I. Description

Requirements for the management of pediatric patients receiving procedural sedation. This policy is intended to promote high quality patient care during sedation. 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. Rationale

The intent of this policy is to provide a consistent standard of care throughout the UNC School of Dentistry Clinics for the management of pediatric patients receiving sedation/analgesia when undergoing therapeutic or diagnostic procedures.

III. 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:
   1. Management of baseline, non-procedure related pain and/or anxiety, seizures, or physiological symptoms;
   2. The administration of a single agent for the sole purpose of achieving anxiolysis.

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.

1. Minimal Sedation (anxiolysis)

Mineral 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.

2. Moderate 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.

3. 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.
4. 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.

**Differences between Moderate Sedation and Deep Sedation**

<table>
<thead>
<tr>
<th>Moderate Sedation</th>
<th>Deep Sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>depressed level of consciousness</td>
<td>more significantly depressed level of consciousness</td>
</tr>
<tr>
<td>follows commands</td>
<td>unable to consistently follow commands</td>
</tr>
<tr>
<td>protective reflexes expected to be maintained</td>
<td>protective reflexes can be affected</td>
</tr>
<tr>
<td>vital signs expected to remain stable</td>
<td>vital signs may be labile</td>
</tr>
<tr>
<td>short post-procedure stay</td>
<td>occasional prolonged post-procedure monitoring</td>
</tr>
<tr>
<td>infrequent sedation-related complications</td>
<td>more frequent sedation-related complications</td>
</tr>
</tbody>
</table>

The transition from anxiolysis 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.

**C. Qualifications Competency Requirements**

1. Faculty, residents and fellows must be ACLS or PALS certified.

2. Supervising faculty must hold an active North Carolina sedation permit and satisfy all requirements for that permit, including certification in Basic Life Support annually.

3. During moderate sedation, a designated individual, other than the practitioner performing the procedure, should be present to monitor the patient throughout procedures performed with sedation. This individual may assist with minor, interruptible tasks once the patient’s level of sedation-analgesia and vital signs have stabilized, provided that adequate monitoring for the patient’s level of sedation is maintained.

**D. 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.
E. 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.

F. 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.

IV. 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
4. Suction
5. Emergency drugs, including reversal and resuscitative agents;
6. Blood pressure monitoring capability;
7. Intravenous line at the option of the responsible provider. In all instances, an individual with the skills to establish intravenous access must be immediately available;
8. End tidal carbon dioxide monitoring device.

B. Monitoring and Documentation : Pre-Procedure
1. A qualified dentist or nurse 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 SOD policy must be followed.
2. A qualified dentist, physician or nurse 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 Appendix)
- 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 for solid foods for six hours prior to elective procedures. Children may have clear liquids up to two hours prior to the procedure.

C. Intra-Procedure

1. During the procedure, 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.

2. 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.

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 are mandatory.

3. All pediatric patients, unless medically contraindicated, should receive supplemental oxygen throughout the sedation period, regardless of baseline oxygen saturation.
4. Immediate access to support from the SOD emergency team (OMFS) must be available throughout the sedation.

5. At no time shall a sedated patient be left unattended.

D. Post-Procedure
   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 by using the Aldrete Scoring System. (Appendix)

   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.

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.

      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.

   2. The Aldrete Scoring System, which may be used without obtaining a dentist'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 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 Appendix)

   3. 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.

   4. Patients 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 a physician.

Severely compromised or medically unstable patients may not be sedated at the School of Dentistry.
APPENDIX

American Society of Anesthesiology Physical Status Classification

<table>
<thead>
<tr>
<th>ASA Physical Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Normal, healthy patient</td>
</tr>
<tr>
<td>2</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>4</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>5</td>
<td>A moribund patient who is not expected to survive without the operation/procedure</td>
</tr>
</tbody>
</table>

ALDRETE SCORING SYSTEM AND AROUSAL SCALE

<table>
<thead>
<tr>
<th>Aldrete Scoring System</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Voluntary movement of all limbs to command</td>
</tr>
<tr>
<td></td>
<td>Voluntary movement of 2 extremities to command</td>
</tr>
<tr>
<td></td>
<td>Unable to move</td>
</tr>
<tr>
<td></td>
<td>Respiration</td>
</tr>
<tr>
<td></td>
<td>Breathe deeply and cough</td>
</tr>
<tr>
<td></td>
<td>Dyspnea, hypoventilation</td>
</tr>
<tr>
<td></td>
<td>Apneic, Unable to move</td>
</tr>
<tr>
<td></td>
<td>Circulation</td>
</tr>
<tr>
<td></td>
<td>B/P + 20% of preanesthetic level</td>
</tr>
<tr>
<td></td>
<td>B/P + 20% - 50% of preanesthetic level</td>
</tr>
<tr>
<td></td>
<td>B/P + 50% of preanesthetic level</td>
</tr>
<tr>
<td></td>
<td>Consciousness</td>
</tr>
<tr>
<td></td>
<td>Fully awake</td>
</tr>
<tr>
<td></td>
<td>Arousable</td>
</tr>
<tr>
<td></td>
<td>Unresponsive</td>
</tr>
<tr>
<td></td>
<td>Color</td>
</tr>
<tr>
<td></td>
<td>Pink</td>
</tr>
<tr>
<td></td>
<td>Pale, dusky, blotchy, jaundice, other</td>
</tr>
<tr>
<td></td>
<td>Cyanotic</td>
</tr>
</tbody>
</table>

The score should be documented at discharge/transfer below.

The range is 10 for complete recovery to 0 in comatose patients. Patients may be discharged without physician intervention with a score of 8, providing that activity, respiration, and color on the scale are scored as “2” and circulation and consciousness.
are scored at “1” or “2”.