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I. POLICY

It is the policy of UPMC to provide safe care to patients receiving moderate sedation for invasive therapeutic or diagnostic procedures.

Links to policies referenced within this policy can be found in Section X.

II. PURPOSE

At UPMC, we seek to ensure that patients are provided consistent administration of agents and monitoring before, during, and after procedures involving sedation. This policy does not apply to medication administered for pain control, seizure control, sedation for mechanical ventilation, minimal sedation, and emergency intubation or other life /limb saving emergency procedures.

III. DEFINITIONS

Administration of sedatives and /or anesthetic drugs for the above purpose encompasses the following:

A. Minimal Sedation (anxiolysis)

This is 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.

This policy does not address the use of minimal sedation. However, the nurse or qualified practitioner must realize and be prepared to deal with the minimal sedation leading to a deeper state of sedation in some patients.

B. Moderate sedation/analgnesia (“conscious sedation”)

This is an intentional 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.

C. 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. Cardiovascular function is usually maintained. (Note: While the definition of deep sedation is included, the conduct and policy for administering deep sedation is located separately).

D. Anesthesia

Consists of general anesthesia and spinal or major regional anesthesia. General anesthesia is any drug-induced loss of consciousness during which patients are not arousable even by painful stimulation for any period of time. The ability to independently maintain ventilatory function is often impaired. 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. Anesthesia is to be induced only by those persons trained and credentialed in the conduct of general anesthesia.

IV. SCOPE

The scope of this policy is limited to moderate sedation as described above (III.B.) These guidelines pertain to all clinical areas in which diagnostic and/or therapeutic procedures are performed using moderate sedation.

The conduct of deep sedation and general anesthesia is specifically excluded from this Policy HS-HD-CP-05, Guidelines for Administration of Planned Moderate Sedation for Therapeutic or Diagnostic Procedures. The conduct of deep sedation is addressed in Guidelines for Administration of Deep Sedation, Policy HS-HD-CP-06.

V. CREDENTIALS, COMPETENCY, AND EDUCATION

Licensed Independent Practitioners ordering moderate sedation must be specifically privileged as per Medical Staff privileging requirements. Board eligible or certified Anesthesiologists, Critical Care Medicine Physicians, and Emergency Medicine (including Pediatric Emergency Medicine) Physicians are granted this privilege if requesting by virtue of the core competencies associated with these specialties. Individual UPMC sites may create a sedation service where appropriately trained and credentialed licensed independent practitioners exist to deliver the care needed.
A. Requirements for all patients receiving moderate sedation

1. Personnel

   a. A Licensed Independent Practitioner (LIP) outside of above groups, who maintains current Advanced Cardiac Life Support (ACLS) or Advanced Trauma Life Support (ATLS) certification and who is familiar with this policy, must be immediately available during the sedation and until the procedure is complete and the patient’s vital signs and state of consciousness have returned to baseline. Pediatric Advanced Life Support (PALS) or Advanced Pediatric Life Support (APLS) current certification is required if requesting this privilege in children (under age 14 yrs.), or at Children’s Hospital, and the American Academy of Pediatrics Neonatal Resuscitation Program certificate is accepted for those caring for only neonates. The LIP is responsible for ordering the medication including dose, route, frequency, interval, and with understanding the pharmacology and complications associated with the drugs. The LIP is responsible for identifying and treating airway compromise, managing overdoses related to the use of a specific agent, managing hemodynamic instability and cardiopulmonary distress. The competency to provide moderate sedation must be documented in the LIP’s privileges and scope of practice.

   b. Registered nurses (RN) who maintain current Advanced Cardiac Life Support (ACLS) certification, or have completed the Pediatric Sedation Course and maintain at least BLS certification, and who are familiar with this policy, with further competency in the use of the physiologic monitoring required, emergency response and management, and identification of complications associated with sedation can administer sedatives under the direction and supervision of the privileged LIP.

   c. Continuous monitoring of the patient must be performed as outlined in the policy below, by an individual trained to recognize signs of airway compromise, hemodynamic instability, and complications of sedative agents. This individual cannot be actively involved in the diagnostic or therapeutic procedure as the LIP or assisting or circulating during the procedure.

   d. The use of Propofol, Etomidate, or Ketamine (latter by any parenteral route) can only be administered when used for moderate sedation under the direct supervision of those also specifically privileged as per the Deep Sedation policy HS-HD-CP-06 that have the training and ability to rescue a patient from general anesthesia.
VI. **PRE-PROCEDURE REQUIREMENTS**

1. Outside of emergency settings and conditions, informed consent must be obtained for the procedure being performed and for moderate sedation. The consent will include an explanation of the risks, benefits, alternatives, and options of sedation.

2. A pre-procedure assessment shall be completed by the LIP prior to administering sedation. The pre-procedure assessment shall include history of airway problems, history of previous untoward effect with moderate or deep sedation, airway assessment, NPO status (see Table VI), and all significant health history with the review of documented age and weight to determine that the patient is an appropriate candidate for the planned procedure and sedation.

3. The classification of the patient’s physical status as outlined by the American Society of Anesthesiologists (ASA) will be determined by the performing physician as part of the pre-procedure assessment. The ASA criteria are as follows:

   - **Class 1** - A normal, healthy individual
   - **Class 2** - A patient with a mild systemic disease.
   - **Class 3** - A patient with a severe systemic disease that limits activity but is not incapacitating
   - **Class 4** - A patient with an incapacitating systemic disease that is a constant threat to life.
   - **Class 5** - A moribund patient who is not expected to survive 24 hours with or without the procedure.

   **E - Emergency.** May be used in conjunction with any of the above.

4. Airway Classification may be determined with the “Samsoon’s Modification of Mallampati’s Airway Classes” chart by the Privileged Provider. (Refer to Table VIII). Documentation of the airway assessment is by circling the picture of the associated airway or noting class in the record.

5. Each pre-sedation assessment, if all screening above is deemed satisfactory, will consist of a baseline “WAKE score” value or a Children’s Hospital of Pittsburgh of UPMC pre-sedation assessment. A neonatal equivalent assessment may be used in this population. All patients not managed under a Children’s protocol should have all WAKE score parameters evaluated before the procedure sedation is given, before the procedure is begun, and/or before entering the procedure room. These parameters include preoperative pain score with movement, room air oxygen saturation, blood pressure in a sitting or reverse-Trendelenburg tilted-table position (exemption for patients with clinical contraindications). In addition, the presence of Zero Tolerance Criteria, i.e. nausea, vomiting, shivering, and lightheadedness should be either ruled out, or clearly documented as a baseline characteristic that was treated or refractory to treatment. The remainder
of the itemized WAKE score assessment is detailed later in this document (SEE TABLE VII).

6. The LIP performing the procedure will at his/her discretion consult the Department of Anesthesiology or the sedation service at the Children’s Hospital of Pittsburgh of UPMC for patients with an ASA rating of Class 3 or greater. Additional guidelines for the selection of patients who would benefit from Department of Anesthesiology coverage are attached to this policy. See attached “List of Preconditions to Identify Anesthesiology Coverage.”

7. A pre-sedation plan is developed to meet the patient needs identified through the pre-procedure assessment.

8. Patient must have a patent intravenous access with running fluids to facilitate the administration of additional sedation and resuscitative medications, to ensure the medications are circulating appropriately, and to decrease venous irritation. Exceptions include those patients receiving oral or IM moderate sedative medications, notably children, given in the absence of IV access.

9. An immediate pre-induction reassessment will be performed and authenticated by the physician. The LIP will document the presence of any changes as well as the absence of any changes. Vital signs will be assessed and documented immediately prior to induction.

10. An oxygen source and method to provide positive pressure ventilation will be available. Suction and suction catheters suitable for effectively clearing upper airway secretions or vomitus will be available. An emergency crash cart will be available for immediate use including emergency airway equipment availability.

11. Use of capnography during the procedure is strongly recommended when patients are at high risk or have experienced a previous untoward event with moderate sedation.

   a. These include but are not limited to:

   1. patient with obesity or evidence of any anatomic or physiologic airway access impairment
   2. patient with respiratory disease
   3. patient with history of sleep apnea
   4. patient with cardiac disease
   5. when the patient will be physically separated from the caregiver (i.e. CT, MRI)

   b. Capnography may be used for any patient at the discretion of the physician.

   c. A baseline reading can aid before the administration of sedation.
VII. INTRA-PROCEDURE REQUIREMENTS

1. A LIP will order the medications to achieve sedation and is immediately available when the medication(s) are administered for moderate sedation. Sedation will be administered by an RN or LIP with slow, incremental titration of the drug while maintaining verbal contact with the patient and observing the patient’s response closely during and after the administration of these drugs. Supplemental oxygen may be administered as indicated to support SaO2 > 90%.

2. When providing sedation to older patients (> 70 years old) time should elapse (at least 3 minutes) between incremental doses, with dosage titrated to patient response. Reduced total doses of all agents should be used along with closer observation for older patients who have received combination therapy.

3. Medications that may be administered by an RN are delineated and approved by Pharmacy and Anesthesiology Services. (See Table I and II).

4. In addition to the availability of suction equipment, a table of “Measures to Reduce the Risk or Complications of Aspiration” (Table V) is attached to this policy for patients who have not maintained NPO status due to emergent treatment.

5. Monitoring parameters: continuous monitoring of respiration via oxygen saturation (Sp02) via pulse oximetry, blood pressure, heart rate with ECG monitoring, level of consciousness, and pain level are documented. Parameters will be documented immediately before the initial administration of sedating agent; after each administration of sedating agent; at least every five minutes during the procedure; and following any change in patient status.

The patient’s response to verbal commands during the procedure performed under moderate sedation will serve as a guide to their level of consciousness and documented according to the following:

1. Anxious and agitated or restless or both
2. Cooperative, oriented and tranquil
3. Responds to commands only
4. Brisk response to light tactile or loud auditory stimulus
5. Sluggish response to light tactile or loud auditory stimulus
6. No response to light tactile or loud auditory stimulus

*Exception*: Any monitor that interferes with the accuracy or reliability of any diagnostic procedure (e.g., during MRI) may be removed at the discretion of the physician performing the procedure. The RN monitoring the patient must increase his/her level of vigilance of the patient in this instance. Pediatric patients will have all monitors in place throughout, and use MRI-safe materials as needed.
6. An RN performing the sedation will continuously monitor the patient receiving sedation and provide care throughout the procedure and/or until the patient is recovered according to discharge criteria. The RN monitoring the patient will have no other responsibilities during the procedure that may interfere with the continuous monitoring of the patient’s response to the sedation. Additional personnel must be available to assist if needed.

7. If during continuous monitoring the patient exceeds the level of planned sedation (for moderate sedation achieving a level “6” as outlined in the guide above exceeds moderate sedation as defined in section III of this policy), no additional sedative drugs will be delivered until the level of consciousness returns to the level of planned sedation as defined in section III of this policy.

8. Emergency/resuscitative equipment will be immediately available based upon age-and size-appropriateness. The following equipment will be available: a code cart including resuscitation medications; intravenous access equipment; intravenous fluids; and life support equipment; suction; non-invasive blood pressure monitoring device; pulse oximetry; electrocardiograph; and sedative/analgesic antagonists. There will also be immediate access to personnel who are experts in airway management and advanced life support by calling a Condition A or C.

VIII. POST PROCEDURE REQUIREMENTS

1. The RN may transfer the patient from the post-procedure/recovery area based on the following guidelines:

   A. Documentation of the WAKE Score (Table VII) or Children’s/neonatal equivalent score will be completed at a minimum of every fifteen minutes times two, then a minimum of every 30 minutes until discharge from the unit. For Children’s Hospital of Pittsburgh of UPMC, this is every fifteen minutes times 4 for a minimum 60 minutes of recovery prior to discharge from the unit. For children less than 12 months of age, they shall be recovered for a minimum of two hours prior to discharge.

   B. Once patients who meet WAKE criteria (score of 8+ out of 10, plus meeting all of the listed “Zero Tolerance Criteria (nausea, vomiting, shivering and lightheadedness) or return to a baseline Children’s score, they may be transferred to a lower ratio of nursing care within the given procedural recovery unit (e.g., shifted from a 1:2-3 nurse-to-patient ratio to a 1:4-6 ratio, or similar pattern consistent within an individual unit’s policy and procedure for staffing based on level of care intensity. However, during the Pre-Procedure assessment, if an outpatient is determined to have OSA, then a WAKE Score of 9 out of 10, plus meeting all of the “Zero Tolerance Criteria is necessary before transfer to a procedural recovery area.
C. No minimum WAKE score or children’s score is required before transport to an ICU.

D. For return to an inpatient unit, patients must meet WAKE criteria (score of 8+ out of 10, plus meeting all of the listed “Zero Tolerance Criteria.”) A WAKE score of 9 out of 10, plus meeting all of the listed “Zero Tolerance Criteria” are required for all patients diagnosed with Obstructive Sleep Apnea (OSA) or considered to be at risk for OSA by any relevant attending physician of record if transferred to a non-monitored unit.

A sufficient time interval must have passed between the last administration of an antagonist (e.g., naloxone, flumazenil) to prevent re-sedation of the patient. For children, a return to Children’s sedation score baseline is also adequate.

Note: One exception: If the patient is diagnosed with Obstructive Sleep Apnea and received IV opioids during procedure, apply a "WAKE 9 Plus Time" with Time = 30 consecutive undisturbed minutes without an apneic episodes before sending to the next Phase. (i.e., WAKE 9 plus Time PACU before Phase 2 would not force OSA patient to wait an additional 30 min in Phase 2 if WAKE had been 9+ throughout, but Phase 2 to home without having gone thru a Phase 1 would require the 30 additional uninterrupted minutes without apnea in Phase 2.

Finally, there must be no excessive bleeding or drainage.

E. For discharge home, patients must have returned to the pre-procedural or baseline WAKE Score (Table VII) or a CHP of Pittsburgh sedation score; a sufficient time interval must have passed between the last administration of an antagonist (e.g., naloxone, flumazenil) to prevent re-sedation of the patient, and there must be no excessive bleeding or drainage. Pediatric patients must be monitored for a minimum of 60 minutes prior to discharge.

In the event of an adverse patient outcome, the physician responsible for the sedation makes the determination of the patient’s disposition post procedure, i.e., PACU, intensive care unit, or admission to the hospital.

2. Discharge Criteria - The patient will be discharged by LIP order, and as part of the WAKE Score/CHP sedation score discharge criteria described above and in Table VII, plus based on any existing policies relevant to the recovery form the specific procedure performed (e.g., a defined number of minutes after an angiography/intravenous catheter is removed).
3. Outpatient/Significant Other Instructions
   a. Outpatients should be discharged with a responsible accompanying person. Patients receiving procedural sedation will be advised pre-procedurally not to drive themselves home after receiving any sedation.
   b. The LIP and/or RN will provide verbal and written instructions to the patient or responsible person accompanying the patient. Information shall include objectives of the sedation and anticipated changes in behavior during and after sedation.
   c. A 24-hour telephone number of the LIP and/or associate shall be available to the patient and/or family.
   d. Instructions shall include limitations of activities, appropriate dietary and medication instructions and follow up care.

IX. OUTCOME MEASUREMENT AND POLICY OVERSIGHT

1. All departments utilizing moderate sedation will adhere to the guidelines for selection, monitoring, and discharge of patients.

2. Adverse events will be reported by submitting an IIER.

3. The responsible division chief or nurse manager of each site administering moderate sedation will monitor monthly patient selection, administration, recovery, and discharge and forward these reports to the Chief of Anesthesiology or designee. At Children’s Hospital of Pittsburgh of UPMC, the responsible division chief or nurse manager will make these available to the Procedural Sedation Committee. The Procedural Sedation Committee reports to the Chief of Anesthesiology as well as the Perioperative Steering Committee.

4. The outcomes listed below will be systematically aggregated, trended, and analyzed by each site and forwarded to the Chief of Anesthesiology or designee. At Children's Hospital of Pittsburgh of UPMC, these outcomes will be forwarded to the Procedural Sedation Committee. Except for Children’s Hospital of Pittsburgh of UPMC, the facility wide outcomes will be reported to the appropriate Operative and Invasive Procedures Committee at least quarterly by the Chief of Anesthesiology or designee:
   a. Use of reversal agents Naloxone or Flumenazil
   b. Unplanned tracheal intubation
   c. Unanticipated hospital admission

5. In addition, a formal case review will be conducted with each of the following events by the responsible division chief or nurse manager and provided to the Chief of Anesthesiology or the Procedural Sedation Committee at Children’s Hospital of Pittsburgh of UPMC:
a. Use of reversal agents Naloxone or Flumenazil
b. Required use of assisted ventilation
c. Drop in Oxygen Saturation to < 90% for more than 5 minutes (unless baseline saturation is normally below 90%, e.g. patients with congenital heart disease)
d. Hemodynamic stability as defined by a 30% change in baseline in blood pressure or heart rate and/or the occurrence of dysrhythmias
e. Unanticipated hospital admission or transfer to ICU within 48 hours of procedure
f. A detailed review of these cases will be collaboratively conducted by the appropriate department / division and Anesthesiology or the Procedural Sedation Committee at Children's Hospital of Pittsburgh of UPMC and forwarded to Quality Management as per the Peer Review Policy.

X. POLICIES REFERENCED WITHIN THIS POLICY

HS-HD-CP-06 Guidelines for Planned Deep Sedation for Diagnostic or Therapeutic Procedures

SIGNED: Donald M. Yealy, MD
Senior Medical Director, Health Services Division, UPMC

ORIGINAL: October 10, 2011

APPROVAL:
Executive Staff: February 29, 2016

PRECEDE: February 27, 2015

SPONSOR: Chairman, Department of Anesthesiology

* With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.

Attachments
LIST OF PRECONDITIONS TO IDENTIFY ANESTHESIOLOGY COVERAGE

1. **PATIENT WITH SEVERE PULMONARY DISEASE**
   - Uses O2 at home
   - Utilizes CPAP for sleep apnea
   - Morbidly obese* patients with impaired breathing while lying flat (orthopneic)

2. **PREDICTED AIRWAY COMPROMISE**
   - Micrognathia (recessed jaw)
   - Inability to flex or extend the cervical spine (i.e. history of spinal fusion, contractures, rheumatoid arthritis)
   - Patient who experienced a previous airway emergency during moderate or deep sedation technique
   - Trisomy 21 patients

3. **PEDIATRIC PATIENTS**
   *Guidelines are institution specific: Please refer to your institution’s individual guidelines

4. **COMPLICATED LASER LEAD EXTRACTIONS** (Individualized for type of lead and other factors such as screw-in-atrial/ventricular lead, etc., upgrading from abdominal site with tunneling of leads to pectoral site)

5. **PATIENT WITH PREVIOUS FAILURE TO COMPLETE STUDY/PROCEDURE UTILIZING MODERATE SEDATION TECHNIQUE**
   *Guidelines are institution specific: Please refer to your institution’s individual guidelines.

6. **Patients with a class ASA 4 or greater.**

   *Morbid Obesity* - 100 lb. above the IBW (ideal body weight) or > 200% of IBW.

   IBW calculations - **Males**: 106 lb. for the first five ft.; then 6 lb. for each inch over 5 ft.
   **Females**: 100 lb. for the first five ft.; then 5 lb. for each inch over 5 ft.

TABLE I: Guidelines for Administration of Sedation and Analgesia for the Adult Patient

The agents listed shall be titrated to effect in accordance with the monitoring standards. The dosing schedule can be modified according to the judgment and practice of the prescribing physician. This list is not intended to be exhaustive (Tables I & II).

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>ROUTE</th>
<th>DOSE</th>
<th>ONSET</th>
<th>DURATION</th>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Midazolam (Versed)</td>
<td>I.M.</td>
<td>2.5 - 5. mg</td>
<td>15 min</td>
<td>1-2 hrs</td>
<td>Do not exceed 2.5 mg/2 min. Do not administer as a bolus dose. Use cautiously for patients with CHF, COPD. Contraindications: Acute angle closure Glaucoma. Reversal Agent: Flumazenil</td>
</tr>
<tr>
<td></td>
<td>I.V.</td>
<td>0.05-0.075 mg/kg Slow I.V. push</td>
<td>1 - 2.5 min</td>
<td>20-40 min</td>
<td></td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>P.O.</td>
<td>1 - 10 mg/day in 2-3 divided doses</td>
<td>60 min</td>
<td>6-8 hrs</td>
<td>Reversal agent: Flumazenil</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>I.V.</td>
<td>25 mcg and repeat q5 min with 25 mcg increments</td>
<td>1-5 min</td>
<td>30-180 min</td>
<td>Total dose: 50-100 mcg/hr. USE 100 mcg/2cc amp when available. Give slowly over 1 min. Reversal agent: Naloxone HOLD for RR &lt; 12.</td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>I.V.</td>
<td>4-15 mg slow IV push (over 4-5 min)</td>
<td>1-5 min</td>
<td>30-180 min</td>
<td>Do not give if respirations are below 12/min. Reversal agent: Naloxone</td>
</tr>
<tr>
<td>Propofol</td>
<td>I.V.</td>
<td>10 – 20 mg incremental doses every 5 minutes</td>
<td>30 sec</td>
<td>10 – 15min</td>
<td>Must have Deep Sedation Privileges – risk of severe hypotension and bradycardia particularly in the elderly, debilitated, cardio-vascular compromised or concomitant beta blocker use. Has minimal to no analgesic effects. Combinations of Propofol with opioid narcotics may produce profound respiratory depression.</td>
</tr>
<tr>
<td></td>
<td>I.M.</td>
<td>0.2 – 1.0 mg/kg May be repeated to a maximum dose of 2mg/kg 1-4 mg/kg</td>
<td>1 – 2 minutes</td>
<td>15 – 30 minutes</td>
<td>Must have Deep Sedation Privileges – produces a cataleptic-like state in which the patient is dissociated from the surrounding environment. Produces intense analgesia and sedation. Can cause hypertension and tachycardia and should be avoided in patients with aneurysms, elevated ICP, or uncontrolled hypertension. Adverse psychotic reactions may be avoided with pretreatment with benzodiazepines. Emergence psychotic reactions may last longer than sedative/analgesic effects. Combinations of ketamine and opioids may produce profound respiratory depression. An increase in oropharyngeal secretions is often triggered and diligent patient monitoring for laryngospasms needs be employed.</td>
</tr>
<tr>
<td>Ketamine</td>
<td>I.V.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Etomidate | I.V. | 0.1 – 0.2 mg/kg slow IV push over 30 secs | 30 sec | 2 – 10 minutes | Must have Deep Sedation Privileges – may cause transient adrenal suppression, high incidence of pain on injection and nausea and vomiting associated with bolus injection. May lower seizure threshold. Have no analgesic properties.

Additional Caution Notes:

(1) There is an increased risk of respiratory and cardiovascular depression with combinations of benzodiazepines and opioids.
(2) Respiratory depression effects may last longer than analgesia; monitor for respiratory depression and apnea.
(3) Use smaller incremental doses in the elderly, patients with COPD, and in chronically debilitated patients.
(4) Use of Narcan (at 0.4 mg dose) to reverse opioid respiratory depression can result in a surge in sympathetic tone, hypertension, and rarely pulmonary edemas.
<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>ROUTE</th>
<th>DOSE</th>
<th>ONSET (min)</th>
<th>DURATION (hour)</th>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral Hydrate</td>
<td>P.O./P.R.</td>
<td>50 -75 mg/kg/dose</td>
<td>10-20</td>
<td>4-8</td>
<td>May cause laryngospasm if aspirated. Starting dose 75 mg/kg. Maximum single dose: Infants (&lt;1 year) - 1 g children (&gt;1 year) - 2 g</td>
</tr>
<tr>
<td>Lorazepam (Ativan)</td>
<td>I.V.</td>
<td>0.05-0.1 mg/kg/dose</td>
<td>15-30</td>
<td>8-12</td>
<td>Maximum dose: 2mg. Do not exceed 2mg/min. or 0.05 mg/kg over 2-5 min. Reversal agent: Flumazenil.</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>I.V.</td>
<td>1-2 mcg/kg</td>
<td>Immediate</td>
<td>30-60 min.</td>
<td>Give IV dose slowly over 3-5 min. to prevent respiratory depression and chest wall rigidity. Respiratory depression may persist beyond the period of analgesia. Reversal agent: Naloxone.</td>
</tr>
<tr>
<td>Midazolam (Versed)</td>
<td>I.V.</td>
<td>0.05-0.1 mg/kg over 2 min. May repeat 0.05 mg/kg prn in 2-3 min intervals up to max total dose of 0.2 mg/kg.</td>
<td>1-5</td>
<td>1-2</td>
<td>Maximum IV concentration: 1 mg/ml; Maximum IV dose: 5mg. Reversal agent: Flumazenil.</td>
</tr>
</tbody>
</table>
Note: CHP medication schedule.

<table>
<thead>
<tr>
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<th>ROUTE</th>
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<th>ONSET (min)</th>
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<td>P.O./P.</td>
<td>50 -75 mg/kg/dose</td>
<td>10-20</td>
<td>4-8</td>
<td>May cause laryngospasm if aspirated. Starting dose 75 mg/kg. Maximum single dose: Infants (&lt;1 year) - 1 g children (&gt;1 year) - 2 g</td>
</tr>
<tr>
<td>(not used on adults)</td>
<td>R.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td>I.V.</td>
<td>0.05-0.1 mg/kg</td>
<td>Immediate</td>
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<td>1-2</td>
<td>Maximum IV concentration: 1 mg/ml; Maximum IV dose: 5mg. Reversal agent: Flumazenil.</td>
</tr>
<tr>
<td>Ketamine</td>
<td>I.V./I.M.</td>
<td>1-2 mg/kg I.V. over 1 min. 3-7 mg/kg I.M. May repeat 0.5 mg/kg</td>
<td>2-3 I.V. 5-10 I.M.</td>
<td>1 I.V. or I.M.</td>
<td>No reversal agent</td>
</tr>
<tr>
<td>Pentobarbital</td>
<td>I.V.</td>
<td>1-3 mg/kg</td>
<td>1-5</td>
<td>15</td>
<td>No reversal agent</td>
</tr>
<tr>
<td>Dexmedetomidine</td>
<td>I.V.</td>
<td>0.5-1 mcg/kg bolus Subsequent infusion: 0.2-0.7 mcg/kg/hr</td>
<td>Immediate</td>
<td>1</td>
<td>No reversal agent Can be administered as an infusion</td>
</tr>
<tr>
<td>Propofol</td>
<td>I.V.</td>
<td>1 mg/kg bolus Subsequent infusion: 120 mcg/kg/min</td>
<td>Immediate</td>
<td>N/A</td>
<td>No reversal agent Can be administered as an infusion</td>
</tr>
<tr>
<td>Nitrous oxide</td>
<td>Inhalation</td>
<td>&gt;50% concentration</td>
<td>Immediate</td>
<td>N/A</td>
<td>No reversal agent</td>
</tr>
</tbody>
</table>
TABLE III: REVERSAL AGENTS

ADULTS

- **Naloxone** (Opioid Reversal) 0.04 mg IV push
  - Dilute 0.4 mg of naloxone in 10 ml of normal saline (1 ml = 0.04 mg) and give in 1 ml increments.
  - If an inadequate response is obtained with this dose, additional 0.04 mg (1 ml) doses may be given every 1 minute until the desired degree of reversal is obtained.
  - *Caution*: Larger than necessary dosages of Narcan may result in significant reversal of analgesia and an increase in blood pressure.

- **Flumazenil** (Romazicon) 0.2 mg IV Push
  - If the desired consciousness is not obtained after one minute, additional 0.2 mg dose may be administered at one minute intervals up to a maximum cumulative dose of 1 mg.
  - If resedation occurs, the initial dosing regimen (i.e., up to 1 mg in divided 0.2 mg doses at one minute intervals) may be repeated no more frequently than every 20 minutes up to a maximum of 3 mg in any one hour period.
  - *Caution*: The effects of both Flumazenil and Naloxone may subside prior to those of the benzodiazepine and therefore, the patient may require additional ventilatory support.
  - *Do not use in patients requiring a benzodiazepine for control of a potentially life-threatening condition or in patients with serious concurrent tricyclic antidepressant overdose.*

PEDIATRIC PATIENTS

- **Naloxone** (Opioid Reversal): 1-10 micrograms/kg/dose IM/IV/SC/ET to 0.4 mg initial dose (may be higher if needed). Repeat PRN q3-5 min.
  - Duration of action is shorter than many opioids and therefore may need multiple doses or a continuous infusion.

- **Flumazenil**: Start with 0.01 mg/kg IV. If no response in 30-60 seconds, repeat dose of up to 0.1-0.2 mg per minute.
  - May repeat above doses to max total cumulative dose of 1 mg in 1 hour.
  - *Do not administer if patient is taking benzodiazepines for seizure control or if child co-ingested a tricyclic antidepressant since administration may precipitate seizures.*
**TABLE IV:** Guidelines from Department of Anesthesiology Regarding Sedation and Analgesia/Sedation

1. The physician shall consider an anesthesia consult for the patient who by history and/or physical exam has an airway abnormality.

2. The physician shall consider an anesthesia consult for the patient with an ASA rating for greater than or equal to 3.

3. The physician shall consider MAC (Monitored Anesthesia Care) for the patient with an ASA rating of greater than or equal to 4.

4. See “List of Preconditions to Identify Anesthesiology Coverage” for additional guidelines.
TABLE V: MEASURES TO REDUCE RISK or Complications OF ASPIRATION in the Adult Patient

The following medications may be used to reduce the risk of aspiration complications when administering systemic sedation (and analgesia).

<table>
<thead>
<tr>
<th>MEDICATION</th>
<th>ROUTE</th>
<th>DOSE</th>
<th>ONSET (min)</th>
<th>DURATION (hour)</th>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Famotidine (Pepcid)</td>
<td>IV</td>
<td>20 mg</td>
<td>&lt;30</td>
<td>10-12</td>
<td>Dilute in 10ml N.S. Inject over 2 min.</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>PO</td>
<td>250 mg</td>
<td>10-15</td>
<td>8-12</td>
<td>250 mg IV infused over 5 min. Approved by PUH-Shadyside Pharmacy and Therapeutics committee as a formulary extension (for the gastric emptying indication) to reduce the side effects and adverse drug interaction potential of metoclopramide (10 mg IV or IM)</td>
</tr>
<tr>
<td></td>
<td>IV</td>
<td>250 mg</td>
<td>2-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Citric Acid</td>
<td>PO</td>
<td>30 cc</td>
<td>60</td>
<td>4</td>
<td>Assess for metabolic alkalosis. Dilute medication in 30 cc of regular water.</td>
</tr>
</tbody>
</table>
TABLE VI: NPO STATUS

Except in emergency situations, the use of sedation must be preceded by an evaluation of recent food and fluid intake.

Widely accepted NPO protocols established to reduce the risk of vomiting and aspiration of gastric contents in patient undergoing elective procedures include the following:

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Solids and Non-clear Liquids*</th>
<th>Clear Liquids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>8 hrs/NPO after midnight</td>
<td>2-3 hours</td>
</tr>
</tbody>
</table>

Note: UPMC Children’s Hospital NPO Guidelines:

2hrs for clears
4 hrs for breast milk
6hrs for formula
8 hrs for solids

WAKE Score v080610

Phase 1 – Phase 2 Patient Recovery Evaluation Criteria and Scoring System after Moderate Sedation


“Phase 1” Recovery Bypass (e.g., a 1:2 nurse-patient ratio) should only be considered when such patients do not require any parenteral interventions for pain, nausea, vomiting, pruritis, shivering, or hypotension/orthostasis/lightheadedness (a.k.a. “Zero Tolerance Criteria”). A score of ≥8 or above, based on the parameters below, is recommended for rapid transition from “Phase 1 Recovery” into “Phase 2 Recovery” (e.g., a 1:4 nurse-patient ratio), along with meeting the Zero Tolerance Criteria.

Patient pain scores should not exceed 3-4 (out of 10, if baseline pain score is ↑ zero) at the time of Phase 1 Recovery Bypass.

<table>
<thead>
<tr>
<th>§ Movement</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purposeful movement of (at least) one lower and one upper extremity</td>
<td>2</td>
</tr>
<tr>
<td>Purposeful movement of at least one upper extremity (but neither lower extremity)</td>
<td>1</td>
</tr>
<tr>
<td>No purposeful movement</td>
<td>0</td>
</tr>
</tbody>
</table>

**Movement Score:**

<table>
<thead>
<tr>
<th><strong>Blood Pressure (BP):</strong> Two evaluations for lightheadedness (with patient sitting on a 45-degree-tilted-gurney) 5-10 minutes apart, within 15-20 minutes of the “End Procedure Time.” BP must be checked at one or both of these evaluations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 20% of pre-procedure baseline, without orthostatic changes/lightheadedness</td>
</tr>
<tr>
<td>Between 20-40% of pre-procedure baseline, without orthostatic changes/lightheadedness</td>
</tr>
<tr>
<td>Less than 40% of pre-procedure baseline, and/or orthostatic changes/lightheadedness</td>
</tr>
</tbody>
</table>

**BP Score:**

<table>
<thead>
<tr>
<th>Level of Consciousness</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awake and/or immediately aroused when called, follows commands without delay</td>
<td>2</td>
</tr>
<tr>
<td>Arousable to stimuli (delayed), exhibits protective reflexes, and follows commands (but delayed)</td>
<td>1</td>
</tr>
<tr>
<td>Obtunded or persistently somnolent; ± protective reflexes; ± following commands</td>
<td>0</td>
</tr>
</tbody>
</table>

**LOC Score:**

<table>
<thead>
<tr>
<th>Respiratory Effort</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coughs and deep-breathes freely, and/or on command</td>
<td>2</td>
</tr>
<tr>
<td>Coughs involuntarily, but not on command; maintains airway without support</td>
<td>1</td>
</tr>
<tr>
<td>Tachypnea, dyspnea or apnea, and/or requiring airway maintenance</td>
<td>0</td>
</tr>
</tbody>
</table>

**Respiratory Score:**

<table>
<thead>
<tr>
<th><strong>Oxygen Saturation</strong></th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\text{SaO}_2 \geq 95% \text{ or } \geq (\text{Pre-procedure reading minus 2}) \text{ without supplemental O}_2$</td>
<td>2</td>
</tr>
<tr>
<td>$\text{SaO}_2 \geq 95% \text{ or } \geq (\text{Pre-procedure reading minus 2}) \text{ with supplemental O}_2$</td>
<td>1</td>
</tr>
<tr>
<td>$\text{SaO}_2 \leq 94% \text{ or } &lt; (\text{Pre-procedure reading minus 2}) \text{ with or without supplemental O}_2$</td>
<td>0</td>
</tr>
</tbody>
</table>

**Saturation Score:**

<table>
<thead>
<tr>
<th>Total Score:</th>
<th></th>
</tr>
</thead>
</table>
Table VII continued: WAKE Score Footnotes
Definitions, Suggestions, and Other Considerations

* The listed nursing ratios are for illustration only; actual nurse-patient ratios should be based on existing policy and procedure statements for the given moderate sedation procedural recovery unit. “Phase 1 Recovery” is defined as “Emergence from Anesthesia.” Typically, moderate sedation patients should not need to “emerge from anesthesia.” However, patients with any “Zero Tolerance Criteria” and/or with a WAKE Score of <8 are recommended to be under the care of a 1:2-3 nurse-patient ratio. “Phase 2 Recovery” is defined as “Preparation for Homegoing;” patients in this category are most commonly appropriate to a less-intensive nurse-to-patient ratio, e.g., 1:4-6). Phase 3 Recovery is defined as “Resuming Normal Activities After Discharge Home.”

In order to evaluate the patient’s discharge readiness from Phase 1, it is required that all patients have all WAKE score parameters evaluated before entering the procedure room (e.g., preoperative pain score with movement, room air oxygen saturation, blood pressure in a sitting or reverse-Trendelenburg tilted-table position (exemption for patients with clinical contraindications) and all other WAKE parameters).

- **For discharge from a post-procedural moderate sedation recovery unit to an ICU, no minimum WAKE score is required.**

- **For discharge to an inpatient floor:** WAKE score ≥8 is required (plus meeting all zero tolerance criteria). A WAKE score of 9 out of 10 is required for transfer to a non monitored inpatient unit in all patients diagnosed with OSA or at risk of OSA.

- **For safe discharge home using WAKE criteria:** WAKE score ≥ baseline WAKE (usually 10, plus meeting all zero tolerance criteria to the extent feasible) is required, along with other criteria for discharge as previously enforced by the specific procedural recovery unit. In other words, patients may, for example, have mild nausea or mild lightheadedness, either or both of which having been appropriately treated, with all other WAKE factors satisfactory, and the patient, family, and attending physician are all agreeable to patient discharge home.

† Patient pain scores that are higher than zero at baseline (with movement) will have their postop pain score criteria (with movement) adjusted to 3-4 units above the baseline pain score. For example, a patient with a baseline pain score of 4 (with movement) is eligible for transition from Phase 1 to Phase 2 Recovery WAKE criteria if the postop pain score with movement is ≤ 7-8, and all other zero tolerance criteria are achieved, and the WAKE score is ≥ 8.

‡ After a moderate sedation procedure, if any health care provider (e.g., moderate sedation recovery unit nurse) evaluates a new patient to have a WAKE score of < 8 (or if any hypotension/orthostasis/lightheadedness is noted), and it appears that these patient care complexities preclude safe nursing care in a 1:2 nurse-to-patient ratio, then that health care provider reserves the right to arrange for immediate patient transport back to a “post-anesthesia care unit (PACU)” within the hospital.
§ In clinical contexts where regional anesthesia is not used (such as in moderate sedation procedural units), the Extremity Movement scores considered before Phase 1 transitions to Phase 2 recovery (or later discharge to home) should be appropriate to the patient’s baseline medical condition.

** Consecutive evaluations for lightheadedness, as described, in the 5-10 minute time frame after “End of Procedure” are required to ensure safe progression from Phase 1 to Phase 2 Recovery (and corresponding nurse-to-patient ratios).

†† The presence of supplemental oxygen (defined as the equivalent of 4L nasal cannula, or less) during transport to an inpatient floor after Phase 2 recovery should never be considered a contraindication for the patient being declared as eligible for discharge from the procedural recovery unit to the floor. The benefits of supplemental oxygen outweigh its risks under all circumstances, assuming the WAKE criteria are met (i.e., ≥8 / 10, with no symptoms from the Zero Tolerance Criteria).

Under any and all circumstances, patients that “numerically” meet WAKE criteria (including Zero Tolerance Criteria), yet are otherwise unsuitable for transition from Phase 1 recovery (e.g., 1:2 nurse-to-patient ratio) to Phase 2 recovery (e.g., 1:4 nurse-to-patient ratio), may be retained in the Phase 1 status assuming that appropriate communication has occurred among all responsible health care professionals involved with the patient. The medical record should then indicate the specific discharge criterion that the involved health care professionals are trying to achieve, and document the details of either achieving the described criterion, or the changing of the patient’s disposition (e.g., “patient retained due to EKG abnormalities that were not present before the procedure”).
Table VIII: Airway Classification

Airway Classification is determined with the “Samsoon’s Modification of Mallampati’s Airway Classes” chart below by the Credentialed Physician.

<table>
<thead>
<tr>
<th>SAMSOON’S MODIFICATION OF MALLAMPATI’S AIRWAY CLASSES</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mallampati Samsoon classes are useful to classify a patient into populations with varying difficulties of intubation. The oral cavity is examined with the patient seated upright, head in neutral position, mouth opened as wide as possible, and tongue protruded maximally.</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>• Class I: soft palate, tonsillar fauces, tonsillar pillars, uvula visualized - “easy” intubation</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>• Class II: soft palate, tonsillar fauces, uvula visualized - “mildly difficult” intubation</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>• Class III: soft palate, base of uvula visualized - “much more difficult” intubation</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>• Class IV: soft palate not visible - “near impossible” intubation</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
</tbody>
</table>