Supportive Data:

Many hospitalized children undergo painful or frightening invasive procedures. Procedures range from simple venipunctures and insertion of intravenous catheters to more stressful procedures such as lumbar punctures, bone marrow aspirates and biopsies, chest tube insertions, circumcisions, catheterizations and dressing changes. Children often describe such procedures as the most distressing aspect of disease or hospitalization. Therefore, aggressive efforts to decrease pain and distress are warranted.

Sedation/analgesia allows pediatric patients to tolerate unpleasant procedures by relieving anxiety, discomfort and/or pain associated with therapeutic, diagnostic, invasive and/or non-invasive procedures. Sedation/analgesia may also be utilized to perform procedures that are not particularly uncomfortable, but require that the patient be kept still during the procedure.

A collaborative effort by the American Academy of Pediatrics (AAP), American Society of Anesthesiologists (ASA), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has produced comprehensive standards for safe sedation practices. The new guidelines stress the level or score referring to the patient’s level of sedation is independent of drug choice, route of administration, or the intended level of consciousness. Rather, patient’s are to be sedated and then continuously evaluated with respect to their actual (not intended) level of consciousness, presence or absence of protective reflexes, and response to painful stimuli.

Purpose:

To delineate hospital-wide guidelines for the administration of moderate/procedural sedation to the pediatric patient by Resident Physicians privileged through the Department of Pediatrics and Non-Anesthesiologist Licensed Independent Practitioners in order to provide their patients the benefits of sedation/analgesia during procedures while minimizing the associated risks. This policy will provide guidelines for the appropriate pre-procedure, intra-procedure and post-procedure assessment and monitoring of the patient undergoing moderate/procedural sedation.

Important Note: It is NOT the medication, dose of medication, or route of administration that determines the application of this policy. The level of sedation achieved and/or intended for the procedure solely drives application of this policy to a given patient situation!
Policy Statement:
These guidelines apply to sedation/analgesia administered by ANY ROUTE. Evaluation of Mallampati airway classification and ASA classification are the ultimate responsibility of the sedating physician.

Policy Exclusions: Guidelines in this policy DO NOT APPLY to the following situations:

- Patients who are NOT undergoing a diagnostic or therapeutic procedure
- Patients receiving medications for control of seizures
- Patients receiving medications for the therapeutic management of pain
- Sedation/analgesia of mechanically ventilated patients *** (see special note for monitoring criteria)
- Patients receiving medications for physiologic emergencies
- Rapid sequence intubation

Locations Moderate/Procedural Sedation for Pediatrics may be Administered

- The Children’s Hospital Treatment/Procedure Room
- Children’s Hospital Outpatient Procedure Services (CHOPS)
- Pediatric Intensive Care Unit (PICU)
- Pediatric Intermediate Care Unit (PIMCU)
- Intensive Care Nursery (ICN)
- Radiology, to include MRI
- Emergency Center
- Center for Ambulatory Services – Operating Room Only

Definitions:

1. **Minimal Sedation** (anxiolysis/analgesia) ~ a drug-induced state during which patients responds normally to all physical and verbal stimulation. There is no to minimal loss of ventilatory responsiveness. The patient is attentive to environmental stimuli with no to minimal change in orientation to person and place. There may be minimal to mild alteration in gross motor function. **Minimal sedation correlates with a score of 2 on the University Hospitals of Cleveland Sedation Scale.**

2. **Moderate Sedation** ~ 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 airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. **Moderate sedation correlates with a score of 3 on the University Hospitals of Cleveland Sedation Scale.**

3. **Deep Sedation** ~ is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. 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. Cardiovascular function is usually maintained. **Deep sedation correlates with a score of 4 on the University Hospitals of Cleveland Sedation Scale.**

4. **General Anesthesia** ~ Exists when a patient is unarousable even with painful stimulus and the ability to independently maintain ventilatory and cardiovascular function may be impaired. Patients require assistance in maintaining an adequate airway. Only anesthesiologists or CRNA’s are privileged to administer planned general anesthesia care.

5. **Pediatric Patient** ~ Patients 16 years of age or younger or those patients, up to age 21, who receive their primary or specialty care from a pediatric care provider.
QUALIFICATIONS/INITIAL COMPETENCIES

1. **Registered Nurse**

   The registered nurse responsible for the monitoring of the patient during the procedure will be **PALS** certified. In addition, they will have demonstrated understanding of the pharmacological agents administered for moderate sedation as well as the antagonists for opioids and benzodiazepines with a passing score on both the MCCG Moderate Sedation training module and the Pediatric Specific education module. A certificate of completion will serve as verification of successful completion of educational requirement. **This will be an annual competency requirement in high risk/low volume areas or at the discretion of the area director.**

2. **Physician Staff**

   The practitioners responsible for administering procedural sedation/analgesia for pediatric procedures shall be trained and have the appropriate credentials to manage these pediatric patients. **Credentialing for the administration of pediatric sedation/analgesia is granted through the MCCG Credentials Committee, MEC and the MCCG Board.** Refer to MCCG Privilege Delineation Criteria for Pediatric Moderate Sedation.

3. **Resident Staff**

   Resident physicians from the two MCCG teaching services that may be privileged to provide procedural sedation/analgesia to pediatric patients are Pediatric Residents and Surgery Residents. **Specifically:**
   - **Pediatric Residents** ~ P.L. 2 & P.L. 3 ONLY
   - **Surgery Residents** ~ P.G. 4 & P.G. 5 ONLY

   *The Residency Program in the Department of Pediatrics grants privileging ONLY after the following criteria are met:*

   1. **Current Pediatric Advanced Life Support (PALS) Certification: AND Completion of:**
      - Two week pediatric sedation rotation
      - Completion of pediatric sedation course provider training manual

Pre-Procedure Patient Evaluation, Documentation & Preparation

*Please Note*: The literature supports the use of supplemental oxygen during moderate sedation to reduce the frequency of hypoxemia. There is agreement that supplemental oxygen decreases patient risk during moderate sedation. Supplemental oxygen should be considered for moderate sedation, unless contraindicated by patient diagnosis/condition.

**Normothermic** is best defined as a core temperature range between 36.5° C and 37.5° C (97.7° F – 99.5° F). Hypothermia prolongs drug action by decreasing metabolism, causes protein wasting, impairs platelet and clotting-cascade enzyme function, and triggers shivering and thermal discomfort. **More importantly, core temperatures only 1- 2° C below normal are associated with adverse patient outcomes.**

Clinical Practice Guidelines developed by the American Society of Peri-Anesthesia Nurses recommends the following interventions:

**Institute preventive warming measures for patients who are normothermic**: 36.5° C - 37.5° C [97.7° F – 99.5° F]. A variety of measures may be used, unless contraindicated. Passive insulation may include warmed cotton blankets, limited skin exposure, circulating water mattresses and increase in ambient (room) temperature to 20° C – 23.8° C [minimum 68° F - 75° F].

**Institute active warming measures for patients who are hypothermic**: 35.3° C [95.9° F or below]. Active warming is the application of a forced air convection warming system (i.e. Bair Huggar).
Pre-Procedural Patient Evaluation, Documentation & Preparation (continued)

1. Physician, Advanced Practice Registered Nurse (APRN), or Physicians Assistant (PA), utilizing Children's Hospital Pediatric Procedural Sedation/Analgesia documentation form E6001 (Pediatric Sedation/Analgesia Documentation), will perform baseline history and physical examination prior to beginning the procedure. This includes, but is not limited to the following:
   - Systems assessment and any abnormalities of major organ systems
   - Current medications and any drug allergies
   - History of any medication reactions
   - Any previous reaction/problems with sedation/analgesia, local anesthesia, regional anesthesia or general anesthesia
   - Review any relevant diagnostic tests
   - Assignment of an ASA classification (addendum A)
   - Evaluation of patient’s airway (Addendum B)
   - Obtain fasting history

Fasting Recommendations to Reduce the Risk of Pulmonary Aspiration

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>2 hours</td>
</tr>
<tr>
<td>Breast milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 hours</td>
</tr>
<tr>
<td>Non-human milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 hours</td>
</tr>
</tbody>
</table>

These recommendations apply to healthy patients who are undergoing elective procedures. Following the guidelines does not guarantee complete gastric emptying has occurred.

* The fasting periods apply to all ages

◆ Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea

♫ Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period

✓ A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

** For emergency procedures, when fasting has not been confirmed, the increased risks of sedation should be weighed against the benefits. In these cases, protection of the airway prior to sedation may be required.

2. Documentation on Sedation/Analgesia Record (E6001) will include the following:
   - MD signature, date and time indicating patient has been evaluated immediately prior to sedation
   - Assignment of an ASA classification
   - Evaluation of the patient’s airway

Note: Department of Anesthesia or a Pediatric Intensivist should be consulted for patients when the MD procedure feels there may be problems with sedation. Emergency conditions sometimes mandate the initiation of a procedure prior to being able to obtain a consult on such patients.
3. Informed consent
   - Risks, benefits and possible alternatives to the procedure will be discussed with the patient and/or family (if procedure not emergently necessary) by the physician and appropriate consent form signed.
   - Risks, benefits and possible alternatives of sedation will be discussed with the patient and/or family (if procedure not emergently necessary). Patient and/or family should receive a copy of the Pediatric Sedation Teaching Record - form G7287.

4. Formulate a plan for procedural/moderate sedation

**Nursing Responsibilities**

1. Facilitate/assure consent form is signed prior to start of procedure
2. Facilitate/assure pre-sedation history/physical is complete prior to start of procedure
3. Baseline patient assessment to include: temperature, blood pressure, heart rate, respiratory rate, oxygen saturation, level of consciousness as defined by University Hospitals of Cleveland Sedation Scale
4. Assure patent intravenous access
5. For sedatives administered by routes other than intravenous ~ the sedating MD will determine need for IV access on a case by case basis

**Equipment**

Pediatric emergency resuscitative equipment is immediately accessible to every location where procedural/moderate sedation is administered and where patients are recovered, including but not limited to:

1. Code PALS cart
2. Defibrillator
3. Suction
4. Airway equipment, oxygen, appropriate size ambu bag & mask
5. ECG monitor
6. Reversal agents ~ Naloxone & Romazicon
7. Personnel skilled in establishment of IV access are immediately available
8. Personnel skilled in pediatric airway management are immediately available
9. Equipment to administer supplemental oxygen should be present when sedation/analgesia is administered

**Medications** (addendum C)

1. Physician selects and orders the medications and dosage(s). Medications approved for use in Pediatric Moderate/Procedural Sedation include but are not limited to the following:
2. Narcotics ~ for example: morphine, fentanyl
3. Benzodiazepines ~ for example: midazolam, lorazepam, diazepam
4. Use of medications classified as “anesthetic agents” (i.e. Ketamine, Sodium Pentothal, Dipvran) are prohibited for Pediatric Moderate/Procedural Sedation. Use of these medications requires special privileging.
**Medications** (addendum C)

5. The physician MUST be present for the administration of the sedating medication(s) and for assistance regarding any untoward effect of the medication(s)

6. Intravenous sedative/analgesic drugs should be **administered in small, incremental doses** that are titrated to the desired endpoints of analgesia and sedation. *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 non-intravenous routes, (i.e. oral, rectal, intramuscular) allowance should be made for the time required for drug absorption before supplementation is considered.

7. Combinations of sedative and analgesic agents should be administered as appropriate to the procedure being performed and the condition of the patient. **Ideally**, each medication should be administered individually to achieve the desired effect (i.e. 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.**

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**Intra-Procedure Monitoring, Management and Documentation**

*Special Note*: Patients who receive **Minimal sedation (anxiolysis/analgesia) prior to a procedure** will be assessed by the RN following the administration of the anxiolytic/analgesic to ensure that the patient continues to respond normally to verbal commands. **If, at any time, level of consciousness becomes diminished, RN will follow documentation and monitoring criteria for moderate sedation!**

1. The minimum number of personnel available during pediatric procedural/moderate sedation shall be two - the physician performing the procedure and the physician or PALS Certified Registered Nurse administering the medications and monitoring the patient.

2. The PALS Certified Registered Nurse monitoring the care of the patient receiving sedation shall have no other responsibility that would leave the patient unattended or compromise continuous monitoring. **Monitoring of the patient is to be continuous throughout the procedure.**

3. Pediatric CODE SHEET should be visible during procedural/moderate sedation - where applicable

4. **Emergency equipment/medications will be immediately available**

5. If sedative/analgesics will be administered intravenously, maintain IV access. For sedatives administered by routes other than intravenous, ~ the sedating MD will determine the need for IV access on a case-by-case basis

6. **Continuous monitoring of oxygen saturation via pulse oximetry, heart rate and rhythm throughout the procedure**

7. Heart rate, respiratory rate, oxygen saturation, blood pressure and level of consciousness as defined by University Hospitals of Cleveland Sedation Scale will be monitored and documented a MINIMUM of every 5 minutes during the procedure and more often if the patient condition warrants.

   - **Special Note** - at the discretion of the physician ordering sedation, vital signs for pediatric CT or MRI patients may be monitored as: oxygen saturation, BP, and heart rate every 5 minutes

8. Document all medications administered including dose, route, and time of administration

9. Document type and amount of all IV fluids administered

10. Document any unusual events during the procedure

11. Document the use of supplemental oxygen

12. Document status of the patient at the conclusion of the procedure/ sedation

13. **At the completion of the procedure** ~ record HR, RR, B/P, temperature, oxygen saturation and LOC
Post Procedure (Post-Sedation) Monitoring, Management and Documentation

1. The patient’s condition shall be evaluated continually for a **MINIMUM of 60 minutes** after the last dose of sedation medication is administered.

2. A Registered Nurse or an individual trained in recognition of post procedure/post sedation complications monitors the patient until discharge criteria is satisfied. **Discharge criteria include, but are not limited to:**
   - Vital signs return to pre-sedation status
   - Level of consciousness returns to pre-sedation status
   - Patient is able to tolerate p.o. fluids when appropriate
   - Ambulate consistent with development
   - Head control consistent with development

3. **Particular attention is given to monitoring oxygenation, ventilation, circulation, and temperature**
   - During recovery from procedural sedation, oxygen saturation shall be continuously monitored by pulse oximetry.
   - Vital signs will be monitored and recorded at the beginning of the recovery period and at least every 15 minutes, until return to baseline. **Vital signs include:** heart rate, respiratory rate, blood pressure. **Documentation should also include:** LOC, color, airway and respiratory effort.
   - Temperature should be documented at the beginning of the recovery period and prior to discharge.

4. The responsible physician is notified of **significant variations** in vital signs, oxygen saturation and/or sedation level.

5. Maintain IV access until the patient meets discharge criteria.

6. **If reversal agents are used,** the patient will be observed for re-sedation effects for a **minimum of 2 hours** or a length of time based on half-life of medications used (whichever is greater).

7. Discharge instructions, when applicable, should include the following information:
   - emergency contact phone#
   - when to call
   - medications received

8. Prior to discharge from the sedation area, the physician who performed the sedation will complete the **Pediatric Post-Sedation Procedure Note.**

**Special Note: Monitoring of Ventilated Patients**

Ventilated patients are monitored continuously. With the understanding that sedation can cause physiologic changes, those ventilated patients, who require additional sedation/analgesia for procedures, will have the following documentation in the medical record:

1. **Heart rate, respiratory rate, blood pressure, oxygen saturation every 5 minutes during the procedure.**
2. **Heart rate, respiratory rate, blood pressure, and oxygen saturation every 15 minutes at the end of the procedure until the vitals return to pre-sedation baseline.**
References:


Addendum A ~ ASA Classification

The ASA Physical Status Classification System

P1    A normal healthy patient

P2    A patient with mild systemic disease

P3    A patient with severe systemic disease

P4    A patient with severe systemic disease that is a constant threat to life

P5    A moribund patient who is not expected to survive without the operation

P6    A declared brain-dead patient whose organs are being removed for donor purposes
Addendum B ~ Mallampati Airway Classification

Mouth:  □ OK  □ Small

Neck:  □ Free ROM  □ Decreased ROM

Indicate airway evaluation below:

Class I:  The soft palate, fauces, uvula and anterior and posterior tonsillar pillars can be seen.

Class 2:  All of the above (class 1) features can be seen except the tonsillar pillars, which are hidden by the tongue.

Class 3:  Just the base of the uvula is visible.

Class 4:  Not even the uvula can be visualized.

**NOTE:** Anesthesiology Department will be consulted for patients when the MD procedurist feels there may be problems with sedation. Emergency conditions sometimes mandate the initiation of a procedure prior to being able to obtain an anesthesiology consultation on such patients. If a patient presents with an unstable physiologic condition and/or a difficult airway, an anesthesiology consult should be considered.
## ADDENDUM C

Guidelines for Moderate/Procedural Sedation for Pediatric Procedures

### INTRAVENOUS GUIDELINES

<table>
<thead>
<tr>
<th>Classification: Opioid Analgesics</th>
<th>Reversal Agent: Naloxone (Narcan)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug</strong></td>
<td><strong>Onset/Duration</strong></td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>Onset: 3 – 10 minutes</td>
</tr>
<tr>
<td></td>
<td>Duration: 1 – 2 hours</td>
</tr>
<tr>
<td>Meperidine (Demerol)</td>
<td>Onset: 5 – 10 minutes</td>
</tr>
<tr>
<td></td>
<td>Duration: 1 – 3 hours</td>
</tr>
<tr>
<td>Fentanyl (Sublimaze)</td>
<td>Onset: 20 – 90 seconds</td>
</tr>
<tr>
<td></td>
<td>Duration: 30 – 60 min.</td>
</tr>
</tbody>
</table>

### ORAL GUIDELINES

<table>
<thead>
<tr>
<th>Classification: Opioid Analgesics</th>
<th>Reversal Agent: Naloxone (Narcan)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug</strong></td>
<td><strong>Onset/Duration</strong></td>
</tr>
<tr>
<td>Meperidine (Demerol)</td>
<td>Onset analgesic effect: within 10 – 15 minutes</td>
</tr>
<tr>
<td></td>
<td>Peak analgesic effect:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### REVERSAL AGENT FOR OPIOID ANALGESICS

<table>
<thead>
<tr>
<th>Naloxone (Narcan)</th>
<th>Dose: 0.001 – 0.01 mg/kg</th>
<th>Onset: 1 – 2 minutes</th>
<th>* Continue to monitor respiratory rate, heart rate and blood pressure until half-life of narcotic is gone ~ may have rebound effect.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Give slow IV push at 2 – 3 minute intervals to desired response</td>
<td>Duration: 20 – 60 minutes</td>
<td></td>
</tr>
</tbody>
</table>
ADDENDUM C

Guidelines for Moderate/Procedural Sedation for Pediatric Procedures

INTRAVENTOUS GUIDELINES

Classification: Benzodiazepines  Reversal Agent: Flumazenil (Romazicon)

(NOT ANALGESICS!)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Onset/Duration</th>
<th>Potential Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>Onset: 1 – 4 minutes  Duration: 1 – 4 hours</td>
<td>Monitoring parameters: respiratory rate, heart rate and blood pressure  * May cause paradoxical excitement!</td>
</tr>
<tr>
<td>(Valium)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midazolam</td>
<td>Onset: 1 – 5 minutes with peak at 10 minutes  Duration: 1 – 2 hours</td>
<td>Monitoring parameters: respiratory rate, heart rate and blood pressure  * May cause profound respiratory depression when combined with narcotics!  Retrograde amnesia.</td>
</tr>
<tr>
<td>(Versed)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Onset: 2 – 4 minutes for sedation – approx. 20 min. for amnesia  Duration: 2 – 6 hours</td>
<td>Monitoring parameters: respiratory rate, heart rate and blood pressure.</td>
</tr>
<tr>
<td>(Ativan)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REVERSAL AGENT FOR BENZODIAZEPINES

Although the manufacturer does not recommend the use of Flumazenil (Romazicon) in Pediatrics, the AphA Drug Information Handbook (4th Edition 1996 – 97) lists the following recommendations for the use of Flumazenil with the caution that further studies are needed.

| Flumazenil (Romazicon) | Dose: 0.01 mg/kg over 15 seconds  Maximum dose: 0.2 mg  Repeat doses 0.005 – 0.01 mg/kg at 1 minute intervals. Administer IV through a freely running IV infusion into a large vein to minimize pain at the injection site. | Onset: 1 – 2 minutes  Duration: 45 - 90 minutes | * Continue to monitor respiratory rate, heart rate and blood pressure  Monitor for return of sedation, respiratory depression. |
ADDENDUM C

Guidelines for Moderate/Procedural Sedation for Pediatric Procedures

Classification: Sedative Hypnotic

Reversal Agent: None

(NOT ANALGESICS!)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Onset/Duration</th>
<th>Potential Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlornal Hydrate Oral Dose</td>
<td>Onset: Peak effect within 30 min. – 1 hour</td>
<td>Monitoring parameters: vital signs, O2 saturation and blood pressure</td>
</tr>
<tr>
<td></td>
<td>Duration: 4 – 8 hours</td>
<td>* May cause paradoxical excitement!</td>
</tr>
</tbody>
</table>

* Please note: this is not recommended for routine pediatric procedures as there is not a reversal agent
University Hospitals of Cleveland Sedation Scale

1 = Awake

2 = Drowsy, anxiety free

3 = Sedated, but wakes to voice

4 = Sedated, arousable to pain

5 = Sedated, *not* arousable to pain

Moderate Sedation = Level 3

Deep Sedation = Level 4

For purposes of this policy, patients Level of Consciousness should not stay beyond Level 3