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Pediatric Sedation Policy for Non-Anesthesiologists

I. Description

Requirements for the management of pediatric patients receiving procedural sedation are explained below. The intent of this policy is to provide a consistent standard of care throughout the Hospitals and Ambulatory Care Clinics for the management of pediatric patients receiving sedation/analgesia when undergoing therapeutic or diagnostic procedures. The policy is not intended as a standard order, or to replace clinical judgment, but shall be considered minimum requirements when sedative medications are used.

II. Policy

A. **Exceptions**

- **This policy does not apply to situations in which anesthesia staff is present or to the utilization of sedatives and analgesics for:**
    a. Management of baseline, non-procedure related pain and/or anxiety, seizures, or physiological symptoms;
    b. Pre-medication of patients prior to surgery or chemotherapy;
    c. Patients who are intubated and on ventilatory support in the Emergency Department or in an Intensive Care setting; or
    d. The administration of a single agent for the sole purpose of achieving minimal sedation (old terminology anxiolysis).
    e. For use of Nitrous Oxide greater than or equal to 50% in pediatric procedural sedation refer to Nitrous Oxide for Pediatric Sedation (Restricted)

B. **Definitions**

- Definitions of levels of sedation/analgesia are as defined by the American Society of Anesthesiologists Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists.
    - Minimal Sedation (old terminology: anxiolysis)
        - Minimal sedation is defined as 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 not.
    - Moderate sedation (old terminology: conscious sedation)
        - Moderate sedation is defined as 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
        - Deep sedation/analgesia is defined as a drug-induced depression of consciousness during which patients cannot be aroused easily but respond purposefully following repeated or noxious stimulation. The ability to independently maintain ventilatory function and a patent airway may be compromised. Cardiovascular function is usually not impaired. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes.
    - General anesthesia
        - General anesthesia is defined as a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Anesthetized patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

C. **Differences between Moderate Sedation and Deep Sedation**

Moderate Sedation	Deep Sedation
Depressed level of consciousness	More significantly depressed Level of consciousness
Follows commands	Unable to consistently follow commands
Protective reflexes expected to be maintained	Protective reflexes can be affected

Vital signs expected to remain stable	Vital signs may be labile
Short post-procedure stay	Occasional prolonged Post-procedure monitoring
Infrequent sedation-related complications	More frequent sedation-related complications

The transition from minimal sedation to moderate sedation to deep sedation, and from deep sedation to general anesthesia is a continuum. This transition can be difficult to predict and must be anticipated whenever sedation is administered. If this transition is not appreciated and appropriate measures not taken, the child's condition can rapidly deteriorate resulting in hypoxemia, hypotension, respiratory arrest, cardiac arrest and even death.

D. **Qualifications (See Attachment A)**

- **A qualified practitioner's order is required for all sedations.**
  - A qualified practitioner is a physician or advanced practice provider who has successfully completed all pediatric sedation credentialing requirements and has privileges to administer pediatric sedation outside the operating room.
  - Sedation providers must successfully complete competency testing during each credentialing and re-credentialing period. Clinical professionals monitoring sedation procedures or administering medications under a privileged physician or advanced practice provider must successfully complete competency testing at least every two years.
  - Individuals administering sedation shall do so on the order of a qualified physician or advanced practice provider. A resident physician with privileges to administer sedation must be supervised by a qualified attending physician.
  - A competency-trained registered nurse may administer sedation/analgesia with an order from, and under the supervision of, a qualified physician or advanced practice provider privileged to sedate pediatric patients.
  - A qualified physician or advanced practice provider is ultimately responsible for ensuring that appropriate care is provided to the child during all phases of sedation. A qualified physician or advanced practice provider will be designated to be responsible for the sedation, including assessment and monitoring during the pre, intra, and post sedation phases.

E. **There must be sufficient numbers of qualified staff present to:**

- Evaluate the patient, assist with the procedure; provide sedation, monitor, and recover the patient. The person evaluating the response of the patient to sedation must not be the person performing the procedure. The person monitoring the patient must be in constant attendance and be able to initiate and assist with life support measures.

F. **Sedation/analgesia is provided in areas where:**

- Personnel have had competency-based education, training, and experience in evaluating patients before providing sedation, monitoring patients during and after sedation, airway management, CPR, set up of equipment for care and resuscitation, use of necessary medications, ability to manage IV lines and the ability to distinguish lethal arrhythmias.+
- Sedation may only be performed in treatment areas with appropriate equipment and trained staff.

G. **Patients for Whom Adult Sedation Policy and Procedures May Be Applicable:**

- A patient aged 14 to 17 years may be considered appropriate for adult sedation policy and procedures if that patient is 40kg or greater and post-pubescent without chronic pediatric disease. Patients aged 18 and older are appropriate for adult sedation policy and procedures.

III. Procedure

A. **Emergency Equipment Needed**

1. Oxygen delivery system capable of 15 liters/min flow rates for greater than 60 min;
2. Oxygen saturation monitor and appropriate sized pulse oximeter probe;
3. Appropriate sized ambu bag & mask, oral airways, laryngoscope, endotracheal tubes and laryngeal mask airways;
4. Suction;
5. Emergency drugs, including reversal and resuscitative agents;
6. Blood pressure monitoring capability;
7. Intravenous line at the option of the responsible physician. In all instances, an individual with the skills to establish intravenous access must be immediately available;
8. Continuous EKG monitor and defibrillator with appropriate sized paddles or patches; and
9. End tidal carbon dioxide monitoring device.

B. **Monitoring and Documentation**

- Standard templates for pediatric sedation will be used throughout the hospital system.
    - Pre-Procedure
        a. A qualified physician or advanced practice provider will obtain written informed consent from the child's legal guardian and verbal assent (where possible) from the patient prior to the start of the procedure. This consent process must include a detailed discussion of the need for sedation, the risks, benefits and alternatives (if any). No sedation shall be initiated until the consent form is signed, witnessed and placed on the patient's medical record. In the event that the patient's legal guardian is

unavailable, appropriate hospital policy must be followed.

b. A qualified physician or advanced practice provider must document a baseline history and physical assessment related to sedation/analgesia on the patient care record as part of the pre-procedure assessment.
    - The history must include the following:
        - Age
        - Drug allergies
        - Recent or current illness
        - Major illnesses or congenital defects
        - Previous hospitalizations, surgeries, sedations and anesthesia
        - Previous problems with anesthesia/sedation
        - Current medication use (including opioid and sedative use in the past 24 hours)
        - Time and type of last enteral intake (i.e., solids, liquids, clears, breast milk)
    - The assessment must include the following:
        - Weight in kilograms
        - Assessment for risk of airway compromise (i.e., dysmorphic facies, tonsillar hypertrophy,history of obstructive sleep apnea or snoring)
        - Respiratory and cardiovascular status
        - ASA status classification score (see Attachment B)
        - A brief neurological examination and determination of developmental status, heart rate, blood pressure, respiratory rate, oxygen saturation, and temperature.
        - Baseline assessment of pain, where appropriate
        - Baseline sedation score

NOTE:	**Pediatric patients should be NPO according to the following guidelines*:** ▪ **2 Hours for APPROVED Clear Liquids** ▪ **4 Hours for Breast Milk**

	▪ **6 Hours for Formula and Solids** ▪ **8 Hours for heavy or fatty meals**
	APPROVED Clear Liquids ▪ **Water, Apple Juice, Pedialyte, Sprite, Ginger Ale** ▪ **ABSOLUTELY NO broth, Jello, or juice with pulp**

- *Guidelines match the NPO guidelines used by the pediatric sedation service at NC Children's Hospital. In the general and pediatric emergency departments appropriate NPO time for pediatric procedural sedation should be at the discretion of the qualified/ credentialed attending physician, taking into account the patient's past medical history, type of last oral intake, urgency and duration of procedure and choice of medication.

C. **Intra-Procedure**

1. The UNC Medical Center Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery for Non-surgical Areas must be adhered to for all sedations and documented as part of the patient's permanent medical record.
2. Evaluation of the patient's response to the drugs is the primary responsibility of the individual giving the drugs and monitoring the patient and must NOT be the person performing the procedure.
3. During the procedure, oxygen saturation, pulse rate and end tidal carbon dioxide level shall be continuously monitored. Blood pressure, pulse rate, respiratory rate, oxygenation saturation and end tidal carbon dioxide level should be monitored and recorded as part of the permanent record to document care. Charting of blood pressure, pulse, oxygen saturation and end tidal carbon dioxide level should be done at a minimum of five-minute intervals and more often if the patient's condition warrants. Continuous EKG monitoring should be performed on all pediatric patients. The blood pressure monitoring interval may be adjusted during moderate sedations by the individual needs of the patient and clearly documented on the patient's record. It is specifically acknowledged that the stimulus of the inflation of a blood pressure cuff may be undesirable because it may arouse a sleeping child. It is therefore permissible to make the judgment that it will be safe to defer blood pressure measurement in an otherwise stable child when moderate sedation is being performed. In such cases, continuous pulse oximetry, end tidal CO2 monitoring, and visual observation of the child is mandatory.
4. All Sedations excluding general anesthetics must document Pediatric Sedation State Scale (PSSS). See Attachment F. An ideal sedation state is defined as a pain and anxiety free patient who is not moving and has normal vital signs during the

procedure (PSSS Level 2). PSSS must be documented when patient is released and at least one time after procedure start and before procedure ends.

5. Supplemental oxygen may be used to keep oxygen saturation above 92% or at pre-sedation oxygen saturation.
6. Immediate access to support from Anesthesiology, the Pediatric Rapid Response and Pediatric Code Blue Teams must be available throughout the sedation.
7. At no time shall a sedated patient be left unattended by at least one member of the team qualified to sedate a pediatric patient (a Qualified Practitioner, Advanced Practice Provider, or Competency-Trained Registered Nurse).

D. **Post-Procedure**

1. Inpatients - Disposition of an inpatient will depend on the status of the patient. Conditions for leaving the procedure area are as follows:
    a. Non-ICU inpatients will be monitored until awake and alert or returned to the pre- sedation level of consciousness (Attachment C). Transportation of a sedated non-ICU inpatient must be performed by an individual capable of maintaining a patent airway and competent to perform CPR. Sedated patients must be transported on continuous cardiorespiratory monitoring and pulse oximetry with oxygen and an appropriate size facemask and ambu bag immediately available.
    b. ICU and other critically ill patients may be transported back to critical care areas as soon as the procedure is completed. Full cardiovascular monitoring must be maintained during transport and airway support as needed. A qualified physician or advanced practice provider and/or registered nurse must be in attendance during transport.
    c. Non-ICU patients should be monitored for at least one hour following any usage of reversal agents regardless of Aldrete score.
2. Outpatients
    a. Monitoring of vital signs and oxygen saturation will be documented every fifteen minutes until the patient's respiration and level of consciousness (awareness of person, place) return to the pre-procedure baseline level and the oxygen saturation returns to the pre- procedure baseline level, with the patient breathing room air for at least five minutes. Patients may be sent to non-monitored area or discharged to home, without a physician order, by using the Aldrete Scoring System. (Refer to Section III, Discharge Guidelines, this policy and Attachment C.)
    b. Patients receiving sedation/analgesia will be kept in a monitored area if:
        i. The patient does not achieve pre-procedure baseline levels of oxygenation when removed from supplemental oxygen for a five-minute period.
        ii. Reversal agents were required. Patients receiving reversal agents should be monitored for at least one-hour prior to discharge, regardless of Aldrete score. Use of reversal agents is

discouraged and must never be used to expedite discharge.

iii. The patient required supplemental oxygen prior to receiving sedation medications. These patients must meet pre-procedure baseline levels, prior to being sent to a non-monitored area or discharged to home with a physician order

Access to support from Anesthesiology, the Pediatric Rapid Response and Pediatric Code Blue Teams must be readily available throughout the recovery period.

E. **Discharge Guidelines**

1. Patients should be alert and oriented. Infants and patients whose mental status was altered pre-procedure should have returned to baseline.
2. Note: Practitioners must be aware that pediatric patients are at risk for airway obstruction should the head fall forward while the child is secured in a car seat. Parents should be notified of this potential.
3. The Aldrete Scoring System, which may be used without obtaining a physician's order, will be used to determine readiness for discharge. The Aldrete score should be documented on discharge/transfer. The score range is "10" for complete recovery to "0" in comatose patients. Patients may be discharged without physician intervention with a score of "8" or above, provided that activity, respiration, and color on the scale are scored as "2" and circulation and consciousness are scored at "1" or "2". (See Attachment C.)
4. In the outpatient setting, a responsible adult should be provided with written instructions regarding post procedure diet, medications, activities, and a phone number to use in case of emergency.
5. Outpatients should be discharged to a responsible adult who assumes responsibility for transport and who has been educated to post-procedure complications and the appropriate reporting mechanism.

F. **Consultation in Special Situations**

- In patients with significant underlying medical conditions (e.g., cardiac, pulmonary, hepatic, or renal disease; pregnancy; drug or alcohol abuse), pre-procedure consultation with an appropriate medical specialist may be helpful.
- In patients with significant sedation-related risk factors (e.g., morbid obesity, potentially difficult airway, significant medical history), pre-procedure consultation is required from an intensivist or anesthesiologist.
- For severely compromised or medically unstable patients, practitioners who are not trained in the administration of general anesthesia must consult an anesthesiologist or pediatric intensivist.

G. **Responsibility and Performance Improvement**

- The Pediatric Sedation Committee is responsible for overseeing the performance improvement process for assessing outcomes in patients receiving moderate/deep sedation.

- All departments utilizing pediatric moderate/deep sedation will be responsible for monitoring continuous quality outcomes through data entry in the Pediatric Sedation Research Consortium Database (PSRC) for benchmarking. or through the use of the standard "Outcome Evaluation" tool with quarterly reporting to the UNC Performance Improvement and Patient Safety Department. The outcome evaluation tool may be ordered from Central Distribution. Participation in the PSRC quality improvement database can be accomplished through assistance from the Pediatric Sedation Committee.
- Unusual, unanticipated, or adverse events shall be reported to Risk Management through the SAFE reporting tool (formerally Patient Occurrence Reporting System).
- The Pediatric Sedation Committee will meet semi-annually to review outcomes data, and the policy and protocols. Any committee member may call a special meeting at any time if a problem develops that requires urgent review or a change in process.

H. **Propofol Deep Sedations**

- The use of Propofol for deep sedations in pediatric patients is considered separately and is outlined in the Pediatric Propofol Policy. (See Attachment D and Attachment E.)

I. **Guidelines for alternative medication and non-medication approaches to sedation in children for short procedures and imaging studies including computed tomography scans (CT), intravenous (IV) starts, echocardiogram, magnetic resonance imaging (MRI), positron emission tomography (PET), X-rays and nuclear medicine scans:**

- For infants 0-3 months old, attempt to obtain imaging scans without medication. Recommend to feed and swaddle the infant. If feed and swaddle fails, consult the Pediatric Sedation Team. Consider using 24% sucrose solution with a pacifier or syringe when attempting short imaging scans and IV starts to decrease pain.
- For developmentally and age appropriate children requiring other short procedures or scans, utilize a Child Life Specialist (CLS). The CLS can offer developmentally appropriate interventions such as distraction to reduce fear, anxiety and pain for children undergoing procedures without the use of medications.
- For developmentally and age appropriate children (ages 4+) requiring an MRI, discuss and offer the option to watch a movie while getting the MRI by utilizing the MRI compatible goggles and headphones.
- For PIV placement and phlebotomy draws consider CLS, topical anesthetic cream or spray, Buzzy Bee and distraction.

IV. Reference

Coté CJ, Wilson S, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016. *Pediatrics.* 2016; 138(1):e20161212

Cravero, J., Askins, N., Sriswasdi, P. et al (2017). Validation of the pediatric sedation state scale. *Pediatrics*, 139 (5). doi: 10.1542/peds.2016-2897.

V. Related Policies

Nitrous Oxide for Pediatric Sedation (Restricted)

Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery for Non-surgical Areas

Attachments

Attachment A Requirements for Individual Credentialing.docx

Attachment B American Society of Anesthesiology Physical Status Classification.docx

Attachment C Aldrete Scoring System and Arousal Scale (2).docx

Attachment D Pediatric Propofol Guidelines for Emergency Department.docx

Attachment E Pediatric Propofol Guidelines for Pediatric Intensive Care Unit.docx

Attachment F Pediatric Sedation State Scale (PSSS) (2).docx

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Kimberly Novak-Jones: Nurse Educator	05/2023
CMO/VP Medical Affairs	Thomas Ivester: CMO/VP Medical Affairs	05/2023
VP Assoc CNO	Jacqueline Jacobs: Assoc CNO UNCH	04/2023
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