CHAPTER 7

VOLUME THIRTY-FOUR

# *Sedation/Analgesia for Diagnostic and Therapeutic Procedures in Children Outside of the Operating Room*

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The American Society of Anesthesiologists, Inc.

ISSN 0363-471X
ISBN 0-7817-9664-4

*An educational service to the profession under the auspices of*
*The American Society of Anesthesiologists, Inc.*

*Published for The Society*
*by Lippincott Williams & Wilkins*
*530 Walnut Street*
*Philadelphia, Pennsylvania 19106-3621*
*Library of Congress*
*Catalog Number 74-18961.*

# Sedation/Analgesia for Diagnostic and Therapeutic Procedures in Children Outside of the Operating Room

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Sedation and analgesia in pediatric patients for procedures outside the operating room as well as in offices and free-standing medical facilities is becoming more frequent as health care is being driven to be cost-effective and "efficient." Sedation for procedures at the Children's National Medical Center (CNMC) in Washington, DC, occurs in the emergency department (fractures, lacerations; 1,500 per year); diagnostic imaging area (computed tomography scan, magnetic resonance imaging [MRI], barium studies; 2,500 per year); gastrointestinal suite (endoscopy; 1,000 per year); pulmonary suite (bronchoscopy; 100 per year); cardiology lab (echocardiography, catheterization; 750 per year); burn unit (dressing change); and in other areas (*e.g.,* chest tube removal, bone marrow aspirations). These procedures require various depths of sedation. Some procedures by their very nature (*i.e.,* upper esophagoscopy, bronchoscopy) are associated with loss of airway reflexes and an increased risk for complications. Although anesthesiologists may direct care of these patients, there is a high likelihood that they will be integrally involved in creating, revising, and organizing sedation services in light of recent American Society of Anesthesiologists (ASA) Practice Guidelines[1] and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) definitions and regulations on sedation outside the operating room.[2]

## The Continuum of Sedation/Anesthesia

The JCAHO regulations[2] contain recommendations made by the American Society of Anesthesiologists.[1] The ASA's efforts in developing guidelines for sedation have recently been revised.[3] The revised standards include new language pertaining to the definition of the continuum of sedation/anesthesia (Fig. 1). The definition of the four levels of sedation and anesthesia are:

"**Minimal sedation (anxiolysis)** *A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.*"[2] In the author's opinion, this level of sedation is rarely adequate for completion of diagnostic/therapeutic procedures in children.

"**Moderate sedation/analgesia** *A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent*

 

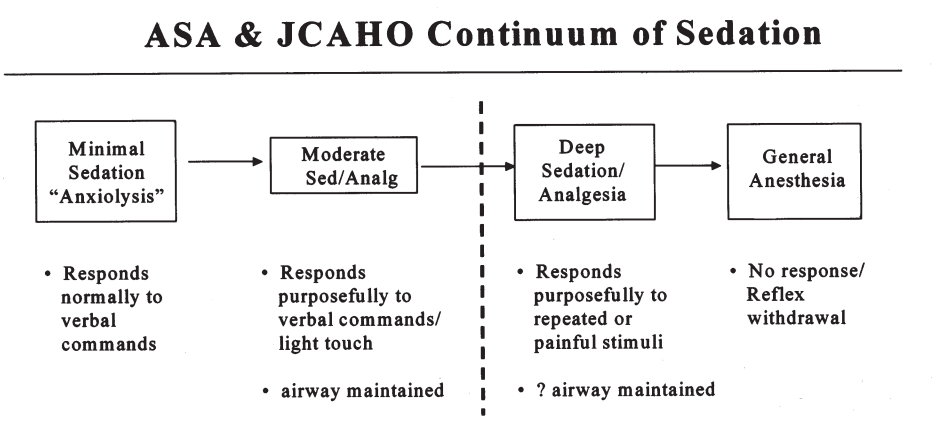


FIG. 1. The American Society of Anesthesiologists (ASA) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) continuum of sedation.

*airway and spontaneous ventilation is adequate. [Cardiovascular] CV function is usually maintained. This level of sedation was referred to as 'conscious sedation' in the past. The old terminology is confusing and inaccurate and is no longer used.*[2]

**Deep sedation/analgesia** *A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal is not considered a purposeful response. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. CV function is usually maintained.*[2]

**Anesthesia** *General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. CV function may be impaired."*[2]

These terms were not specifically designed for children. Many pediatric patients are developmentally delayed or too young to understand verbal commands. There is also a tendency to misinterpret any response to stimulation as a purposeful one. Thus, the patient may be classified as moderately sedated when they are truly deeply sedated or classified as deeply sedated when they are truly under anesthesia. Clear examples of the stages of sedation for different age groups are very helpful in clarifying any misconceptions. There is also the assumption in these definitions that there is a consistent correlation between different levels of sedation and the ability to maintain a patent airway. This correlation has not been carefully studied in children (or adults) with any of the different drugs used for sedation.

## Guidelines and Regulations— Key Components of JCAHO Standards

Most hospitals already have a functioning sedation policy and sedation flow sheet based on the 1992 American Academy of Pediatric Guidelines.[4] These guidelines have been modified[5] to clarify the definition of "conscious sedation" and to emphasize the

risk of sedation when given outside of hospitals. The recent JCAHO definitions and regulations[2] will require modifications of most centers' sedation policies and guidelines to assure compliance.

The updated regulations require similar "assessment" and "care of patient" standards for moderate and deep sedation as are used for patients having general anesthesia. Specifically, new regulations for moderate and deep sedation include: 1) PE.1.8.1—presedation assessment; 2) PE.1.8.2—candidate appropriate for sedation; 3) PE.1.8.3—immediate reevaluation; 4) PE.1.8.4—recovery area admission and discharge assessment; 5) TX.2.1.1—sedation planned and communicated among providers; 6) TX.2.2—patient understands options and risks (education); 7) TX.2.3—patient's physiological status is monitored; 8) TX.2.4—postprocedure and postdischarge status assessed; and 9) TX.2—outcomes collected to improve patient care. Regulations covering minimal sedation (anxiolysis) are not addressed in this document.

Care of patients section TX.2[2] contains wording that will require the greatest change in previous sedation policies and have the greatest effect on anesthesiology departments. This requirement states that qualified individuals must have "competency-based education, training, and experience": 1) in evaluation of patients, 2) in performing sedation, 3) to "RESCUE" the patient from the next level of sedation/anesthesia (*i.e.,* practitioners who perform conscious (moderate) sedation must be able to RESCUE FROM DEEP SEDATION. Practitioners who perform deep sedation must be able to RESCUE FROM GENERAL ANESTHESIA. The JCAHO guidelines state: "Practitioners intending to induce moderate sedation are competent to manage a comprised airway and inadequate oxygenation and ventilation. Practitioners intending to induce deep sedation are competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation."[2] Our Children's Hospital has asked our anesthesiology department to help comply with these requirements. Our department's response has been to:

1. Create an online intranet course on sedation. The course is mandatory for sedation practitioners and is given to all faculty, residents, and RNs. It is required every 2 years. The course describes personnel, regulations, drugs (including reversal drugs), and techniques. A postcourse quiz is required (>80% correct).
2. BLS certification is required for practitioners of moderate sedation. BLS training should provide basic airway support and thus allow RESCUE from deep sedation.
3. PALS certification is required for practitioners of deep sedation. PALS training should provide airway and cardiovascular support training and thus allow RESCUE from general anesthesia.
4. Intranet course attendance, postcourse quiz score, and BLS/PALS certification are tracked by the medical staff office and is a requirement for hospital privileges in sedation.

## Risks of Sedation

There are numerous case reports and clinical studies attempting to document and quantitate the risks of sedation. The Food and Drug Administration (FDA) has collected more than 150 severe adverse drug reactions using a self-reporting system.[6]

### Conclusions From the FDA and Other Studies

- ALL sedatives and narcotics have caused problems even in "recommended doses."
- ALL areas using sedation have reported adverse events.

- Children 1 to 5 years of age are at most risk. Most had no severe underlying disease.
- Respiratory depression and obstruction are the most frequent causes of adverse events.
- Adverse events involved—multiple drugs, drug errors or overdose, inadequate evaluation, inadequate monitoring, inadequate practitioner skills, and premature discharge.

Two publications[7,8] emphasize these results and bring to light complications both inside and outside of the hospital setting. They point to the need for uniform, specialty-independent guidelines for monitoring children during sedation both inside and outside of the hospital setting.

## Specific Sedation Techniques

A sedation treatment plan analyzing the requirements for analgesics, anxiolytics, or both is necessary for each patient and will vary depending on the procedure and the anxiety of the patient and family. Psychologic techniques to allay anxiety (cuddling, parental support, warm blankets, and a gentle reassuring voice and hypnosis) are extraordinarily useful adjuncts to the sedation plan. Many drugs used for sedation and analgesia are not approved by the FDA for use in young children. Two recent Federal laws have given the FDA authority to gain better information on safety and efficacy of drugs in children. The Best Pharmaceuticals for Children Act (January 2002)[9] allows for an additional 6 months patent exclusivity if a patented drug is studied in children. It also gave the FDA authority to request and fund pediatric studies on off-patent drugs. The Pediatric Research Equity Act of 2003[9] requires all new drugs to contain safety and efficacy information for children when appropriate. It is hoped that these new laws will improve our understanding of drug safety and efficacy in children.

Local anesthetics play a critical role in analgesia for painful procedures and greatly reduce requirements for systemic sedatives and opioids. Application of local anesthetics to skin and mucosal membranes as well as local and regional blocks (including Bier blocks) are easily done. Maximum doses (5–7 mg/kg lidocaine with epinephrine, 2 mg/kg tracheal lidocaine, 2–3 mg/kg bupivacaine with epinephrine, 3 mg/kg cocaine, 1.5 mg/kg tetracaine) should be calculated and not exceeded to avoid toxicity. The toxic effects of local anesthetics are additive. The "total" toxic dose must not be exceeded when used in combination. ELA-Max (4% topical lidocaine) is particularly useful for starting intravenous lines, performing lumbar punctures, and facilitating skin infiltration. Mucosal administration of topical lidocaine must be avoided because systemic absorption can cause toxicity. TAC (tetracaine 0.9%; adrenalin 1:200,000; cocaine 4% to 7%) has been used in emergency rooms to repair skin lacerations. The cocaine component can cause arrhythmias and cardiovascular collapse if administered mucosally. Other combinations without cocaine (prilocaine–phenylephrine, bupivacaine–phenylephrine) have been shown to be as effective.[10]

Chloral hydrate is one of the most commonly used sedatives in infants and young children (<3 years).[11] Doses range from 25 to 100 mg/kg with a limit of 1.0 g per dose (2 g per day). It can be given orally or rectally. The main disadvantages are its onset of 30 to 60 minutes and prolonged duration (half-life 10 hours in toddlers). Although it is said to have minimal respiratory effects, it can cause severe airway obstruction in children with obstructive sleep apnea.[12] Chloral hydrate has caused the death of a healthy infant who was given the drug at home before an office procedure. The child

died while being transported in a car seat. Apparently, the child became deeply sedated and was unable to maintain a patent airway. Proper supervision for all sedative drugs is mandatory. Possible toxic metabolites are not an issue when a single dose is administered.

Pentobarbital is a long-acting barbiturate with minimal respiratory depression when used alone. Typical doses are 2 to 5 mg/kg intravenously. A major disadvantage is the prolonged duration (4–6 hours) and slow wakeup, which is associated with agitation.

Midazolam's amnesic effect, short duration (half-life 100 minutes), and ease of administration and reversibility (0.1 mg/kg flumazenil intravenously) make it particularly useful. The dose and onset times of midazolam are: oral 0.5–0.75 mg/kg for 10 to 30 minutes; nasal 0.1–0.3 mg/kg for 10 minutes; rectal 0.3–0.5 mg/kg for 20 to 30 minutes. Intravenous doses start at 0.05 to 0.1 mg/kg. Sedative doses cause mild depression of the hypoxic ventilatory response. Severe respiratory depression can occur when opioids and midazolam are used together.[13]

DPT (Demerol, Phenergan, and Thorazine) has been popular to create an immobile patient both for painful and nonpainful procedures. This drug combination should be abandoned. It usually causes deep sedation and may cause loss of airway reflexes. It has a prolonged effect (4–8 hours) and severe side effects from the opioid (hypoventilation) and phenothiazine (seizures, extrapyramidal effects).

Fentanyl is a potent opioid (100 times more potent than morphine) with rapid onset, intermediate duration (30–45 minutes), and reversibility (0.01 mg/kg naloxone intramuscular or intravenous). It is very useful for short, painful procedures. The respiratory depressant effect is much longer (4 hours) than its analgesic effect. As is true for all opioids, fentanyl can cause apnea and chest wall rigidity when administered rapidly. Doses starting at 0.5 to 1.0 μg/kg should be titrated to effect or a maximum of 5 μg/kg. Respiratory depression can be severe in infants less than 3 months.

Oralet (oral transmucosal fentanyl citrate; Abbott) had limited use in pediatric sedation. It has been replaced by Actiq (Cephalon). The PDR[14] contains a boxed warning stating,"to be used only in the care of cancer patients" . . . "can be fatal to a child." It is therefore not recommended for sedation in children.

Nitrous oxide ($N_2O$) used alone in concentrations <50% is a useful mild (anxiolytic) sedative agent, which causes analgesia. Verbal contact must be maintained with the patient. Appropriate monitoring and guidelines must be in place when $N_2O$ is used in conjunction with other sedatives (*i.e.,* moderate/deep sedation guidelines).

Ketamine is an excellent analgesic and amnesic, which can be given intravenously (0.25–0.5 mg/kg), orally or rectally (6–10 mg/kg), or intramuscularly (2 mg/kg). It increases heart rate, blood pressure, and intracranial pressure. It can cause copious secretions and lead to laryngospasm. Ketamine in large doses can cause an incompetent gag reflex, deep sedation, or general anesthesia. To avoid complications, it is recommended that intravenous ketamine be administered only in acute care areas and that the intravenous dose be limited to 0.25 to 0.5-mg/kg boluses with a maximum of 2 mg/kg more than 20 minutes. An anesthesiologist should be consulted if greater doses are required.

Propofol's sedative/hypnotic effect, fast onset, and extremely short duration have made it useful for sedation/anesthesia in the operating room. "Patient-controlled sedation" (minimal sedation) using boluses of 25 to 50 μg/kg is becoming popular in adults. Propofol administered by anesthesiologists as a continuous infusion of 50 to 200 μg/kg per minute intravenously is extremely useful in nonpainful pediatric deep sedation procedures (*e.g.,* MRI) in which a quick wakeup is desirable. Its antiemetic effect makes it particularly useful for ambulatory procedures. Clinical experience shows that propofol "sedation" in children can lead to deep sedation and airway obstruction.

There is presently a desire for clinicians other than anesthesiologists (*e.g.,* intensivists, pulmonologists, gastroenterologists) to use propofol for sedation in pediatric patients.[15] The most recent ASA statement on sedation with propofol[16] states that "propofol is an anesthetic drug, and the ASA believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. Other providers, however, do administer this drug and we need to have the information to help set up policies and care processes so that all patients will receive safe care."[16] Although the ASA guidelines apply to all ages, our Children's Hospital has more strict regulations on the use of propofol by nonanesthesiologists. The reasons include: 1) propofol causes significant decreases[17] and changes[18] in airway dimensions in children in sedation doses; 2) propofol can unpredictably cause loss of airway reflexes even in sedative doses in children; and 3) the package insert does not recommend the use of propofol for sedation of pediatric patients in the intensive-care unit. It also must be appreciated, however, that many drugs presently used in children are not recommended for such use by the FDA and that propofol (although not approved for pediatric sedation) may be the drug of choice for sedation in some circumstances. Therefore, until further studies on safety are published, our Children's Hospital recommends that propofol sedation be considered deep sedation/general anesthesia. Its use by nonanesthesiologists should be restricted to short procedures in intensive-care units in intubated children only. Monitors, equipment, and personnel skilled in airway resuscitation and deep sedation must be immediately available.

## Magnetic Resonance Imaging: Anesthesiology-Supervised Deep Sedation Service

There is a growing need to provide deep sedation for children needing MRIs. An anesthesiology-supervised deep sedation service is efficient, provides deep sedation with agents that allow smooth and rapid induction and emergence, and is uniquely qualified to "rescue" patients from general anesthesia. Furthermore, if general anesthesia is required, then rescheduling is not necessary. RNs involved in deep sedation receive extensive training in management of the difficult airway and airway obstruction, resolving airway obstruction, PALS, vascular access, and the pharmacology and use of agents for deep sedation.

Anesthesia is induced immediately outside of the MRI room using propofol (1–2 mg/kg) or sevoflurane (if an intravenous line is not initially placed). The child is then stabilized, nasal cannulae (with $CO_2$ sampling) applied, and a propofol infusion is started and titrated to a level of deep sedation (100–250 μg/kg per minute). Deep sedation is verified when the child moves appropriately to a painful stimulus (lifts arms toward a painful stimulus at the shoulder in an attempt to remove the stimulus).

There are several options for infusing propofol in the MRI room. We use the "Medrad" MRI-compatible infusion pump inside the MRI room. If a pump is not available, then we use a dilute solution of propofol in a microdrip Burette (60 qt/mL). The amount of propofol (in milligrams) to be added to the Burette is calculated by multiplying the weight of the child (in kilograms) by 6. This amount of propofol is then diluted with crystalloid to a total volume in the Burette of 100 mL (rule of 6's). The drip rate (in qt/min) will be approximately[19] equal to the propofol infusion rate (in μg/kg per minute). Thus, for a 10-kg child: 60 mg of propofol ($6 \times 10$ kg = 60 mg), which is 6 mL of undiluted propofol is added to 94 mL of crystalloid solution in the pediatric Burette. The child's heart rate can be used as a convenient starting drip rate. If the child's heart rate is 120 beats per minute, then the drip rate is set at 120 qt/min. This equals an infusion rate of 120 μg/kg per minute. The dose is then adjusted to maintain deep sedation.

Once stable and deeply sedated, the child is transported to the MRI room where the RN stays with the child. Vital signs, including oxygen saturation, end-tidal carbon dioxide, and level of sedation, are monitored and recorded every 5 minutes. Adjustments in propofol administration, if necessary, are made by the anesthesiologist. The anesthesiologist is outside the magnet preparing another child for sedation in the second MRI scanner. After the scan is complete, the child is recovered in the MRI recovery area and is discharged within 1 hour after completion of the study. This technique is efficient, quick, safe, easy, and allows one anesthesiologist to supervise the care of more than 2,500 deeply sedated children for MRIs per year using two MRI scanning machines.

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