a very prolonged effect, and frequent side effects. It can only be given by painful i.m. injection. Accidental i.v. injection has occurred with fatal outcome.

Procedures Outside the Operating Room:

There are two reasons why procedures are performed under anesthesia outside the operating room: either special equipment, particularly radiological equipment (CT, MRI, etc.) exists outside the operating room, or the procedure planned does not require the sterile environment and skilled personnel of an operating room. In my institution, we have realized a significant cost savings by moving many procedures that do not require sterility out of the operating room, such as myringotomy and tube placement, eye exams, naso-lacrimal duct probing, suture removal laser skin treatment, spica cast removal or change, dental restorations, etc. These procedures usually require general anesthesia as they would in an operating room, the anesthetic management and standard of care is the same regardless of site of care, therefore they require no further comment in this review.

Of greater interest are those procedures that generally do not require sedation or anesthesia in adult patients, while the successful and timely completion of the procedures requires either the voluntary or the pharmacological cooperation of the pediatric patient. When the latter is needed (which is generally the case in children), the anesthesiologist is generally the physician called upon to administer the sedation or anesthesia. This is therefore the subject of this lecture.

Table 1 lists the commonest diagnostic procedures performed on children outside the operating room, and the anesthetic considerations that are unique to each procedure.

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Table 1. Common procedures performed outside the operating room.

Procedure (References)	Anesthetic Considerations
CT (14)	<ul style="list-style-type: none"> • Poor access to and observation of patient within gantry • Radiation exposure makes observation and monitoring of patient from outside scan room advisable • Location may be remote from operating room and support personnel • CT guided needle biopsies require analgesia and a motionless patient • Procedures are generally short (<20 min)
MRI (12,15,16)	<ul style="list-style-type: none"> • Location is remote from operating room and support • Magnet precludes routine monitoring (ECG, invasive monitors) or requires specially designed monitors (SpO₂, capnometry) • Magnet precludes some anesthetic equipment (laryngoscope, syringe pumps) and requires special non-ferrous anesthesia machines • Mechanical ventilation is difficult to accomplish with existing MRI compatible technology • Very poor access to and observation of patient within the magnet gantry; ambient noise level precludes use of precordial/esophageal stethoscope • Some anesthesiologists may not be able to work in the magnetic environment (pacemakers, implanted hardware, etc.) • Procedures are generally long (>45 min)
Radiation Therapy	<ul style="list-style-type: none"> • Location is usually very remote from support and assistance • The anesthesiologist must not remain with patient during radiation exposure; closed circuit TV is needed to observe patient • The patient must remain motionless to avoid radiation toxicity to adjacent anatomy • Procedures are brief and painless, allowing rapid recovery • Procedure is repeated daily to three times a day for many days in a row; tolerance to anesthetic agents is common • Procedures are generally very short (<15 min)
Angiography Suite	<ul style="list-style-type: none"> • After initial catheter placement, little or no further stimulation occurs • Dye injection may be stimulating, and may result in anaphylactoid reactions • Procedures are often lengthy (>60 min)
Emergency Department	<ul style="list-style-type: none"> • Common procedures: laceration closure, fracture reduction • Few if any patients have had an adequate period of fasting • Anxiety and pain are significant • No recovery facility may be available; rapid emergence and

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	recovery are ideal
<i>GI Endoscopy</i>	<ul style="list-style-type: none"> • Procedures may be remote from operating room support personnel • Upper and lower endoscopies are stimulating • Upper GI endoscopy requires tracheal intubation (LMA acceptable?)
<i>Derm. Laser Rx</i>	<ul style="list-style-type: none"> • Procedure is very stimulating (contrary to expectations) • Postoperative pain is significant but transient • Potent analgesics smooth intra- and postoperative course • Duration of therapy 15-30min
<i>Needle Solid Organ Biopsies</i>	<ul style="list-style-type: none"> • Procedures require analgesia; local anesthesia is ideal • Procedures are very short • Prolonged observation in PACU is usually expected
<i>BM's and LP's</i>	<ul style="list-style-type: none"> • Performed on leukemic patients on chemotherapy • Anxiety level is heightened • Procedures are short and are only briefly stimulating
<i>Fiberoptic Bronchoscopy</i>	<ul style="list-style-type: none"> • Examination of upper airway may preclude placement of ETT • Examination of lower airway may be accomplished with or without an ETT • Topicalization of airway to level of carina with local anesthetic is advantageous • Spontaneous ventilation should be maintained

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