

Policy #:	03.11.020
Issued:	4/8/1998
Reviewed /	7/2004, 7/2007, 2/2008, 3/2009, 10/2010,
Revised:	12/2012, 8/2014, 2/2018, 12/2018, 9/2019,
	10/2024
Section:	Clinical Care/Patient Rights

Pediatric Moderate Sedation and Analgesia

Purpose:

To provide patients with the benefits of pediatric sedation and analgesia while avoiding the potential associated risks of hypoxia and respiratory arrest during procedures.

Policy Statement:

A. Pediatric Moderate Sedation and Analgesia provides four primary benefits:

- i.) During uncomfortable procedures (such as central line placement or a fracture reduction), sedation and analgesia minimizes anxiety and discomfort, while also reducing undesirable autonomic responses to painful stimuli.
- ii.) Sedation may also help the patient through a procedure (such as CT/MRI examinations) that is not uncomfortable but requires that the patient remain still for an extended period of time.
- iii.) Guard patient's safety and welfare.
- iv.) Return the patient to a state in which safe discharge from medical supervision is obtained, as determined by recognized criteria.
- B. The level of sedation necessary to ensure patient comfort through a procedure is highly variable and dependent upon the actual or perceived invasiveness of a procedure, the developmental level of the infant/child, the patient's history of interacting with personally challenging environments, and their evolving capacity to tolerate stress.
- C. It is the goal of pediatric sedation and analgesia (moderate sedation) to maintain a patent airway with significant levels of sedation while maintaining the ability to withdraw from painful stimuli.
- D. Multiple trauma patients in emergency situations are not candidates for moderate sedation. If these patients require sedation, intubation to secure the patient's airway control may be needed. If no life threatening injuries and no injuries requiring immediate surgical intervention are identified by the pediatric trauma team, but a further work up is needed that requires a procedure (MRI, CT Scan) that may require pediatric sedation, the senior surgical resident, pediatric surgical attending and pediatric attending credentialed in moderate sedation may collaborate to approve its use in this diagnostic work-up.
- E. If an infant, who is a former premature infant, has a corrected gestational age of less than 60 weeks, and receives sedation or general anesthesia, that infant must be admitted and observed for 24 hours post procedure. Admission is arranged by the primary care physician.

Application:

This policy applies to patients up to 23 years of age receiving moderate sedation under the care of Pediatrics. For patients aged 24 years or older and for patients receiving moderate sedation under the care of an adult medical specialty, refer to *Policy #03.11.010 - Adult Moderate Sedation*.

Exceptions:

- Patients age 24 years and older.
- Patients receiving moderate sedation under the care of an adult medical specialty

- Perioperative medication of patients
- Postoperative analgesia
- Patient controlled analgesia
- PICU/NICU patients on ventilators
- Drug/alcohol withdrawal prophylaxis
- Treatment of seizure disorders
- The use of a standard dose of PO/PR/Intranasal monotherapy benzodiazepines and Pentobarbital as these medications delivered by these routes are not considered procedural sedation. This standard dose is not expected to result in the loss of airway protective reflexes. These patients must be monitored in compliance with the standards in Appendix A. (See Appendix D for Pentobarbital dosing and administration guidelines).

Definitions:

<u>Minimal Sedation</u>: A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination might be impaired, ventilatory and cardiovascular functions are unaffected.

<u>Sedation and Analgesia (Moderate Sedation)</u>: A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

<u>Deep Sedation (DS)</u>: 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 could be impaired. Patients might require assistance in maintaining a patent airway and spontaneous ventilation might be inadequate. Cardiovascular function is usually maintained.

Anesthesia: Consists of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia.

In actuality, a continuum exists among moderate sedation, deep sedation and general anesthesia. The patient's age and preexisting medical condition may significantly alter the dosing requirements for moderate sedation. If either deep sedation or general anesthesia is required for a procedure, skilled anesthesia personnel will be available for patient management.

Procedure

1. Credentialing and Privileging

- 1.1. Attending Physicians will be credentialed and privileged according to the procedures described in the Medical Dental Staff Bylaws. Residents, fellows, nurse practitioners, and physician assistants are not authorized to administer moderate sedation independently and can do so only under the direction of a privileged Attending Physician, who is responsible at all times for the administration of sedation and analgesia (moderate sedation).
 - 1.1.1. Physician requesting privileges must:
 - 1.1.1.1. Submit a request to the Medical Staff Office for sedation and analgesia privileges.
 - 1.1.1.2. Document completion of training upon initial credentialing.
 - 1.1.1.3. Successfully complete an exam for initial and recredentialing.

- 1.1.1.4. Demonstrate proof of current certification in Pediatric Advanced Life Support (PALS) or Neonatal Resuscitation Program (NRP) based on clinical practice.
- 1.1.1.5. Demonstrate proof of current capnography interpretation training.

1.1.2. Education: The BMC Department of Anesthesia will be responsible for educational programs to instruct health care personnel in the proper use of sedation and analgesic agents and monitoring modalities.

- 1.1.3. Credentialing Records Records of the credentialing exam will be kept by the Medical Staff Office Educational programs outside the BMC Department of Anesthesia will be evaluated individually by the Chief of Anesthesia, or designee, to determine if they are acceptable substitutes.
- 1.2. Registered nurses (RN) who are authorized to administer moderate sedation and monitor the patient through recovery shall demonstrate and maintain competency in the following areas):
 - Airway management
 - Use of medications and dosages
 - Pulse oximetry
 - Cardiac monitors and arrhythmia recognition
 - PALS (pediatric) or NRP (neonatal)
 - Capnography interpretation
- 1.3. The American Society of Anesthesiologists (ASA), Centers for Medicare & Medicaid Services (CMS), and Board of Registration in Nursing (BORN) place restrictions on who can administer medications classified as an anesthetic (i.e. ketamine, propofol). For the purposes of procedural sedation, only privileged physicians may administer ketamine.
 - Nurses, who are not Certified Registered Nurse Anesthetists (CRNAs), may only
 administer ketamine and propofol if the patient is undergoing rapid sequence intubation
 with a privileged physician in the room or is already intubated.

2. Staffing

- 2.1. A minimum of <u>three people</u> must be present to care for patients receiving moderate sedation.
 - 2.1.1. The person who performs the diagnostic, therapeutic or surgical procedure.
 - 2.1.2. An individual, MD or RN, who is responsible for administering medications and monitoring the patient's response to both the sedation and the procedure. This person will have no other significant responsibility from the time the sedation is initiated until the time when the recovery of the patient is judged complete, or the care of the patient is transferred to personnel performing recovery care. This person will titrate the sedative medications as needed, maintain a patent airway, and administer reversal agents if required.
 - 2.1.3. A third individual, MD or RN, who will record vital signs, including the sedation level and document the administration of medications. This person may leave the procedure room for brief periods of time to perform tasks directly related to the procedure.
- 2.2. At least one of these individuals must be a physician who has Moderate Sedation privileges.
- 2.3. The means for notifying additional support staff services such as Respiratory Therapy and "Code Blue" pages should be clearly identified and posted in procedure/sedation areas.

3. Available Equipment During and Post Procedure

- 3.1. A pulse oximeter for non-invasive monitoring of heart and oxygen saturation
- 3.2. Cardiorespiratory monitor
- 3.3. Bag mask valve system (i.e. Ambu, Mapelson) capable of administering greater than 90% oxygen at a 15 L/min flow for at least 60 minutes
- 3.4. Wall or portable suction with a rigid tonsil suction catheter
- 3.5. Non-invasive BP machine with appropriately sized cuff
- 3.6. Oral and nasal airways size appropriate
- 3.7. Reversal agents, flumazenil and naloxone, if benzodiazepines and narcotics are being administered
- 3.8. A standard pediatric code cart or neonatal code cart
- 3.9. Non-invasive end-tidal CO2 monitor
- 3.10. Heating Pad (NICU)

4. Patient Selection Criteria

4.1. The American Society of Anesthesiologists (ASA) guidelines for risk classification are utilized in the selection of patients to receive sedation and analgesia (moderate sedation).

Class I:	A normally healthy patient	
Class II:	A patient with mild systemic disease	
Class III:	A patient with severe systemic disease that limits but is not incapacitating	
Class IV:	A patient with severe systemic disease that is a constant threat to life	
Class V:	A morbid patient who is not expected to survive with or without the operation/procedure	

- 4.2. All patients should be evaluated by the privileged Attending Physician and stratified in the proper ASA Classification. Patients with ASA classification I and II are eligible to receive procedural sedation without anesthesiology consultation.
- 4.3. Anesthesiology must be consulted for ASA III or greater, or if classification is unable to be determined. Anesthesia consultation is required under the following circumstances:
 - 4.3.1. ASA Class III or greater
 - 4.3.2. Airway abnormalities (large tonsils or adenoids with signs of obstruction, obstructive sleep apnea, tracheomalacia or tracheal stenosis, previous airway instrumentation, congenital anomalies such as Pierre Robin syndrome, Treacher-Collins syndrome, Crouzon disease, trisomy 21); increased risk for upper airway obstruction
 - 4.3.3. Pulmonary disorders (chronic lung disease, reactive airway disease Class III or greater and active respiratory disease)
 - 4.3.4. Cardiovascular disorders (heart failure, right-to-left shunt, and rhythm disturbances) increased risk for hypotension and hypoxia
 - 4.3.5. Neurologic/developmental/psychiatric disorders: level of sedation difficult to assess, paradoxical reactions to sedatives, increased metabolism of sedatives if taking anticonvulsants, drug interactions
 - 4.3.6. Renal/hepatic disorders: altered metabolism of sedative/analgesics
 - 4.3.7. History of sedation complications: increased risk for sedation failure, over sedation and paradoxical reactions
 - 4.3.8. GI disease such as vomiting, bowel obstruction or gastroesophageal reflux
 - 4.3.9. Morbid obesity
 - 4.3.10. Pregnant patients

5. Clinical Sedation Score

Clinical Score	Patient Characteristics	
1	Anxious, agitated or restless	
2	2 Cooperative, oriented, or tranquil	
3	Asleep, brisk response to a light stroke to the cheek	
4	Asleep, sluggish response to a light stroke to the cheek	
5	No response to a light stroke to the cheek but responds to a painful stimulus	
	(nail bed pressure)	
6	No response to a painful stimulus (nail bed pressure)	

6. Consent

6.1. The patient/guardian must be informed about the risks and alternatives of sedation as a component of the planned procedure. Documentation of the consent for both the procedure and the administration of moderate sedation will be included in the patient's chart. In the event that the parent or legal guardian does not accompany the patient, he or she must be available to provide consent for moderate sedation by fax machine or to give verbal, witnessed consent by telephone.

7. Nil Per Os (NPO) Guidelines

7.1. Patients undergoing sedation and analgesia (moderate sedation) for elective procedures should not eat or drink for a sufficient period of time to allow for gastric emptying before their procedure (see below). In urgent, emergent, or other situations when gastric emptying is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining the timing of the intervention and the degree of moderate sedation.

INGESTED MATERIAL	MINIMUM FASTING PERIOD (in hours)
Clear liquids	2
Breast milk	4
Infant formula	6
Non-human milk	6
Light meal	6
High fat or protein content meal	Clinician may consider > 6

- 7.2. If the patient requires an emergency procedure where the patient has not been NPO, moderate sedation may be dangerous. The ASA states that in such a case, the safest thing maybe to modify the planned level of sedation to minimal sedation if possible, depending on patient or procedure, or escalate to general anesthesia (by anesthesiologist) with rapid sequence induction and intubation for airway protection.
- 7.3. In emergency situations, the appropriate NPO status may be determined by the attending physician, taking into account the patient's acuity and the urgency of the proposed procedure. Evidence shows that adherence or non-adherence to fasting guidelines for solids and liquids does not affect the frequency of emesis, desaturation or serious adverse events during sedation.(1,2,3).
- 7.4. Note: If the patient requires an emergency procedure and he or she has not been NPO, moderate sedation may be dangerous. In such situations, alternative options to moderate sedation/analgesia must be considered by the MD who will determine if it will be:
 - Delayed;
 - Done judiciously to avoid unconsciousness and suppression of airway reflexes;
 - Not administered; or

- Endotracheal intubation and general anesthesia.
- 7.5. Critical oral medications are excluded from NPO guidelines.

8. Drug Dosage Guidelines (See Appendix B, C, D and E)

- 8.1. Medication for the purpose of moderate sedation will not be administered without the presence of the privileged physician. There must be a written, signed, dated and timed physician medication order specifying route and dosage to be administered to the patient.
- 8.2. The list of medications and dosages in Appendices B, C, D and E are provided to serve as guides for administration. The use of drugs outside these guidelines must be approved by the Chief of Anesthesia, or designee, except in emergency situations.
 - 8.2.1. Nurses may not administer anesthetics (e.g. Ketamine, Propofol), except to patients with a protected airway.

9. Pre-Procedure:

9.1. Obtain and Document the following using the pre-admission form:

- 9.1.1. Appropriate state of consciousness and medical condition
- 9.1.2. Appropriate NPO guidelines (See Section 7 NPO Guidelines) have been followed and documented.
- 9.1.3. Presence of an individualized sedation plan including the intended level of sedation level to be achieved during the procedure and strategy to achieve the intended level of sedation. The level of sedation necessary to accomplish the procedure is identified by the responsible physician and communicated to members of the care team. A clinical sedation score should be used to enhance communication and assessment of the end point (refer to the Clinical Sedation Score Section 5).
- 9.1.4. A written sedation order signed by the credentialed Attending Physician
- 9.1.5. Absence of allergies or sensitivities to the prescribed medication
- 9.1.6. Appropriate history and physical performed within 48 hours of procedure and documented in the patient's chart prior to the procedure:
 - 9.1.6.1. Actual weight in kilograms
 - 9.1.6.2. Allergies and previous allergic reactions
 - 9.1.6.3. Concurrent medications including time, dose, and route of administration
 - 9.1.6.4. Nature and time of last oral intake
 - 9.1.6.5. History of tobacco, alcohol or substance abuse
 - 9.1.6.6. History of other diseases, disorders, hospitalization
 - 9.1.6.7. History of sedation/anesthesia and problems that have been experienced by the patient
 - 9.1.6.8. Family history of problems relating to anesthesia and/ or sedation
 - 9.1.6.9. Review of systems with specific statement describing the airway assessment
 - 9.1.6.10. Baseline vital signs including blood pressure, heart rate, respiratory rate, O2 saturation, and level of consciousness
 - 9.1.6.11. Physical exam to include a minimal examination of airway, neurological, pulmonary and cardiac status
 - 9.1.6.12. ASA category documented
- 9.1.7. Obtain written consent from parent or guardian

- 9.1.8. Establish and document a competent adult who will be taking the patient home (for outpatient population)
- 9.1.9. Obtain IV line or saline lock
- 9.1.10. The patient and/or caregiver has:
 - 9.1.10.1. been instructed in the concepts of sedation analgesia (moderate sedation) and about the sedation planned for the procedure, and
 - 9.1.10.2. been instructed to report any problems associated with the procedure or moderate sedation (e.g., pain, tender site, itching, difficulty breathing) to the individual responsible for monitoring the patient, and reviewed and received written post sedation/procedural instructions.

10. During the Procedure:

- 10.1. Immediately prior to administrating sedative medications perform a "Time Out" and verification of correct patient and correct procedure with nurse before beginning the sedation.
- 10.2. Continuously monitor and document the following parameters on the Moderate Sedation Procedure Record Part II. Record every 5-10 minutes
 - 10.2.1. Heart Rate
 - 10.2.2. EKG Rhythm
 - 10.2.3. Respiratory Rate
 - 10.2.4. O2 sat
 - 10.2.5. Pain
 - 10.2.6. Blood Pressure
 - 10.2.7. End tidal CO2 (except for premature infants and neonates being cared for in the NICU)
 - 10.2.8. Patient's responsiveness (level of consciousness) utilizing a sedation scale. The level of sedation is assessed frequently (1-minute intervals) during the onset of sedation and after administration of additional medications hallmarked by a change in the level of consciousness. Once the desired level of sedation is achieved the patient's level of consciousness is monitored every 5 10 minutes to avoid interfering with the procedure.
- 10.3. The patient's head position, airway and chest excursions are continuously monitored. The patient is repositioned as necessary to ensure adequate spontaneous respiration.
- 10.4. Document all IV fluids, including blood products, and medications(s) administered including route, site, time, dosage, and initials of individual administering medication.
- 10.5. Record any oxygen therapy given in liters/minutes or FIO2 and means of oxygen therapy delivery.
- 10.6. The individual who monitors the patient shall inform the MD of any changes in the patient's physiological status from his/her baseline assessment and record its occurrence, interventions and outcome.

11. Post Procedure:

- 11.1. The practitioner(s) whose responsibility it is to monitor the patient shall ascertain and record the patient's vital signs at a minimum of every 15 minutes on the Moderate Sedation Procedure Record Part II for a minimum of 30 minutes following the last dose of medication administered.
- 11.2. After 30 minutes, if stable, vital signs including O2 Sat should be recorded every 15 minutes until discharge criteria are met to end the recovery period.

- 11.3. A Recovery Score (see Appendix A) will be documented at the end of the procedure and every 15 minutes until target recovery score is met. (outpatient 10, inpatient 8-10).
- 11.4. Sedated patients may need to be transported between care areas and must be accompanied by an RN or physician. The appropriate level of care and monitoring will continue during transport. Sedated patients are to be transported in a crib/bed with:
 - 11.4.1. Size appropriate oral airway
 - 11.4.2. Size appropriate Ambu bag and mask
 - 11.4.3. Portable O2
 - 11.4.4. Pulse oximetry monitor.
- 11.5. Patients requiring reversal of narcotics or benzodiazepines will require a minimum recovery period of 2 hours for observation following the administration of the reversal agent.

12. <u>Recovery/Discharge Criteria:</u>

- 12.1. Inpatient Criteria: the following will be met for patients to be transferred to another unit or to end the recovery period.
 - 12.1.1. Recovery score greater or equal to 8 (unless patient being transferred to the NICU or PICU).
 - 12.1.2. Vital signs and O2 sat stable.
 - 12.1.3. Swallow, cough and gag reflexes are present.
 - 12.1.4. Nausea and dizziness are minimal.
 - 12.1.5. Dressing and/or procedure site checked.
 - 12.1.6. Minimal pain managed by appropriate analgesics.
 - 12.1.7. Patient alert.
 - 12.1.8. Patient can sit unaided if appropriate to baseline and procedure.
 - 12.1.9. Discharge order written if applicable.
 - 12.1.10. If patients are to be transferred for further recovery within the institution, they will be accompanied by a physician, PA, or RN to a designated recovery area.
- 12.2. Outpatient Discharge Criteria: For outpatients the above criteria will be met in addition to the following:
 - 12.2.1. Recovery Score 10 (or pre-procedure state).
 - 12.2.2. Hydration adequate/able to drink fluids.
 - 12.2.3. Voided or unable to void but comfortable.
 - 12.2.4. Patient and/or family given written discharge instructions which will include an explanation of anticipated limitation on activities (e.g., refrain from operating heavy machinery, driving a car), behavior (e.g., deferring important decisions) and diet (e.g., refraining from consuming alcohol for the next 24 hours).
 - 12.2.5. A 24 hour emergency contact (person/service).
 - 12.2.6. Discharge order written.
 - 12.2.7. Ambulatory patients may not leave the hospital unless accompanied by a competent adult.
 - 12.2.8. A follow-up phone call is recommended within 24 hours post- procedure.
- 12.3. Discharge orders and follow up care instructions must be written by a physician.

13. Quality Assessment

13.1. Each department/division involved in moderate sedation, must monitor its performance and work to improve it. Each department/division must submit a quarterly report to the Chief of Anesthesia or designee using the BMC format.

Responsibility:

Anesthesiology, Physician privileged in Moderate Sedation, and Nursing

Forms:

Time out Sticker Moderate Sedation Procedure Record Quarterly Report Form

Other Related Policies:

03.02.000 - Patient Consent
03.11.010 - Adult Moderate Sedation
03.33.000 - Patient Identification
03.36.000 - Pain Assessment and Management
03.60.000 - Universal Protocol (Time Out)
03.37.000 - CODE BLUE / Cardiopulmonary Resuscitation
03.37.00h - Rapid Response Team
Nursing 10.03.010 - Medication Administration
Nursing 10.04.060 - Intravenous Therapy

Initiated by: Anesthesiology

Contributing Departments:

- 1. PICU
- 2. NICU
- 3. Anesthesiology
- 4. Pediatric Sedation Team
- 5. Pediatric Emergency Department
- 6. Pharmacy
- 7. Nursing

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- Beach ML, Cohen DM, GallagherSM, Cravero JP. Major adverse events and relationship to nil per os status in pediatric sedation/anesthesia outside the operating room. Anesthesiology. 2016;124(1):80-88.
- 3. Green SM, Roback MG, Krauss B, et.al.; Emergency Department Ketamine Meta-analysis Study Group. Predictors of emesis and recovery agitation with emergency department ketamine sedation. Ann Emerg Med.2009;54(2):171-180.e1,e4.

Related Readings:

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APPENDIX A

RECOVERY SCORE

Respiration	Able to breathe deeply and cough freely.	2
	Dyspnea or limited breathing.	1
	Apneic.	0
Circulation	$BP \pm 20\%$ of preanesthetic level.	2
	BP \pm 21-49% of preanesthetic level.	1
	$BP \pm 50\%$ of preanesthetic.	0
L.O.C.	Fully awake	2
	Arousable on calling/responds to stimuli	1
	Not responding	0
Activity	Moves all extremities	2
	Moves 2 extremities	1
	Unable to move extremities	0
O2 SAT	Pediatric Only	
	100% - 98% on room air	2
	98% - 95% on room air	1
	<95% on room air	0

APPENDIX B Medication Guidelines for Pediatric Patients Excluding Neonates

Medication	Initial Dosage	Dynamic	Comments
<i>Benzodiazepine:</i> Midazolam (Versed)	 IV: 0.05-0.15 mg/kg bolus Repeat as needed in increments of 0.5-0.1 mg/dose. Max. single dose = 2 mg IIN: 0.2 mg/kg, Max 10 mg PR: 0.3-0.5 mg/kg PO: 0.5-1 mg/kg Max. = 20 mg 	Onset: 1-5 min. (IV) Duration: 20-30 min., up to 2 hr. Onset: 20-30 min. (PO, PR)	 Slurred speech is good end point Erratic absorption other than IV Consider lower dose when use in combination with narcotics IN for infants ≥6 months, children and adolescents
Benzodiazepine Antagonists: Flumazenil (Romazicon)	 IV: <20 kg: 0.01 mg/kg/dose, Titrate 0.01 mg/kg every min to a total of 0.04 mg/kg. IV: >20 kg: 0.2 mg over 15 sec; if level of consciousness desired not obtained after 1 min titrate by 0.2 mg and repeat every minute to effect or to a total dose of 1 mg. 	Onset: 1-3 min. Duration: 45 min.	 Obtain history of current Benzodiazepine use May induce Benzodiazepine withdrawal seizure Half life of Benzodiazepine may be longer than half life of Flumazenil, resulting in residual sedation, hypoventilation Flumazenil is not intended for routine reversal of Benzodiazepine related to sedation, due to the risks of serious adverse effects, such as seizures Patients requiring reversal of Benzodiazepine need extended monitoring in the recovery phase for minimum of 2 hours
<i>Narcotics:</i> Fentanyl Morphine	 IV: 1-2 mcg/kg (slowly over 2 minutes) Titrate to desired effect. Max initial dose 100mcg Subsequent doses 0.5-1 mcg/kg, max 50mcg IV: 0.05-0.1 mg/kg (slowly over 4 min.) Maximum initial dose 10 mg Subsequent doses 0.05 mg/kg, 	Onset: 2 - 3 min. Duration: 30-60 min. Onset: 3-10 min. Duration: 1-2 hr Onset: 3-5 min. Duration: 1-2 hr	 Increased risk of respiratory depression when combined with Benzodiazepines Useful as adjunct for sedation Beneficial for pain Monitor for: a. Respiratory depression b. Orthostatic circulatory depression c. Chest wall rigidity (Fentanyl only) d. Nausea, vomiting, constipation, urinary retention e. Pruritis/urticaria (face, esp., nose may itch)

Medication	Initial Dosage	Dynamic	Comments
Ketamine	IV: 1-2 mg/kg Max. initial dose = 50-100 mg Subsequent doses 0.5-1 mg/kg, max 25-50 mg		 Add atropine 10-20 mcg/kg Max. dose = 0.3 mg Midazolam 0.05-0.1 mg/kg post procedure (if needed) for dysphoria and emergence reaction.
Narcotic Antagonist: Naloxone (Narcan)	IV: 0.01 mg/kg, up to 1 mg IV. Titrate to desired effect.	Onset: 3-5 min. Duration: 30-45 min.	 It is important to obtain a history of narcotic use to prevent onset of withdrawal symptoms Agitation due to return of pain Increased sympathetic stimulation may raise BP, HR, and Temp Patients requiring reversal of narcotics need extended monitoring in the recovery phase for a minimum of two hours

Medication Guidelines for Pediatric Patients Excluding Neonates (continued)

Medication	Initial Dosage	Dynamic	Comments
<i>Sedatives:</i> Midazolam (Versed)	IV: 0.05-0.15 mg/kg dose over at least 5 min. Repeat as needed Max dose of 0.3 mg/kg	Onset: 1-5 Min. Duration: 2-6 hr	• See Pediatric comments
<i>Narcotics:</i> Fentanyl (Sublimaze)	IV: 1-2 mcg/kg/dose (slowly over 2 min.). Titrate to desired effect.	Onset: 2-3 min. Duration: Serum half life 1-15 hrs	 Neonates have a great risk of chest wall rigidity Seizures are possible in premature infants Also see Pediatric comments
Morphine	IV: 0.05-0.1 mg/kg/dose Slow IV push	Onset: 3-5 min. Duration: Half life 9 hours in preemies	
Narcotic Antagonists: Naloxone (Narcan)	IV: 0.01-0.02 mg/kg. Titrate to desired effect	Onset: 3-5 min. Duration: 30-45 min.	 Can precipitate seizures in newborns exposed to chronic maternal narcotics See Pediatric comments

Appendix C Medication Guidelines for Neonates

APPENDIX D

GUIDELINES FOR ORAL PENTOBARBITAL

- 1. Only pediatricians with privileges in Moderate sedation will order medications for preprocedure oral sedation. All medications will be ordered in mg/kg with a total dose.
- 2. The recommended doses for Pentobarbital is as follows:
 - Pentobarbital P.O: 2-6 mg/kg with a maximum total dose of 100 mg.
- 3. A minimum of two individuals must be present for the administration of procedures requiring oral sedation. They must include a licensed clinician to monitor the patient and the individual performing the procedure. A physician with moderate sedation privileges must be immediately available.

Appendix E

Guidelines for the Use of Propofol by Members of the Pediatric Sedation Team

- 1. Administration
 - Only Pediatric Attendings who have privileges in Moderate Sedation and are members of the Pediatric Sedation Team are allowed to order Propofol for procedural sedation.
- 2. Eligible Patient Populations
 - Patient is over 1 year of age and meets criteria for the administration of Moderate Sedation
 - Patient is not allergic to propofol
- Equipment
 - Equipment as outlined in the Pediatric Sedation and Analgesia Policy
 - In addition, all patients require non-invasive end-tidal CO2 monitor
- Pre-procedural Hydration
 - Propofol *may* cause hypotension especially in young children who have been NPO for some hours prior to the sedation procedure.
 - To minimize this risk consider initiating a 10 ml/kg bolus of Normal Saline or Lactated Ringers prior to administering propofol.
- Co-Administration of Opioid
 - Propofol has no analgesic properties. For painful procedures, co-administer propofol with an IV analgesic, e.g. Fentanyl 0.5 2 mcg/kg.
 - Decrease propofol dose by 50% of the usual dose, if an opioid is to be coadministered or, if a benzodiazepine has been given recently.
- Co-Administration of Ketamine
 - Comination of ketamine and propofol can reduce the total requirements of either agent
 - Most often recommended in a 1:1 ratio
 - Start at 0.5 mg/kg IV of both ketamine and propofol, and follow with another 0.25-0.5 mg/kg IV which is titrated to desired effect after at least 1 minute
- Propofol Administration Methods
 - A. Propofol Bolus Slow Injection Method:
 - Dilution of propofol 1:1 in normal saline has been reported to decrease pain of infusion
 - Give 1 -2 mg/kg administered over 1 to 3 minutes and repeat if clinically necessary.

- Total recommended dose not to exceed 3 mg/kg over a 20 minute period.
- Allow 2-3 minute intervals between boluses for observation of drug effect.

B. Propofol - Infusion Method (Maintenance of Sedation)

- Propofol infusion: Begin infusion at 100 mcg/kg/min immediately after desired sedation level is achieved.
- Titrate to clinical effect: range 50 to 200 mcg/kg/min.
- Consider decreasing rate of infusion by 50% when the end of the procedure is imminent (e.g. there is only 5 minutes left to the procedure).
- Consider stopping the infusion when only 1 minute is left to the procedure.
- Propofol has a very short half-life. Appropriate supportive measures while stopping the infusion will lead to a return to baseline in approximately 5-10 minutes.

C. Propofol Administration Precautions

- Do not administer through the same IV catheter with blood or plasma compatibility has not been established.
- Handle with scrupulous aseptic technique and discard unused portion.
- Use cautiously in children with compromised cardiac function or hypovolemia.

8. Potential Complications

A. Respiratory compromise:

- If patient demonstrates a respiratory depression as evidenced by airway obstruction, decreased respiratory rate, a sedation score deeper than intended level of sedation or an absent end tidal CO2:
 - Decrease infusion rate or stop infusion, provide stimuli if needed
- If patient demonstrates oxygen desaturation or apnea:
 - Stop infusion, initiate bag valve mask ventilation

B. Cardiac compromise:

- If patient becomes hypotensive:
 - Decrease infusion rate, give IV Normal Saline bolus
- If patient becomes hypotensive with poor perfusion:
 - Stop infusion, administer NS bolus
- If patient becomes bradycardic:
 - Stop infusion, administer NS bolus and provide cardiac support as needed



 Policy #:
 26.38.000

 Issued:
 March, 2014

 Reviewed/
 10/2015, 9/2021, 9/2024

 Revised:
 Emergency Guidelines

Nitrous Oxide (N₂0) Guidelines Procedural Sedation in the Pediatric Emergency Department

Purpose:

To provide patients with the benefits of nitrous oxide for procedural sedation/analgesia while minimizing the associated risks to both patients and staff at Boston Medical Center (BMC).

Policy Statement:

Nitrous oxide may only be administered by specifically privileged physicians in accordance with the BMC credentialing process. Those physicians privileged in moderate sedation (see Pediatric Moderate Sedation and Analgesia #03.11.020) may use nitrous oxide for sedation once they have met the additional criteria specified for nitrous oxide sedation. Registered nurses will be trained in the use and monitoring for nitrous oxide/oxygen sedation.

Nitrous oxide use is restricted to specific locations which have appropriate scavenging and waste anesthetic gas monitoring and which have been approved by the BMC Department of Health and Safety. The use of nitrous oxide will be restricted to areas where it has been established by the Department of Environmental Health and Safety.

Guideline Statement:

Common use of nitrous oxide includes, but is not limited to, laceration repair, incision and drainage of abscesses, removal of foreign bodies and fracture reduction. Fasting is not required for sedation with nitrous oxide alone. Vascular access is not required for nitrous oxide sedation.

Nitrous Oxide may be used in concentrations up to 30 percent oxygen: 70 percent nitrous oxide. The lowest concentration appropriate for the procedure and required level of sedation should be used.

Areas where nitrous oxide is used will have periodic monitoring to ensure safe waste anesthetic gas levels are within NIOSH – acceptable standards.

Nitrous oxide delivery machines must be stored in accordance with current regulations.

Application:

Patients age 2 years and over admitted to the Pediatric Emergency Department (ED). Patients sedated with nitrous oxide as the sole agent of sedation.

If a patient has received opioids (e.g. morphine, fentanyl, oxycodone), benzodiazepines (e.g. lorazepam, midazolam, diazepam), or local anesthetic for analgesia, but is awake and alert at the time of nitrous sedation, nitrous oxide may be used as the sole agent for sedation. Some patients receiving sedatives or analgesic in addition to nitrous oxide may experience additive sedative effects.

Exceptions:

- Age less than 2 years
- ASA (American Society of Anesthesiologists) score 3 or greater
- Patients with sickle cell disease
- Pregnancy
- Acute otitis media
- Tympanic membrane graft or middle ear surgery within the preceding 7 days
- Known or suspected bowel obstruction
- Known or suspected pneumothorax
- Known or suspected air embolus
- Known vitamin B12 deficiency
- Severe emphysema
- Bullous lung disease
- Acute asthma exacerbation (asthma alone is not a contraindication)
- Intraocular gas injection
- Recent retinal surgery
- Increased intraocular pressure
- Patients with severe pulmonary disease, obstructive sleep apnea, congenital heart disease or diseases associated with vitamin B12 deficiency may not be able to tolerate nitrous oxide sedation and their care should be discussed with the Department of Anesthesia.
- Patients with suspected respiratory infection (COVID-19 rule out, persons under investigation) based upon exposure or symptoms
- Positive diagnosis of diseases requiring enhanced and/or contact/droplet isolation (per current BMC infection control procedures)
- Patients with previous adverse reaction to nitrous oxide 50:50
- Hemodynamic instability defined as consistent systolic blood pressure <90 mmHg
- Impaired oxygenation defined as consistent oxygen saturation <95%
- Acute drug or alcohol intoxication

American Society of Anesthesiologists Score (ASA Score)

- 1. A normal healthy patient
- 2. A patient with mild systemic disease
- 3. A patient with severe systemic disease
- 4. A patient with severe systemic disease that is a constant threat to life
- 5. A moribund patient who is not expected to survive without the operation
- 6. A declared brain-dead patient whose organs are being removed for donor purposes

Equipment:

- Approved nitrous oxide delivery system with scavenger system
- Pulse oximeter
- End-tidal CO₂
- Bag valve mask system capable of delivery greater than 90% oxygen at 15 liters/minute
- Wall or portable suction with a rigid suction catheter
- Oral airways of appropriate size
- Personal protective equipment for aerosol generating procedures per current BMC infection control procedures

Consent

The patient/guardian must be informed about the risks and alternatives of sedation as a component of the planned procedure. Documentation of the consent for the administration of nitrous sedation will be included in the patient's chart. In the event that the parent or legal guardian does not accompany the patient, he or she must be available to provide consent for nitrous oxide sedation by verbal, written, or telephone consent.

Procedure:

Administration of nitrous oxide requires that a minimum of three clinicians be immediately available; a clinician (MD/DO) who is privileged in procedural sedation who has the responsibility of sedating and monitoring the patient, the clinician (MD/DO) who is performing the procedure (e.g. laceration repair, abscess incision and drainage) and an RN trained in procedural sedation who is monitoring the patient and recording relevant data including vital signs and level of sedation in the medical record.

Pre-Procedure

- Fasting is not necessary for sedation with nitrous oxide
- Absence of history of bad reaction to nitrous oxide
- History and physical documented prior to sedation
- ASA category
- Obtain written consent for sedation with nitrous oxide from parent, guardian or patient (if 18 or older)
- Written sedation order by credentialed physician
- Vascular access is not required for nitrous oxide sedation

Procedure:

- Prior to administering the nitrous oxide, a procedural "time out" must be performed.
- Continuously monitor and document the patient's oxygen saturation and heart rate via pulse oximetry
- Monitor and document the patient's breathing and head position
- Monitor and document the patient's level of sedation utilizing the clinical sedation scoring tool in Pediatric Moderate Sedation Guidelines, #03.11.020 (see below). For sedation with nitrous oxide, sedation score of 4 or less is generally appropriate.

Clinical Score	Patient Characteristics	
1	Anxious, agitated or restless	
2	Cooperative, oriented, or tranquil	
3	Asleep, brisk response to a light stroke to the cheek	
4	Asleep, sluggish response to a light stroke to the cheek	
5	No response to a light stroke to the cheek but responds to a painful stimulus (nail bed pressure)	
6	No response to a painful stimulus (nail bed pressure)	

Clinical Sedation Score

In the event that the Attending Physician is called away from sedation of a patient in order to go to another emergency, the sedation will be stopped and the patient given 100% oxygen. If the patient has a sedation score of ≥ 5 (arouses slowly to consciousness with sustained painful stimuli) anesthesia may be called to the ED if there is not another physician privileged in sedation with nitrous oxide present.

Post Procedure:

- Once the procedure is complete, remove nitrous oxide and give the patient 100% oxygen for at least three to five minutes.
- Monitor that the patient returns to baseline level of alertness (pre-sedation level of alertness as determined by the Recovery Score Tool, Appendix A of Pediatric Moderate Sedation and Analgesia Guidelines, # 03.11.020).

Responsibility

MD/DO, RN

MD/DO privileged in procedural sedation and nitrous oxide sedation at BMC RN trained in procedural sedation and nitrous oxide sedation at BMC

Contributing Departments

Pediatrics Anesthesia Pharmacy Nursing Clinical Engineering Environmental Health and Safety

Other Related Polices:

03.02.000 Patient Consent 03.11.020 Pediatric Moderate Sedation and Analgesia 03.33.000 Patient Identification 03.60.000 Universal Protocol (Time Out)

References:

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Initiated by:

Pediatric Emergency Department

Appendix A

Pediatric Recovery Score Pediatric Moderate Sedation and Analgesia Guidelines #03.11.020

Respiration	Able to breathe deeply and cough freely. Dyspnea or limited breathing. Apneic.	2 1 0
Circulation $BP \pm 20\%$ of pre-anesthetic level. $BP \pm 21-49\%$ of pre-anesthetic level. $BP \pm 50\%$ of pre-anesthetic.		2 1 0
L.O.C. Fully awake Arousable on calling/responds to stimuli Not responding		2 1 0
Activity	Moves all extremities Moves 2 extremities Unable to move extremities	2 1 0
O ₂ SAT	Pediatric Only 100% - 98% on room air 98% - 95% on room air <95% on room air	2 1 0



Pediatric Moderate Sedation Exam

- 1. The Pediatric Moderate Sedation Policy applies to patients:
 - a. 18 years old and younger
 - b. 23 years old and younger
 - c. 15 years old and younger
 - d. 16 years old and younger
- 2. Which of the following is NOT considered pediatric moderate sedation?
 - a. Patient controlled analgesia
 - b. Alcohol withdrawal prophylaxis
 - c. Postoperative analgesia
 - d. All of the above
- 3. All of the following should be monitored during pediatric moderate sedation, EXCEPT:
 - a. Heart Rate
 - b. Respiratory Rate
 - c. Neuromuscular function
 - d. Oxygen Saturation
- 4. During pediatric moderate sedation the level of consciousness should be monitored:
 - a. Every 3 to 5 minutes
 - b. Every 5 to 10 minutes
 - c. Every 10 to 15 minutes
 - d. Every 15 to 20 minutes
- 5. Which of the following is NOT required during pediatric moderate sedation?
 - a. Flumazenil
 - b. Naloxone
 - c. Neostigmine
 - d. Oxygen

6. Which of the following is INCORRECT regarding NPO guidelines during pediatric moderate sedation?

- a. The patient must stop ingesting solid foods 6 hours prior to the procedure
- b. The patient must stop ingesting non-clear liquids 6 hours prior to the procedure
- c. The patient must stop drinking Breast Milk 4 hours prior to the procedure
- d. The patient must stop drinking Clear Liquids 3 hours prior to the procedure

7. All of the following need to be documented in the patient's chart prior to pediatric moderate sedation, EXCEPT?

- a. Weight in kilograms
- b. Height in centimeters
- c. Time of last oral intake
- d. ASA Risk Category

8. Which of the following best describes Moderate Sedation?

- a. A drug-induced state during which patients respond normally to verbal commands.
- b. A drug-induced depression of consciousness during which patients respond to purposefully verbal commands, either alone or accompanied by light tactile stimulation.
- c. A drug- induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation.
- d. None of the above

9. Which of the following best describes a Class III (three) American Society of Anesthesiologists (ASA) risk classification?

- a. A patient with severe systemic disease that is a constant threat to life
- b. A patient with severe systemic disease that limits but is not incapacitating
- c. A normally healthy patient
- d. A patient with mild systemic disease

10. When flumazenil is administered to reverse the effects of a benzodiazepine, the patient must be observed in the recovery phase for a period of:

- a. 1 hour
- b. 2 hours
- c. 3 hours
- d. 4 hours

11. A patient that is asleep and sluggish to respond to a light stroke on the cheek has a clinical sedation score of:

- a. I
- b. II
- c. III
- d. IV

12. A minimum of three individuals must be present for the administration of procedures requiring oral sedation.

True False

13. An anesthesia consultation is required if the patient is ASA II or greater:

True False

14. An anesthesia consultation is required if the patient has obstructive sleep apnea:

True False

15. Individuals who fail this test must attend a moderate sedation lecture and retake the test.

True False

16. Registered nurses authorized to administer moderate sedation and monitor the patient through recovery shall demonstrate competency in airway management and PALS:

True False

17. If an infant is a former premature infant, has a corrected gestational age of less than 60 weeks, and receives sedation or general anesthesia, that infant must be observed for 12 hours after the procedure.

True False

18. Multiple trauma patients in emergency situations may receive sedation if further workup is required (e.g. CT) and sedation is agreed upon by the senior surgical resident, the pediatric surgeon, and the pediatric emergency attending credentialed in sedation.

True False

19. Under the pediatric moderate sedation guidelines, patients older than 12 months can receive propofol:

True False

20. Residents can administer moderate sedation if supervised by the chief resident or a fellow:

True False

If not requesting Moderate Sedation with Nitrous Oxide, please skip questions 21-24

Nitrous Oxide

21. All of the following procedures may be done under nitrous sedation except for which of the following:

- a. Laceration repair
- b. Abscess incision and drainage
- c. Cautery of a bleeding vessel
- d. Intravenous line placement

22. The maximum percentage of nitrous oxide (nitrous oxide/oxygen mixture) that may be given in the Emergency Department is:

- a. 30%
- b. 40%
- c. 50%
- d. 70%

23. To perform nitrous oxide sedation in the Emergency Department all of the following are necessary except:

- a. Obtain consent from the family and/or patient
- b. Make sure patient has been NPO for at least 4 hours
- c. Set up monitoring with oxygen saturation
- d. Have two clinicians with the patient, one to perform the sedation and anther to do the procedure
- 24. Following sedation with nitrous oxide:
 - a. It is not necessary to observe the patient as she will be return to normal immediately
 - b. Observe the patient for one to two hours
 - c. Give the patient 100% oxygen for 3 to 5 minutes
 - d. Warn the family and patient of delayed hallucinations

Prepared by Rafael Ortega, MD 5/14/2010; edited by David Dorfman, MD 9/4/2013, 11/13/2014

Name:	Date:
1	12
1	13
2	14
3	15
4	16
5	17
6	18
7	19
8	20
9	Nitrous Oxide only (21-24)
10	21
11	22
12	23
	24

Pediatric Moderate Sedation Credentialing Exam

Answer Sheet

25. Further Instructions:

View the link below for education on Capnography https://journals.lww.com/anesthesia-analgesia/fulltext/2023/11000/capnography_video_in_clinical_anesthesia.6.aspx

Score _____

Pass

Fail

Passing score is 80%