



Section: 400.000 - Care of the Patient

Subject: Pediatric Procedural Sedation/Analgesia

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I. Purpose

Procedural sedation/analgesia for diagnostic and therapeutic procedures performed on pediatric patients throughout Jackson Health System. To establish appropriate standards and guidelines for the administration and monitoring of sedation-analgesia to pediatric patients for diagnostic or therapeutic procedures that may result in the loss of patient protective reflexes and/or airway maintenance. To ensure compliance with federal, state and other regulatory regulations.

II. Policy Provisions

1. Sedation and Analgesia for diagnostic and therapeutic procedures on pediatric patients throughout Jackson Health System shall be in accordance with the following guidelines. Patients older than 14 years of age may fall under the Adult Sedation Policy guidelines (JHS Policy No. 400.016).
2. It is the policy of Jackson Health System to provide quality care in a safe environment for all patients within the system. This includes minimizing physical and emotional discomfort during their admission or clinic visit. In order to ensure appropriate safeguards and decrease the risk of adverse outcomes the following sedation-analgesia policy has been developed.
3. These clinical practice guidelines establish the requirements of sedation-analgesia providers to pediatric patients and the procedure to follow for such practices throughout the Jackson Health System. This policy covers guidelines of care from the pre-sedation period until the patient is deemed fit for discharge to the floor or home by a qualified independent licensed practitioner.



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4. This policy does not apply to direct treatment of patient disease, such as pain/anxiety control, but to the active administration of medications to allow for diagnostic or therapeutic procedures. This policy does not apply to the Department of Anesthesiology, to individuals licensed as dentists or oral surgeons by the State of Florida, or to the administration of sedation-analgesia to patients receiving mechanical ventilation or ICU level care due to the progression of their disease state.
5. The loss of a patient's *protective reflexes*, i.e., loss of cough, swallowing and/or gag reflexes, is a complication of excessively deep sedation-analgesia. This means the patient becomes unable to handle their own secretions and/or loses the ability to breathe independently, leading to an increased risk of aspiration, airway obstruction and hypoxia.

III. Levels of Sedation

1. Though the degree of sedation-analgesia follows a continuum, levels can be identified by *hallmark events*, defined by the patient's individual purposeful response to stimuli. Required training and skills for qualified sedation-analgesia personnel include those needed to predictably achieve the desired level of sedation, to monitor the level of sedation and to rescue a patient who has progressed to an excessive level of sedation and has lost his/her protective responses. A response limited to reflex withdrawal from pain is not considered a purposeful response and thus represents stage IV or general anesthesia.

Levels of Sedation

LEVEL	I - Minimal/ Anxiolysis	II - Moderate Sedation/ Analgesia	III - Deep Sedation	IV - General Anesthesia
Response to Stimuli	Normal to <i>verbal</i>	Purposeful to <i>verbal or tactile</i>	Purposeful to <i>repeated or painful stimulation</i>	<i>Unresponsive to pain</i>
Airway	Normal	No required intervention	May require intervention	Often requires intervention
Breathing	Normal	Adequate	May require assistance	Often requires intervention
Cardio-vascular	Normal	Usually normal	Usually normal	May be impaired

2. The administration of *minimal* sedation is allowed in any patient care area under the orders and care of a licensed practitioner with privileges to order medications in their practice within the Jackson Health System. *Moderate (Level II) or Deep (Level III)* Sedation may only be administered in the following patient care areas in a facility where and when the appropriate Anesthesiology Department backup is available:



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Patient Care Areas

- | | |
|--|--|
| <ul style="list-style-type: none"> • Pedi ICU • Radiology-Diagnostic Imaging • ECHO Lab • Cardiac Cath Suite • GI – Procedure Suite • Pulmonary Lab • Pedi Bone Marrow Unit | <ul style="list-style-type: none"> • Emergency Department • Trauma Resus • ET5 Procedure • WW12 BMT • Newborn Special Care Center |
|--|--|

3. All areas where sedation-analgesia occurs will have available equipment for emergency resuscitative measures, including a crash cart with defibrillator, an age-appropriate intubation tray and access to activate the center's emergency alert or code blue in needed cases.
4. Moderate sedation (level II) may be provided by qualified fellows and residents as delineated in this policy, provided that they are under the direction of an attending credentialed to provide procedural sedation/analgesia.
5. The administration of deep (level III) procedural sedation and/or the administration of FDA classified general anesthetics such as Propofol, Ketamine, Thiopental, Methohexital, and Etomidate for procedural Level III sedation by non-Anesthesiologists is reserved for Pediatric Critical Care Medicine attendings and Pediatric Emergency Department medical staff who have:
 - a. met criteria for Moderate Sedation as outlined below;
 - b. are credentialed to perform endotracheal intubation;
 - c. can confirm that they have performed procedural deep sedation (Level III) at least 15 times in the preceding 2 year period;
 - d. approval by the Chief of Anesthesia or his designee through the formal credentials process.
6. The administration of General Anesthesia (level IV) may only be provided by properly credentialed anesthesiologists and oral surgeons/dentists,

B. Certification

1. Any personnel administering and/or monitoring sedation-analgesia to pediatric patients throughout Jackson Health System will have the appropriate training (and privileges, if applicable) as described in this policy and is responsible for maintaining knowledge, skills and certification status prior to administering and/or monitoring sedation-analgesia. These include, but are not limited to, the following areas:

Appropriate patient assessment and selection

 - a. Knowledge of the effects of the drugs used, and their possible reversal agents
 - b. Knowledge of monitoring parameters and recognition of abnormalities
 - c. Recognition of airway obstruction or depressed breathing
 - d. Ability to manage any harmful events until qualified assistance takes over care
2. A licensed credentialed attending physician must concur with the sedation plan and be responsible for the administration of sedation-analgesia. Though the attending performing the procedure can be responsible for the ordering of sedation medication, he/she cannot



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at the same time administer medications and monitor the patient while performing the procedure. During the administration of level II or level III sedation the designated individual who is administering sedation and monitoring the patient will have no responsibilities other than those delineated in this policy and cannot be the person performing the procedure.

3. Ordering of medication to achieve level II sedation-analgesia requires:
 - a. FL licensure as physician (MD, DO)
 - b. Current PALS; ACLS, as applicable; NRP for Neonatology certification
 - c. Knowledge of the Jackson Health System pediatric sedation-analgesia policy
 - d. Completion of the Initial Pediatric Sedation-Analgesia Certification Course
 - e. Current or Biennial Recertification (every 2 years) via the Pediatric Sedation-Analgesia Course and completion of a minimum of 15 sedation procedures during the prior period. A physician new to JHS may be asked to provide cases from a previous work experience, or proof of requisite GME training (e.g. graduates of PCCM or PEM fellowship programs).

KEYPOINT: ARNP or registered FL Resident physician may order medications for moderate sedation (level II) under the direction of the credentialed attending. Medications to achieve deep sedation (level III) may only be ordered by a physician credentialed to provide level III sedation or a critical care fellow under their direct supervision.

4. Administration of medication and monitoring during level II sedation-analgesia requires:
 - a. FL Licensure as physician (MD, DO), nurse (RN, ARNP) or
 - b. Registered FL Resident physician; (specifically credentialed MD, DO required for level III);
 - c. Monitoring according to nursing competencies
 - d. Current PALS; ACLS, as applicable; NRP for Neonatology certification
 - e. Knowledge of the Jackson Health System pediatric sedation-analgesia policy
 - f. Knowledge of the Outcomes Evaluation Tool
 - g. Completion of the Initial Pediatric Sedation-Analgesia Certification Course
 - h. Current or Biennial Recertification (every 2 years) via the Pediatric Sedation-Analgesia Course
 - i. Physicians must demonstrate completion of a minimum of 15 sedation procedures during the prior period.

KEYPOINT: Administration and monitoring of level III sedation may only be performed by a physician credentialed to provide level III sedation or a critical care fellow under their direct supervision.

5. The outcome evaluation tools are maintained by Department of Quality Management who along with the Clinical Department Chiefs or designees will carry out quality improvement functions as delineated in the last section of this policy.

C. Equipment Required

All areas where level II/III sedation is administered must have the following age and size appropriate equipment:



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1. A self-inflating positive-pressure oxygen delivery system for the administration of at least a 10 L/min flow rate for a minimum of 60 minutes. A full E-cylinder at 2200 psi contains approximately 600 L of oxygen.
2. A continuous suction system with catheters and tonsil-type rigid suction tip.
3. Airway management equipment, including an age-appropriate intubation tray.
4. **Monitors:** Pulse oximeter, non-invasive blood pressure device, ECG Monitor and ETCO₂. Monitor alarms should be on and appropriate alarm limits set.
5. Emergency resuscitation cart, including resuscitative drugs and defibrillator.
6. Reversal agents, such as Naloxone and Flumazenil.
7. Capability to summon assistance in the case of an emergency or initiation of a rescue procedure.

IV. Procedures for Level II/III Sedation

A. Pre-Sedation Patient Assessment

The following will be obtained in assessing the patient for sedation-analgesia:

1. Informed consent for the planned procedure - each patient, if age appropriate, is entitled to information by the credentialed physician regarding the risks of sedation/analgesia or deep sedation. Consent will be obtained from a parent or guardian.
2. A history that includes:
 - a. Age in years and months
 - b. Allergies and previous drug reactions
 - c. Current medications, dose and times
 - d. Diseases, disorders and abnormalities
 - e. NPO status (Addendum I)
 - f. Previous hospitalizations
 - g. Previous procedures/anesthetics and notations of any problems
 - h. Pertinent family history
 - i. Review of systems with concentration on cardiopulmonary function and airway patency.
 - j. Pertinent lab or test results
3. A physical exam that includes:
 - a. Weight (kilograms), Height (centimeters)
 - b. Baseline vital signs, heart rate, blood pressure, respiratory rate and temperature
 - c. Complete physical examination is documented including airway assessment. Body habitus (significant obesity or deformities – especially neck and facial features).
 - d. Head and neck (short neck, limited neck extension, decreased hyoid-mental distance, neck mass, cervical spine disease or trauma, tracheal deviation, previous surgery or radiation)
 - e. Mouth (small opening, protruding incisors, removable dentures,
 - f. loose or capped teeth, high arched palate, macroglossia,
 - g. tonsillar hypertrophy, non-visible uvula); Mallampati Score
 - h. Mallampati Score (See Addendum II)
 - i. Jaw (small or receding)
4. Focused Pre-Sedation Patient Assessment:



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Consultation with or referral to the Anesthesia department is strongly recommended in the following cases:

- a. Morbidly obese or patients with history of severe snoring or obstructive sleep apnea
 - b. High risk children with severe renal, hepatic, pulmonary, cardiovascular or central nervous system disease
 - c. Prior adverse response to sedation or anesthesia
 - d. Known gastro esophageal reflux disease
 - e. Pregnant patients
 - f. An airway exam with signs of difficult management
 - g. Non-standard NPO status if the attending covering the
 - h. Procedure feels and documents an emergency situation that requires overriding the need of standard NPO status as defined in Addendum I. The risks and benefits of overriding standard NPO status must be discussed with the patient or consenting individual and documented.
5. Prior to commencing sedation and before the procedure, the following must be documented in order to allow for risk assessment:
- a. Patient weight, height
 - b. Complete H&P
 - c. Patient allergies
 - d. NPO status (see Addendum I)
 - e. ASA physical status (see Addendum III)
 - f. Airway assessment; Mallampati Score (see Addendum II)
 - g. Informed consent
 - h. Time-Out (Universal Protocol)
 - i. A pre-sedation set of vital signs (including: blood pressure, heart rate, respiratory rate, SpO₂ on room air (or baseline supplemental oxygen) and temperature) must be obtained and documented together with pertinent lab results.
 - j. A pre-procedure Post-Anesthesia Recovery (PAR) score must be obtained for comparison at end of procedure and at discharge (see Addendum IV).
 - k. A statement of NPO status (see Addendum I).
 - l. A female patient, who has commenced the menstrual cycle, must have a negative urine pregnancy test noted within the prior 10 days. If pregnancy test is refused by patient/parent, documentation of refusal must appear in chart.
 - m. The supervising physician must document the above with a sedation plan as well as indicate that sedation options and associated risks have been discussed with the person consenting for the procedure.
 - n. An order from the responsible physician must state: "Initiate Pediatric Procedural Sedation/Analgesia Protocol" prior to writing the orders for specific medications.
 - o. In cases where patient is receiving multiple procedures requiring sedation, the initial pre-sedation assessment is sufficient as long as a note indicates no change in the patient's clinical status that would alter the outcome of the sedation and the procedure.
 - p. All qualified sedation-analgesia personnel must have IV placement competency in order to replace a lost IV or to place an IV if required in the case of an emergency situation.
6. Medications:
- a. All sedation-analgesia cases will have an initial order stating "Initiate Pediatric Procedural Sedation/Analgesia Protocol" prior to ordering of medications.



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- b. During the procedure qualified sedation-analgesia personnel will document medications administered (time, dose and method of administration – PO/IV/IN/IM/PR).
- c. Medications available for the practice of sedation-analgesia include, but are not limited to sedatives and/or opiates (see Addendum V). All medications administered will be ordered by the responsible physician with sedation-analgesia privileges. Orders will indicate patient's weight, allergies, medication, dose, route and rate if administered as an infusion. Medications will be specified in mg/kg/dose or mcg/kg/dose.
- d. Pharmacological antagonists or "reversal agents", including Naloxone and Flumazenil must be immediately available in area where sedation takes place. Routine use of reversal agents is not recommended as they have their own side effects and complications. If reversal agents are administered, patient must remain monitored for cardiorespiratory depression until the effects of the reversal agents dissipate, i.e., at least 4 hours to ensure patients will not become re-sedated.

B. Monitoring During Procedures

1. The patient will be under continuous monitoring of ECG, pulse oximetry (SpO₂), non-invasive blood pressure (BP) and ETCO₂; and alarms must be on and alarm ranges set appropriately. Refer to JHS Policy No. 400.048, Sedation/Analgesia Monitoring Record (C-410E) Guidelines.
2. Supplemental oxygen via mask or nasal cannula will be administered unless there is a specific contraindication.
3. A qualified, licensed health provider with Jackson Health System certification for the monitoring of sedation-analgesia will continuously assess respiratory adequacy and rate (RR) and level of patient responsiveness (documented as I-IV, as defined in the above table). This will be documented on the Sedation/Analgesia Monitoring Record, together with HR and rhythm, BP and SpO₂ and ETCO₂ every five (5) minutes throughout the procedure. The level of oxygen therapy will also be documented. Documentation is to occur every five (5) minutes.
4. If restraining devices are in place, utilization must be in accordance with JHS policies and devices must not impede chest wall excursion.
5. Patients receiving intravenous sedation/analgesia shall have an RN or physician in attendance throughout the sedation and recovery period.

C. Deep Sedation

Documentation and patient monitoring (refer to Sedation/Analgesia Monitoring Record C-410E) shall be in accordance with sedation/analgesia guidelines with the following additions:

D. Drugs/Dosage Ranges

1. Administration of the medications for Pediatric sedation/analgesia listed in Addendum V, in doses above the recommended range for sedation/analgesia, requires adherence to the standards for deep sedation.
2. The name of the drug, dose, route, site, and time of administration shall be documented.
3. Medication administrations shall be titrated for desired effect, providing adequate time to assess level of consciousness/degree of sedation.



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KEYPOINT: Consultation with an anesthesiologist is recommended when prior attempts at achieving sedation using standard dosages have been unsuccessful or when physiologic or anatomic abnormalities exist which might predispose to complications or difficult management. If there is a significant likelihood of inducing general anesthesia for a non-emergent situation, the anesthetic agents should be administered under the direct supervision of an anesthesiologist

V. Post Procedure Monitoring and Recovery Care

A. Post-Sedation

Post-procedure is defined as the termination of procedural stimuli. All hospital areas that practice sedation-analgesia must have a post-procedure recovery area (with all equipment and monitoring as stated above immediately available) for patients until discharge criteria are met.

1. The patient will remain on continuous monitoring and supplemental oxygen therapy, if applicable, and attended by qualified sedation-analgesia personnel who will continue documentation of SpO₂, HR and rhythm, BP, RR and level of consciousness every **15** minutes. Supplemental oxygen therapy is weaned as tolerated and documented.

KEYPOINT: Premature infants whose post conceptual age (gestational age plus postnatal age in weeks) is less than 50 weeks, full term infants less than 4 weeks of age and infants on medications for apnea or home monitoring for apnea are at an increased risk for post sedation apnea. This subgroup of patients receiving level III sedation and higher should receive extended monitoring.

2. The frequency of obtaining and documenting VS requires adjustment to patient status. In the case of decreased level of consciousness, respiratory depression, SpO₂ less than 90% or a fall of 10% or greater despite supplemental oxygen, or if BP falls out of 30% above or below pre-procedure baseline, documentation every five (**5**) minutes is resumed and the **rescue procedure** is initiated.
3. Upon completion of procedure and post-sedation monitoring, the "QPS Sedation/Analgesia Monitoring Form" (Quality Patient Safety form on JHS Net portal) must be completed. In addition, the time and condition of the patient should be documented in the medical record upon transfer/discharge or completion of procedure.

B. Rescue Procedure

From initiation of sedation-analgesia until discharge criteria are met, the credentialed sedation-analgesia provider must be vigilant to detect potentially life-threatening occurrences. These include loss of protective reflexes, lack of patient purposeful response to repeated verbal or pain stimuli (general anesthesia), unstable vital signs (hypotension, hypertension, new dysrhythmias, hypoventilation, low SpO₂ despite supplemental oxygen) the qualified sedation-analgesia personnel monitoring during the protocol will:

1. Halt the procedure
2. Begin interventional measures: airway, breathing, circulation
3. Initiate PALS, ACLS, NRP, as needed
4. Notify responsible attending physician as soon as possible
5. Activate the center's code blue system or notify anesthesia services for assistance, as required
6. Consider administration of reversal agents



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7. Return to documentation of every five (5) minutes vital signs

C. Discharge Criteria

Patient may be discharged from a monitored setting when all the following criteria are met:

1. Patient is easily awakened by normal verbal commands, is appropriately oriented and/or returned to baseline condition.
2. No apparent risk of losing protective reflexes.
3. Vital signs are stable and at pre-procedure baseline.
4. PAR score of 9-10 documented three times or equivalent to pre-procedure PAR score three times
5. SpO2 of 95% without supplemental oxygen or at pre-procedure baseline
6. Outpatients must be able to tolerate oral intake and ambulate independently or at pre-procedure baseline. All outpatients must be accompanied on discharge by a parent or responsible adult.
7. All outpatients and responsible parent and/or adult will be provided with verbal and written information regarding medications, activity level allowed, signs/symptoms of complications and course of action to proceed with in the event of a complication or emergency. This information must be documented.
8. An order stipulating "discharge to floor or home" must be documented by the licensed independent practitioner in order to discontinue monitored care. Any case requiring unexpected hospital admission or upgrade to a special monitoring unit (e.g., PICU, PARU) requires documentation of events and subsequent plan by the responsible attending.
9. Inpatients returning to previous hospital area or those requiring planned admission, will require that procedure area provide verbal report to accepting nursing staff. Additionally, Nursing Transfer Report Checklist must be completed prior to transport. Verbal nursing report will include procedure performed, sedation/analgesia administered, and any complications or side effects.
10. The Outcomes Monitoring Tool (QPS Sedation-Analgesia Form, JHS Net portal) must be completed for each sedation case.

D. Risk Management and Quality Improvement Monitoring and Reporting

The following mechanisms are in place to assure quality patient care related to the administration of Sedation-Analgesia:

1. It is the responsibility of the qualified sedation-analgesia personnel to complete the QPS Sedation-Analgesia Outcomes Evaluation Tool (JHS Net portal) as noted above.
2. The Pediatric Sedation Committee, co-chaired by Pediatric Anesthesia and Pediatric Critical Care Medicine provides ongoing reassessment of pediatric sedation needs and practice throughout PHT facilities. Quality Improvement and review of cases will be conducted at quarterly meetings of the Holtz Children's Hospital Pediatric Sedation Committee. Quality Reports are completed at the conclusion of procedural sedation for on-line review; these reports can be utilized at the time of re-credentialing to confirm the 15 required procedural sedation cases needed. Pediatric Sedation Committee members review reported cases during regularly scheduled Quality Improvement meetings. Should any adverse outcome criteria be met, a review and correction action plan be implemented.
3. The Clinical Chief of Service is responsible for adherence to these guidelines within his/her Department if sedation-analgesia takes place there. A quarterly report will be presented by Quality and Patient Safety at the Medical Review Sub-Committee of the Medical Executive Committee of the Jackson Health System. A yearly report of the



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Outcomes Data will be presented in writing to the Chair of the Department of Anesthesiology.

4. Reportable outcomes include:
 - a. ANY use of a Reversal Agent
 - b. ANY patient requiring Assisted Ventilation (Bag Breathing)
 - c. ANY patient requiring intubation
 - d. ANY cardiac or respiratory arrest
 - e. ANY *new* cardiac dysrhythmias
 - f. ANY seizure event
 - g. ANY allergic/anaphylactic reaction
 - h. ANY desaturation of O₂ below 90% sustained for over 5 minutes
 - i. ANY variation of VS by 30% from baseline
 - j. ANY failure to return to baseline VS or PAR score
 - k. New onset of intractable nausea or vomiting
 - l. ANY case with unplanned admission to a monitored unit or a hospital setting resulting from sedation.
 - m. ANY case wherein review is thought to be beneficial

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Responsible Party: CNO
Holtz Children's Hospital

Reviewing Committee(s): JHS Clinical Policy and Procedure Committee
CNO Council
Medical Executive Committee (MEC)

Authorization: President and CEO, Jackson Health System



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ADDENDUM I:

Fasting/NPO Guidelines:

Definitions:

Clear Fluids: Water, Pedialyte, apple juice, CLEAR fruit juices **without** pulp, carbonated beverages, clear tea and black coffee

Solids: Includes formula.

Pre-Procedure Fasting Guidelines:

Age < 36 months:

1. Solids/milk formula until 6 hours before procedure
2. Clear fluids or breast milk until 4 hours before procedure
3. Infants < 1 year old: Parents are encouraged to offer a clear fluid up to 4 hours before procedure.

Age > 36 months:

1. Solids until 6 hours before procedure
2. Clear fluids until 4 hours before procedure

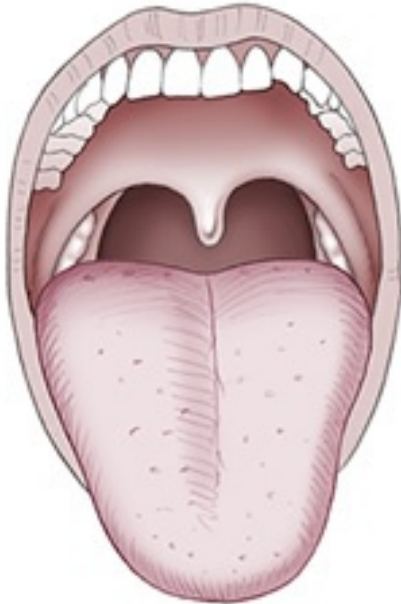
NPO Guidelines for Oral Contrast (Radiology):

1. Contrast amount determined by radiology based on weight)
2. $\frac{3}{4}$ of oral contrast will be given 2 hours prior to sedation
3. Remaining $\frac{1}{4}$ contrast will be given 30 minutes prior to scan concurrent with sedative agent

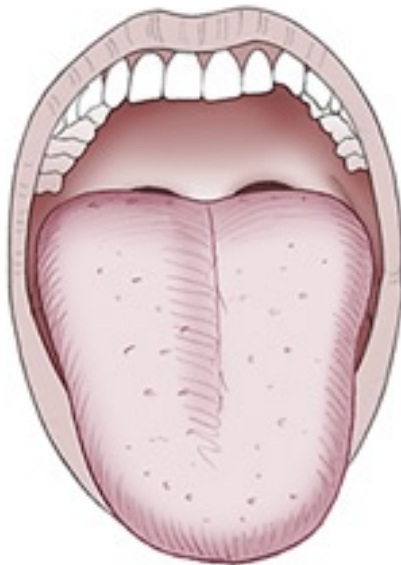


ADDENDUM II: Mallampati Score

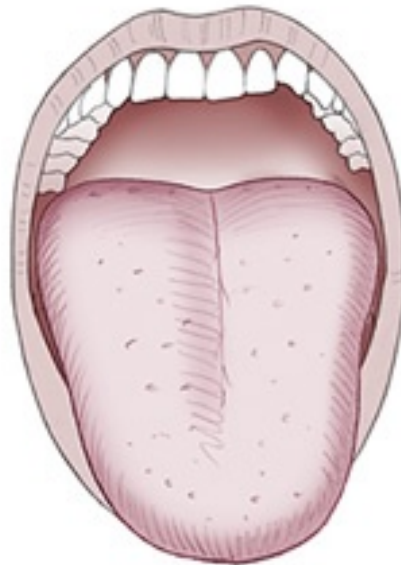
Class I



Class II



Class III



Class IV



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ADDENDUM III: ASA Physical Status Classification

- I. There is no organic, physiological, biochemical, or psychiatric disturbance (e.g., totally healthy).
- II. Mild to moderate systematic disturbance caused either by the condition to be treated or by other path physiological processes (e.g., asthma).
- III. Severe systematic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability (e.g., chronic renal failure).IV. Indicative of the patient with severe disorder already life-threatening, not always correctable by the operative procedure (e.g., uncompensated congestive heart failure, acute bronchospasm, etc.).
- IV. The moribund patient who has little chance of survival but is submitted to operation in desperation.

ADDENDUM IV: Post Anesthesia Recovery Score (Par Score)

The **PAR** score is a numerical scoring system, which assists in the documentation of easily observed signs of physical and physiological recovery from sedation/analgesia/anesthesia.

A **PAR** score must be documented pre-procedure, post-procedure and on discharge.

Parameter	Points	Definition of Point Score
Activity	2	Able to move all extremities voluntarily on command
	1	Able to move 2 or more extremities voluntarily or on command
	0	Able to move 0 extremities voluntarily or on command
Respiration	2	Able to breathe deep and cough freely
	1	Dyspnea or limited breathing
	0	Apnea
Circulation	2	BP +/- 20% of pre-anesthetic level
	1	BP +/- 20 to 50% of pre-anesthetic level
	0	BP +/- 50% of pre-anesthetic level
Consciousness	2	Fully Awake
	1	Patient arouses on calling
	0	Not responsive
Color	2	Pink
	1	Pale/Dusky/Blotchy/Jaundice/Other
	0	Cyanotic

Total PAR Score:



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ADDENDUM V: Recommended medications for pediatric sedation-analgesia**Table 1 - Opiate/narcotic sedative/analgesics for pediatric procedural sedation:**

Drug	Contraindications/Cautions	Dosage	Onset	Duration
Morphine	-Hypersensitivity to morphine or any component. -Increased intracranial pressure; severe liver or renal insufficiency, acute or severe asthma -Some preparations contain sulfites which may cause allergic reactions -Infants < 3 months of age are more susceptible to respiratory depression, use reduced doses	IV: 0.05 – 0.1 mg/kg/dose (max:10mg/dose) may repeat in 5 minutes x1 if needed Administer 5 minutes before procedure Administer IV over at least 5 minutes (Rapid IV administration may lead to Hypotension, bradycardia) IM: 0.05 – 0.1 mg/kg/dose (max:10mg/dose) Administered 0.5-1 hour before procedure	IV: Onset: 3 – 5 min Peak: 10 -15min IM: Onset: 15– 30 min Peak: 30 – 60 min	IV/ IM: 3 – 5 hrs
Hydromorphone (Dilaudid) 1.5 mg = 10 mg Morphine	-Hypersensitivity to Hydromorphone or any component -Increased intracranial pressure; severe liver or renal insufficiency, acute or severe asthma -Some preparations contain sulfites which may cause allergic reactions -Should not be combined with MAO inhibitors, Ritonavir or other protease inhibitors used presently or in the past 14 days -Renal impairment: excitability due to elevated metabolite Liver impairment: accumulation	IV/SC: 0.01-0.015 mg/kg/dose (max: 0.2 mg/dose for patients less than 50 kg, 4 mg for others) Give slowly over 2-3 minutes, may repeat in 5 minutes x3 if needed C.I.= 0.003-0.005 mg/kg/hr (max: 0.2mg/hr) PO/SL: 0.03-0.08 mg/kg/dose	IV: Onset: 3 - 5 min Peak: 10-20 min PO: Onset: 15-30 min Peak: 30-90 min	IV/PO: 4-5 hrs T1/2: 1-3 hours
Fentanyl 75 – 100 times more potent than morphine	-Hypersensitivity to Fentanyl or any component. -Increased intracranial pressure; severe liver or renal insufficiency -Rapid IV infusion may cause skeletal muscle & chest wall rigidity, impaired ventilation, respiratory distress, apnea, bronchoconstriction, laryngospasm. Non-depolarizing skeletal muscle relaxant may be required	IV: 0.25 – 1 mcg/kg/dose (adult dose typically 50mcg/dose) over 3 to 5 minutes, may repeat in 5 minutes x1 if needed (max total dose: 2 mcg/kg or 100mcg)	IV: Onset 1 – 3 minutes Peak: 3 – 5 minutes	IV: 30 – 60 minutes



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Table 2 - Sedative Hypnotics for Pediatric Procedural Sedation:

Drug	Contraindications/Cautions	Dosage	Onset	Duration
Midazolam (Versed®)	<p>-For the syrup: allergies to cherries</p> <p>-Contraindicated in patients with acute narrow-angle glaucoma.</p> <p>-Inhibitors of the CYP 3A4 Enzymes (i.e., erythromycin, protease inhibitors, Cimetidine) expected to produce intense and prolonged sedation & respiratory depression secondary to reduced clearance. Refer to D-D Interaction section</p> <p>-Hepatic dysfunction (prolongs effects)</p> <p>Excessive, rapid, or single large IV injections may result in respiratory depression and/or arrest.</p> <p>-Neonates: Administration of rapid intravenous Midazolam in neonates (< 2 minutes) has been associated with severe hypotension & seizures especially when co-administered with Fentanyl.</p>	<p>Oral: 0.25 – 1 mg/kg/dose maximum: 20 mg/dose</p> <p>Rectal: 0.5 – 1 mg/kg/dose maximum: 20 mg/dose</p> <p>IM: 0.05 – 0.15 mg/kg/dose, maximum: 10 mg/dose</p> <p>IV: 0.025 – 0.1 mg/kg/dose by slow IV push, maximum: 10 mg/dose over 2 min</p>	<p>Oral:</p> <p><i>Onset:</i> 10 – 20 min</p> <p><i>Peak:</i> 10–30min</p> <p>Rectal:</p> <p><i>Peak:</i> 10 – 20 min</p> <p>IM:</p> <p><i>Onset:</i> 5 – 15 min,</p> <p><i>Peak:</i> 15 – 60 min</p> <p>IV:</p> <p><i>Onset:</i> 1 – 5 min</p> <p><i>Peak:</i> 3-5 min</p>	<p>Oral:</p> <p>30 – 45 min</p> <p>Rectal:</p> <p>60 min</p> <p>IM:</p> <p>2 hours</p> <p>IV: 20 – 60 min</p>
Lorazepam (Ativan®)	<p>-Hypersensitivity to benzodiazepines or any ingredients in the formulation (e.g., polyethylene glycol, propylene glycol, or benzyl alcohol)</p> <p>-Excessive, rapid, or single large IV injections may result in respiratory depression and/or cardiac arrest.</p> <p>-Contraindicated in patients with acute narrow-angle glaucoma.</p> <p>-Not recommended in severe hepatic dysfunction and/or renal failure (prolonged effects); in mild/moderate hepatic or renal disease use lowest dose possible</p> <p>-Neonates: Lorazepam for injection contains benzyl alcohol 2%, polyethylene glycol and propylene glycol which may be toxic to newborns in high doses, causing neurotoxicity and myoclonus.</p>	<p>Neonates:</p> <p>Oral: 0.05 mg/kg administered 2 hours before procedure;</p> <p>IV: 0.05 mg/kg administered 15-20 minutes before procedure by slow IV push</p> <p>Pediatric/Adults: oral solution should be diluted in fluids (e.g., water, juices, soda) or in semi-solid foods (e.g., applesauce, pudding) just before administration to decrease GI side effects</p> <p>Oral: 0.05 mg/kg/dose administered 2 hours before procedure by slow IV push; maximum: 4 mg</p> <p>IM: 0.05 mg/kg/dose administered 2 hours before procedure; maximum: 4 mg</p> <p>IV: 0.05 mg/kg/dose administered 15-20minutes before procedure; maximum: 2 mg (Do not exceed 2 mg/min or 0.05 mg/kg over 2 – 5 minutes)</p>	<p>Oral:</p> <p><i>Onset:</i> within 60 min</p> <p>IM: <i>Onset:</i> 30 – 60 min</p> <p>IV: <i>Onset:</i> 1 - 5 min</p>	<p>Oral, IV,IM:</p> <p>8 - 12 hours</p>
Diazepam (Valium®)	<p>-Known hypersensitivity to benzodiazepines or any ingredients in the formulation (i.e. propylene glycol or benzyl alcohol). The emulsified diazepam injection contains soybean oil and egg yolk phospholipids.</p> <p>-Excessive, rapid, or single large IV injections may result in respiratory depression and/or arrest.</p>	<p>Oral: 0.2 – 0.3 mg/kg (maximum 10mg/dose) 45-60 minutes prior to procedure, Administer tablets with food or water.</p> <p>Rectal: 0.5mg/kg/dose then 0.25 mg/kg/dose in 10 minutes if needed (doses for seizures). Can use undiluted 5mg/mL conventional injectable formulation rectally</p>	<p>Oral:</p> <p><i>Onset:</i> 30 min,</p> <p><i>Peak:</i> 60 min</p> <p>Rectal:</p> <p><i>Onset:</i> 2 - 10 min</p> <p>IV: <i>Onset:</i> 1 – 3 min</p>	<p>2 – 6 hours</p>



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	<p>-Inject diazepam into a large vein to avoid thrombosis; small veins such as those of the wrist or the dorsum of the hand should not be used.</p> <p>-Benzodiazepines are contraindicated in patients with acute narrow-angle glaucoma.</p> <p>-Inhibitors of the CYP 3A4 Enzymes (i.e., erythromycin, protease inhibitors, Cimetidine) expected to produce intense and prolonged sedation & respiratory depression secondary to reduced clearance. Refer to D-D Interaction section</p> <p>-Not recommended in severe hepatic dysfunction and/or renal failure (prolonged effects); in mild/moderate hepatic or renal disease use lowest dose possible</p> <p>-Neonates: diazepam injection contains benzyl alcohol, and propylene glycol which may be toxic to newborns in high doses. Benzyl alcohol may also displace bilirubin from protein binding sites.</p>	<p>IV: 0.04 – 0.3 mg/kg/dose (max: 5mg/dose)</p> <p>To avoid precipitation, Diazepam injection should not be mixed with other drugs or IV fluids.</p> <p>Injection: administer slowly, not to exceed 5mg/min in adults or 0.05mg/kg over 3 minutes in children.</p> <p>Intramuscular: not recommended</p>		
<p>Pentobarbital (Nembutal) CII</p>	<p>-Marked liver function impairment or latent porphyria; hypersensitivity to barbiturates or any component.</p> <p>-Use with caution in patients with hypovolemic shock, congestive heart failure, or hepatic impairment.</p> <p>- Available injection formulations contain propylene glycol</p>	<p>IV: 2mg/kg/dose (max: 100mg/dose) over 10 – 30 minutes, may repeat 1 – 2 mg/kg/dose x1 in 5 –10 minutes if needed (max total dose 6 mg/kg or 200mg)</p> <p>-Excessive, rapid, or single large IV injections may result in respiratory depression and/or cardiac arrest.</p> <p>-Parenteral solutions are very alkaline; avoid extravasation or intra-arterial injection</p>	<p>IV: <i>Onset:</i> within 1min <i>Peak:</i> 5- 10 min</p>	<p>IV: 15 min</p>



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Antidote for Opiate Overdose Naloxone (Narcan®):

Drug	Contraindications/Cautions	Dosage	Onset	Duration
Naloxone (Narcan®)	<p>-Hypersensitivity to Naloxone or any component (methyl and propylparabens)</p> <p>-May precipitate withdrawal symptoms (hypertension, sweating, agitation, irritability,) in patients with physical dependence to opiates (including newborns of narcotic dependence)</p> <p>-Use with caution in patients with chronic cardiac or pulmonary disease or coronary artery disease.</p> <p>-Naloxone use following surgery may reverse analgesia and increase blood pressure</p>	<p>IV (preferred route), ET (preferred if IV route not available), IM, SC Note: IM or SC administration in patients with hypo perfusion may result in erratic or delayed absorption</p> <p>Reversal of minor respiratory depression: Infants, children: 0.001 – 0.002 mg/kg/dose (titrate to effect, repeat every 2 – 3 minutes) Adults: 0.1 – 0.2 mg slow and titrate to response</p> <p>Reversal of severe respiratory depression: Premature infants, infants, children, adults: 0.1 mg/kg IV (maximum: 2mg/dose); if no response repeat every 2-3 minutes; Administration: IV: Administer over 30 seconds Endotracheal: dilute to 1-2 mL with NS</p>	<p>Intravenous: within 2 minutes</p> <p>Intramuscular, ET, SC: within 2-5 minutes</p>	<p>20–60 minutes (less than duration of most opiates, may need to repeat dose every 20-60 minutes)</p>

Antidote for Benzodiazepine Overdose:

Flumazenil (Romazicon®)

1. Flumazenil **should not** be used **routinely** to reverse sedation
2. Flumazenil is an adjunct to, not a substitute for, appropriate supportive and symptomatic measures in the management of benzodiazepine overdosage.
3. Flumazenil does not effectively reverse hypoventilation.
4. Patients should have a secure airway and established IV access prior to administration of the drug.

Monitoring Parameters:

Monitor for level of consciousness & re-sedation for 2 hours after reversal of sedation in patients with benzodiazepine sedation. Re-sedation may especially occur in patients on long-acting benzodiazepines (such as diazepam). Blood pressure, heart rate, respiratory rate, continuous pulse oximetry

Drug	Contraindications/Cautions	Dosage	Onset	Duration
Flumazenil (Romazicon®)	<p>-Hypersensitivity to Flumazenil, benzodiazepines</p> <p>-In patients given benzodiazepines for control of potentially life-threatening conditions (e.g., control of intracranial pressure or status epilepticus), Flumazenil may induce seizures or changes in cerebral blood flow.</p> <p>-Patients with signs of serious cyclic antidepressant overdose.</p> <p>-Mixed drug overdose patients who have ingested</p>	<p>Children: 0.01mg/kg (max dose: 0.2mg) IV, then 0.005-0.01 mg/kg (max dose: 0.2 mg) every minute to a maximum cumulative dose of 1 mg or 0.05mg/kg whichever is less</p> <p>Adults: 0.2 mg IV given over 15 seconds</p> <p>-Titrate to effect, if after 45 seconds, additional 0.2 mg doses may be administered (max cumulative dose of 1 mg during an initial 5 minute dosing period).</p> <p>-If re-sedation occurs, the</p>	<p>Onset of benzodiazepine reversal: within 1 – 3 min</p> <p>Peak: 6 - 10 min</p>	<p>usually < 1 hour (less than duration of most benzodiazepines, may need to repeat dose)</p>

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	<p>drugs that increase the likelihood of seizures (e.g., Cocaine, lithium, cyclosporine, cyclophosphamide, antidepressants, Bupropion, methylxanthines, MAO inhibitors, isoniazid or propoxyphene) -May precipitate dose-dependent manifestations of withdrawal (e.g., seizures) in patients with established benzodiazepines physical dependence.</p>	<p>initial dosing regimen may be repeated every 20 minutes (max 3 mg in any 1 hour) -In clinical situations where re-sedation is not yet apparent but must be prevented, the initial dosing regimen can be repeated at 30 – 60 min. Administration: Rapid IV injection (over 15 – 30 seconds) through a free flowing IV into a large vein (to decrease pain and phlebitis). Because of the risk of local irritation, the drug is recommended for IV use only and extravasation should be avoided.</p>		
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