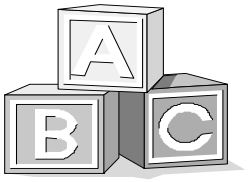

Parkland Health & Hospital System
Women & Infant Specialty Health

Nursery Services Procedure Manual

Moderate Sedation/Analgesia for Nursery Services

Practice Statement

Non-intubated infants who require sedation for invasive and non-invasive procedures shall be monitored by the Moderate Sedation/Analgesia Guidelines.

Non-intubated infants receiving on-going pain control (i.e., fentanyl drip) but require boluses from the drip to enhance the performance of the procedure or gain cooperation for the procedure shall be monitored following the Moderate Sedation/Analgesia Guidelines.

This procedure applies to:
- Any sedation administered by a practitioner/provider other than an Anesthesiologist or Certified Registered Nurse Anesthetist (CRNA).
- Sedation administered outside of the OR.

This procedure DOES NOT apply to:
- The administration of sedative drugs by members of the Anesthesia & Pain Management Department.
- Use of sedatives in Intensive Care areas on ventilator supported patients.
- Use of sedatives to facilitate emergency and life saving procedures.
- This procedure is not intended for patients in labor, for patients needing ongoing pain control, or for emergent conditions.

Providers responsible for prescribing moderate sedation medications must compete sedation training and maintain competency.

The RN managing the patient requiring moderate sedation must complete sedation training and maintain competency.

The RN assigned to administer and monitor patients receiving moderate sedation may not have any other clinical responsibilities.

The provider shall discuss the risks, benefits and alternatives of the procedure with the parent and obtain written consent for the procedure and a separate Anesthesia consent for the use of moderate sedation.

Prior to sedation, a sedation-privileged provider must:
- Review the patient's history and physical and document the plan for sedation.
- Examine patient immediately prior to the sedation

- Be immediately available throughout the sedation, entire procedure and recovery period.
- Assign an ASA score. Refer to Figure 1.
- Assign a Mallampati Class Score. Refer to Figure 2.

Prior to and following the administration of sedation the assigned RN shall perform a patient assessment including assignment of the Aldrete Score and document on the Moderate Sedation Flowsheet.

Sedation medications will be administered in the immediate area in which the procedure will be performed. A sedated patient will not be transported from the procedural area unless the patient is being transported to the ICU. The provider shall schedule the procedure with the charge nurse and the procedure shall be performed in an area/unit where staff is qualified to monitor according to the procedure. Deep sedation and anesthesia *(see definitions)* are restricted to use by Anesthesiologists and CRNAs.

Contraindications for moderate sedation include known hyper-sensitivity, untreated acute narrow-angle glaucoma, hemodynamic instability, abnormal airway, airway trauma and history of sleep apnea.

Only a qualified provider trained in professional standards and techniques to administer pharmacologic agents to predictably achieve desired levels of sedation and to monitor patients carefully in order to maintain them at the desired level of sedation, and who meets the criteria set by the Medical Staff may order drugs to cause moderate (conscious) sedation. *They may do so to only patients with a pre-procedure ASA score of I, II or III. Patients with an ASA score of IV or greater require an anesthesia consultation.*

The provider shall select and order the medication and will determine the maximum dosage and route of administration. The provider shall be present during the initial and continued administration of sedation. Drug dosages shall be recorded on the appropriate form with the patient's responses to each drug documented. An RN shall monitor the patient for potential adverse reactions to the medication(s) being administered. Adverse reactions shall be reported immediately to the provider.

There shall be a registered nurse or other qualified individual dedicated to patient monitoring during the procedure. The person responsible for monitoring the patient may not perform the procedure or have any other patient care responsibilities.

Each patient requiring moderate (conscious) sedation shall have an American Society of Anesthesiologists (ASA) score performed and documented by the primary provider and/or provider performing the invasive procedure.

ASA Physical Status Classification System

I	**A normal healthy patient**
II	**A patient with mild systemic disease**
III	**A patient with severe systemic disease**
IV	**A patient with severe systemic disease that is constant threat to life**
V	**A moribund patient who is not expected to survive without an operation.**

These definitions appear in each annual edition of the ASA Relative Value Guide.
American Society of Anesthesiologists, January 14, 2003

Pediatric Goals of Sedation

The goals of moderate sedation include:

- To provide safe and effective patient care management when moderate sedation is required for diagnostic and therapeutic procedures.
- To minimize physical discomfort and pain.
- To minimize negative psychological responses to treatment by providing analgesia.
- To control behavior.

Guidelines for Sedation

Sedatives are generally administered to the pediatric patient to gain the cooperation of the patient. Infants are particularly vulnerable to the adverse effects of sedatives on respiratory drive, patency of the airway, and protective reflexes. Regardless of the intended level of sedation or route of administration, the sedation of a patient represents a continuum, and may result in the loss of the patient's protective reflexes; a patient may move easily from a light level of sedation to obtundation. Because deep sedation may occur after administration of sedatives in any child, the credentialed provider must have the skills and equipment necessary to safety manage patients who are sedated.

The following principles shall be followed for the use of moderate sedation of children:

1. The patient must undergo a documented presedation medical evaluation, to include the assignment of the ASA patient classification score and a focused airway examination. The history should focus on identifying risk factors that increase the sensitivity to sedatives or analgesic medications, patients at risk of cardiopulmonary complication or difficulties in managing complications if they were to arise. The

physical examination should be thorough but the cardiac, respiratory and airway are emphasized.

2. There should be an appropriate interval of fasting before sedation if required.

3. Children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel.

4. Sedative and anxiolytic medications should only be administered by or in the presence of individuals skilled in airway management and cardiopulmonary resuscitation.

5. Age and size appropriate equipment and appropriate medications to sustain life should be checked before sedation and be immediately available.

6. All patients sedated for a procedure must be continuously monitored with a cardiac monitor and pulse oximetry.

7. An individual must be specifically assigned to monitor the patient's cardiorespiratory status during and after the procedure.

8. Specific discharge criteria must be used when discharging a patient home after the administration of sedation. Premature infants less than 50 weeks postconceptual age shall remain hospitalized on pulse oximetry with heart rate for 24 hours post procedure.

Definitions
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.

Moderate sedation/analgesia (conscious 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.

Deep sedation/analgesia
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. **This is restricted to use by Anesthesiologist and CRNA's.**

Parkland's Interpretation of the Joint Commission definition for Moderate Sedation:

A medically controlled drug induced depression of consciousness that:

1. Allows protective reflexes to be maintained;
2. Retains the patient's ability to maintain a patent airway independently and continuously;
3. Maintains regular, continuous and adequate spontaneous ventilation and cardiovascular function;
4. Permits the patient to have appropriate responses to light physical stimulation or verbal command.

Further clarification:

* Any administration by any route of sedatives, hypnotics or opiates or a combination of two (2) or more sedatives, hypnotics and/or opiate agents that is intended to induce sedation and/or muscle relaxation to facilitate the performance of a procedure is conscious sedation.
* The administration of a medication to relieve pain is NOT conscious sedation.
* Small dosages of a single oral anti-anxiety agent given to relieve anxiety prior to a procedure are NOT conscious sedation.

Qualifications:
Providers, Nurses and Qualified personnel shall meet and maintain the qualifications established. See credentialing criteria.

Equipment **Required at Bedside:**
Consent to Operation or Other Procedure form PS 3776
http://intranet.pmh.org/home/PP-Index/NICU/1100/1100.15A.pdf
Consent for Anesthesia and Sedation form PS 6450
http://intranet.pmh.org/home/PP-Index/NICU/1100/1100.15B.pdf
Provider Procedure Monitoring form PS 2380
http://intranet.pmh.org/home/PP-Index/NICU/1100/1100.15C.pdf
Moderate Sedation Monitoring form PS 5001
http://intranet.pmh.org/home/PP-Index/NICU/1100/1100.15D.pdf
Transport Consent for CMC Procedures form PS 7922
http://intranet.pmh.org/home/PP-Index/NICU/1100/1100.15D.pdf
Cardiac/Respiratory Monitor
Pulse oximeter
Blood Pressure Machine with appropriate cuff
Suction set-up
Oxygen set-up
Anesthesia Bag & Mask

Immediately Available:
Crash Cart with drugs and intubation equipment
Reversal Agents (Naloxone, Flumazenil)
Defibrillator

Required for Transport:

All of the above requirements
Portable Resuscitation Bag
CMC Sedation Assessment and Flowsheet Form
Refer to Nursery procedure 600.25 Preparing and Transporting Neonates to Speciality Procedures http://intranet.pmh.org/home/PP-Index/NICU/600/600.25.pdf

Procedure

A. Pre-Procedure

Provider Responsibilities for Procedures Performed at PHHS

1. A medical history shall be on the medical record indicating any significant medical problems or drug reactions.

2. Pre-procedural assessment including an airway exam and the assignment of an ASA score will be completed by the provider who may utilize the generic Provider Procedure Note form, or may utilize an approved department/unit procedure form. Refer to Administrative Procedure Appendix A Moderate Sedation for Airway Assessment http://intranet.pmh.org/home/PP-Index/Admin/admin6-16a.pdf

3. The provider shall evaluate patient's fluid intake. For scheduled procedures, place patient NPO according to procedural requirements for CMC Moderate Sedation Protocol:

   - For formula feed infants place NPO for 6 hours
   - For breastfeed infants place NPO for 4 hours
   - Oral intake of clear liquids may continue until 2 hours prior to the administration of sedation.

4. Discuss the procedure and the use of sedation with the parent /legal guardian. Obtain consent for the procedure and a separate consent "Consent for Anesthesia and Sedation" for the sedation. For procedures performed at Children's Medical Center the CMC provider will obtain consent for the use of sedation. The NNICU provider will obtain consent for the transport to CMC.

5. The sedation provider shall select and order the medication and be present during the initial and continued administration of sedation.

6. The provider shall perform a time-out with the responsible RN prior to the procedure.

Provider Responsibilities for Procedures Performed at CMC

1. Refer to Nursery procedure Preparing and Transporting Patients to Specialty Procedures http://intranet.pmh.org/home/PP-Index/NICU/600/600.25.pdf

2. Complete the first 6 sections of the CMC Sedation Assessment and Flowsheet Form (Source of Information, Chief Complaint, Medical History, Review of Systems, Physical Examination and Assessment) and document on form the patient is a candidate for sedation and place signature with date and time on the appropriate line.

3. Obtain consent for transport to CMC from parent/legal guardian. The CMC provider will obtain consent for the use of sedation.

RN Responsibilities

1. Identify patient per procedure 100.02 http://intranet.pmh.org/home/PP-Index/NICU/100/100.02.pdf

2. Verify if any pre-procedural orders are written.

3. Obtain a Moderate Sedation Monitoring Form for documentation.

4. Place patient on a cardio/respiratory monitor and a pulse oximeter.

5. Complete patient assessment and document on Moderate Sedation form to include:
   - Blood pressure
   - Heart rate
   - Respiratory rate
   - Oxygen saturation
   - Concentration of oxygen administered, if applicable
   - Level of consciousness/activity level

6. Start an IV if intravenous sedation is to be given. In some situations an IV may be unobtainable.

7. Have available an emergency cart/bag, resuscitation bag and mask, oxygen and suction throughout the procedure. Document on form.

8. Confirm that required provider documentation is present (ASA Score, Airway Examination, Consents for Procedure and Sedation).

9. Perform time-out with the provider and document on appropriate time-out form before sedation is administered.

10. Additional responsibilities for the transport RN for procedures preformed at CMC:

    - Complete page 2 section 1 of the CMC Sedation Assessment and Flowsheet Form, place signature with date and time on the appropriate line.
    - Perform a time-out with CMC LIP and document on the CMC flowsheet.
    - Document the administration of sedation on the CMC flowsheet.

- Obtain a copy of the CMC Sedation Record.

B. Intra-Procedure Monitoring

1. The nurse shall continuously monitor vital signs and oxygen saturation via a cardiac/respiratory monitor and a pulse oximeter.

2. Administer prescribed medication. Document the name, route, and site, time of administration, and dosage of all drugs administered on the MAR and Sedation Monitoring Form.

3. Record **every 5 minutes** on the Moderate Sedation Monitoring form:
   - Blood pressure
   - Heart rate
   - Respiratory rate
   - Oxygen saturation
   - Concentration of oxygen administered if applicable
   - Level of consciousness /activity level/sedation level

   Note: For infants transported to Speciality Procedures at CMC requiring moderate sedation the transport RN shall document on the CMC Sedation Assessment and Flowsheet.

C. Post-Procedure / Post Sedation

1. During the post-sedation monitoring period the nurse shall continuously monitor vital signs and oxygen saturation via the cardiac/respiratory monitor and pulse oximeter.

2. Record **every 15 minutes** until the patient reaches pre-procedure condition on the Moderate Sedation Monitoring form**:**
   - Blood pressure
   - Heart rate
   - Respiratory rate
   - Oxygen saturation
   - Concentration of oxygen administered if applicable
   - Level of consciousness /activity level/sedation level

   Note: For infants transported to Specialty Procedures at CMC requiring Moderate Sedation the transport RN shall document on the CMC flowsheet.

3. Significant variations in physiologic parameters shall be reported to the provider immediately. These include but are not limited too:

   * BP variation +/- 20 % of baseline
   * Heart Rate +/- 20% of baseline
   * O2 saturation < than 88% and infant requiring blow-by oxygen or a significant increase in the oxygen requirement from baseline.

- Dyspnea
- Apnea
- Inability to arouse patient
- Need to maintain airway mechanically
- Required reversal agents
- Other unexpected patient responses

3. Notify the provider if vital signs and level of consciousness do not return to baseline by one hour post-procedure.

4. Once the patient has achieved pre-sedation vital signs and level of consciousness, documentation shall be recorded per level of care on the nursing flowsheet. ICN and ACN patients will continue to be monitored via cardiorespiratory monitoring and pulse oximetry as part of their established level of care.

4. Premature infants (defined as < 37 weeks gestational age at birth) and currently < 50 weeks post-conceptual age in NBN and CCN shall remain hospitalized on a cardiac/respiratory monitor and pulse oximeter until the day after sedation.

5. Post procedure monitoring may be discontinued after 4 hours on term newborns and premature infants greater than 50 weeks post-conceptual age if no apnea, bradycardia, or desaturations occurred. The infant shall remain in the hospital until the day after sedation.

9. The RN shall document a discharge assessment in the patient's medical record acknowledging that discharge criteria have been met.

10. Provide discharge instructions to the parent/legal guardian and a 24 hour contact phone number for reporting problems.

Quality Monitoring

1. Compliance with the procedure will be monitored on a routine basis. Refer to Administrative Policy Moderate Sedation Tool http://intranet.pmh.org/home/PP-Index/Admin/admin6-16b.pdf

2. A Patient Safety Net (PSN) Report should be completed whenever moderate/conscious sedation results in negative patient outcome or significant untoward event.

References

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