MODERATE SEDATION
A SELF STUDY GUIDE

Part I    Self Study Guide
Part II   ASA Practice Guidelines for Sedation
And Analgesia by Non-Anesthesiologists
Part III  Sedation/Analgesia Policy
Introduction

Diagnostic and surgical procedures are being performed in a variety of settings throughout the hospital. This self-study program has been developed to increase your awareness and reinforce your understanding of the use of moderate sedation. It includes indications/contraindications for moderate sedation, accepted medications administration guidelines, and monitoring requirements. Part I is dedicated to an overall review of the principles of moderate sedation, Part II includes the American Society of Anesthesiology’s Practice Guidelines For Sedation And Analgesia by Non-Anesthesiologist. Part 3 is a post-test. Completion of this self-study packet includes learning the following material, satisfactory completion of the post-test and returning the post-test to the Medical Staff Office. Completion of this self-study is required to qualify for privileges to administer Moderate Sedation at St. David’s Medical Center.

Purpose

The purpose of this self-study packet is to increase and reinforce your knowledge of responsibilities and guidelines associated with the care of individuals requiring moderate sedation. On completion of this self-study program, you should be able to:

1. Recognize indications and contraindication for moderate sedation.
2. State appropriate monitoring techniques and requirements for patients undergoing moderate sedation.
3. Identify medications frequently used for moderate sedation, administration guidelines, and potential complications/side-effects.
4. Evaluate and manage expected and unexpected outcomes of moderate sedation

Part I

Definition

Conscious Sedation more accurately termed Sedation/Analgesia or Moderate Sedation describes a state that allows patients to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal commands and tactile stimulation. Sedation/Analgesia may also be referred to as S/A throughout the remainder of the module. Moderate sedation does not refer to medications given for postoperative pain relief, pre medication, or pain control during Labor & Delivery. The ability to independently maintain a patent airway is an important distinguishing feature of moderate sedation. Moderate sedation of the patient is generally achieved when there is an onset of slurred speech. Deep sedation involves the use of medication to induce a controlled state of depressed consciousness or unconsciousness in which the patient may experience partial or complete loss of protective reflexes including the ability to independently and continuously maintain a patent airway. The deeply sedated patient may not be easily aroused and may not purposefully respond to verbal commands or physical stimulation. Only anesthesia providers may purposefully administer deep sedation. It should be recognized that sedation is a continuum. A patient may progress from one degree of sedation to another
depending on their underlying medical status, the medication(s) administered, dosage and route of administration. It is important therefore that the monitoring and staffing requirements be based on the patient’s acuity and the potential response of the patient to the procedure. Progress from one level of sedation to another requires appropriate changes in monitoring and observation of the patient.

The responsibilities of those care providers, physician or nurse, administering conscious sedation is to prepare and monitor the patient before, during and after the procedure. **Informed consent, including options and risks, for both the procedure and the level of sedation must be obtained prior to the procedure and prior to the patient sedative medication.** For outpatient procedures, before sedating the patient, discharge and follow up instructions may need to be given to the patient and/or the person responsible for transporting the patient post-sedation.

<table>
<thead>
<tr>
<th>Administering Clinicians</th>
<th>Minimal Sedation (Anxiolysis)</th>
<th>Moderate Sedation/ Analgesia (&quot;Conscious Sedation&quot;)</th>
<th>Deep Sedation/ Analgesia</th>
<th>General Anesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVN: po, IM, rectal RN/Physicians: po, IM, IV, rectal</td>
<td>Sedation-trained RN, Credentialed physicians</td>
<td>Anesthesiologist Emergency Medicine</td>
<td>Anesthesiologist Only</td>
<td></td>
</tr>
<tr>
<td>Responsiveness</td>
<td>Normal response to verbal stimulation</td>
<td>Purposeful** Response to verbal or tactile stimulation</td>
<td>Purposeful** Response following repeated or painful stimulation</td>
<td>Unarousable Even with painful stimulus</td>
</tr>
<tr>
<td>Airway</td>
<td>Unaffected</td>
<td>No intervention required</td>
<td>Intervention may be required</td>
<td>Intervention often required</td>
</tr>
<tr>
<td>Spontaneous Ventilation</td>
<td>Unaffected</td>
<td>Adequate</td>
<td>May be Inadequate</td>
<td>Frequently Inadequate</td>
</tr>
<tr>
<td>Cardiovascular Function</td>
<td>Unaffected</td>
<td>Usually Maintained</td>
<td>Usually Maintained</td>
<td>May be Impaired</td>
</tr>
</tbody>
</table>

**Minimal Sedation (Anxiolysis)** 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.

**Moderate Sedation / Analgesia ("Conscious Sedation")** is 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** is 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.**
General Anesthesia is 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. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of a depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue patient who enters a state of deep Sedation/Analgesia (including the ability to manage a compromised airway and provide adequate oxygenation and ventilation).

Monitored Anesthesia Care does not describe the continuum of depth of sedation; rather it describes “a specific anesthesia service in which an anesthesia provider has been requested to participate in the care of the patient undergoing a diagnostic or therapeutic procedure.”

Physician Pre-Procedure Assessment

1. The physician will explain the procedure, S/A options, and the risks, benefits, and alternatives associated with each to the patient.

2. The Sedation/Analgesia Form will be completed by the physician prior to ordering and administering moderate sedation.

3. Complete a thorough assessment to include the following:
   a. ASA classification
   b. Airway assessment
   c. All components of the History and Physical

________________________________________________________________________

The ASA Physical Status Classification System

<table>
<thead>
<tr>
<th>ASA</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>A normal healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>A moribund patient who is not expected to survive without operation</td>
</tr>
<tr>
<td>VI</td>
<td>A declared brain-dead patient whose organs are being removed for a donor purposes</td>
</tr>
</tbody>
</table>
4. Using the findings of the pre-procedural assessment, determine if the patient is an appropriate candidate for moderate sedation. Pregnant patients may not receive S/A from a non-Anesthesiologist and an Anesthesia consult should be considered for patients who have a significant airway restriction and/or a life-threatening, severe systemic disease.

5. Based on clinical findings, the procedure, and the patient’s needs, develop a plan for S/A and document it on the Sedation/Analgesia Form.

6. Re-evaluate the patient immediately prior to administration of S/A.

It should also be determined when the patient last ate and drank. The recommendation is: no solid food or full liquids for at least 6-8 hours or none after midnight and no clear liquids for at least 2-3 hours prior to the sedation. In cases where sedation is part of an emergency procedure, careful clinical judgment is required to determine an appropriate level of sedation that does not place the patient at an unacceptable risk for regurgitation and aspiration. The procedure and sedation may be delayed until the risk is diminished. In cases where the procedure cannot be delayed without causing further harm to the patient, practitioners should take precautions to minimize the risk of aspiration.

In anesthesiology, the Mallampati score, also Mallampati classification, is used to predict the ease of intubation. It is determined by looking at the anatomy of the oral cavity; specifically, it is based on the visibility of the base of uvula, faucial pillars (the arches in front of and behind the tonsils) and soft palate. Scoring may be done with or without phonation. A high Mallampati score (class 4) is associated with more difficult intubation as well as a higher incidence of sleep apnea.

Modified Mallampati Scoring is as follows:
Class 1: Full visibility of tonsils, uvula and soft palate
Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula
Class 3: Soft and hard palate and base of the uvula are visible
Class 4: Only Hard Palate visible

Class 0: visibility of Epiglottis

![Mallampati Scoring](image-url)
Equipment and Supplies

Prior to sedating the patient the health care practitioner needs to assure that all monitoring equipment required for moderate sedation is present and functioning. Since moderate sedation depresses the level of consciousness while allowing the patient to maintain their airway independently, the physician and nurse’s responsibility must focus on assessing parameters that may be impacted by sedating medications. Observations of the patient before, during and after the period of sedation are crucial. Discrete changes in patient status are often observed before noticeable changes in vital signs and other parameters occur. Consistent with the ABC’s of resuscitation –Airway, Breathing and Circulation– the ability to maintain an open airway should be assessed and documented by determining the level of consciousness and arousability of the patient. Baseline level of consciousness prior to sedation should also be assessed and documented. Breathing should be assessed through the use of continuous pulse oximetry and observation of respiratory rate, depth and effort. Circulation should be assured through monitoring of blood pressures, pulse and cardiac rhythm. Hypoxemia is often reflected by cardiac dysrhythmias (especially bradycardia), necessitating the need for continuous heart monitoring throughout the period of sedation and recovery. Hemodynamic changes can reflect physiological alterations such as circulating volume changes, vasoconstriction, vasodilatation and other effects of sedation and/or the accompanying procedure. A patent, operational intravenous site should be established prior to sedation and maintained through the recovery stage of sedation. Resuscitation equipment and personnel skilled in advanced life support including airway management should also be available.

Emergency Equipment for Sedation and Analgesia:
Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The table below should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated.

- Intravenous equipment
  - Gloves
  - Tourniquets
  - Alcohol wipes
  - Sterile gauze pads
  - Intravenous catheters [24- or 22-G]
  - Intravenous tubing [pediatric "microdrip" (60 drops/ml)]
  - Intravenous fluid
  - Three-way stopcocks
  - Assorted needles for drug aspiration, intramuscular injection [intraosseous bone marrow needle]
  - Appropriately sized syringes
  - Tape
- Basic airway management equipment
  - Source of compressed oxygen (tank with regulator or pipeline supply with flowmeter)
  - Source of suction
  - Suction catheters [pediatric suction catheters]
  - Yankauer-type suction
• Face masks [infant/child]
• Self-inflating breathing bag-valve set [pediatric]
• Oral and nasal airways [infant/child-sized airways]
• Lubricant

• Advanced airway management equipment (for practitioners with intubation skills)
  • Laryngoscope handles (tested)
  • Laryngoscope blades [pediatric]
  • Endotracheal tubes
    • Cuffed; 6.0, 7.0, or 8.0 mm ID [Uncuffed; 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, or 6.0 mm ID]
  • Stylet (appropriately sized for endotracheal tubes)

• Pharmacologic antagonists
  • Naloxone
  • Flumazenil

• Emergency medications
  • Epinephrine
  • Ephedrine
  • Atropine
  • Lidocaine
  • Glucose, 50% [10% or 25%]
  • Diphenhydramine
  • Hydrocortisone, methylprednisolone, or dexamethasone
  • Diazepam or midazolam
  • Ammonia spirits
Agents Used for Moderate Sedation

Moderate sedation is achieved by administering pharmacological agents. The most common route of administration is intravenous (although medications may be given orally (PO), rectally, intramuscularly (IM), subcutaneous (SQ), or nasally. The most commonly used agents are benzodiazepines, narcotics, barbiturates, and certain hypnotics (such as chloral hydrate).

The agents used depend on the type, duration and intensity of the procedure. Physicians and nurses who do not have privileges in anesthesiology should not administer drugs classified as anesthetic agents, including but not limited to, ketamine, sodium pentothal, methohexital, etomidate and nitrous oxide. Differences in patient’s health status with variable ability to metabolize medications should be considered when selecting and administering the medications. The nurse is responsible for validating the physician’s order, obtaining the medications, and assuring administration of medications according to the hospital’s policy. This includes the **right medication** in the **right dose**, to the **right patient**, over the **right time frame and the right route**. All medications, including reversal agents, should be documented on the appropriate patient permanent record.

Moderate sedation is achieved using the same medications and delivery methods used for anesthesia and deep sedation. Health care providers monitoring the sedated patient must demonstrate knowledge of anatomy, physiology, dysrhythmia recognition, complications related to moderate sedation, and knowledge of the pharmacology of the medications and the reversal agents. They must also have the skills necessary to assess, diagnose, and treat any complications that may arise.

The **importance of incremental dosing of these sedative agents cannot be over emphasized**

Benzodiazepines

Benzodiazepines have anti-anxiety, anti-convulsing, sedation, muscle relaxation, and amnesic properties. The medications used in the Operating Room in this category are midazolam (Versed) and diazepam (Valium).

Midazolam (Versed) is a short acting benzodiazepine CNS depressant. It is indicated for moderate sedation prior to short diagnostic or surgical procedures, either alone or with narcotic. It may be administered IV, IM, PO, rectally, or nasally. The most common route of administration is IV.

Midazolam is a potent sedative agent that must be given slowly. Administration over 2 or more minutes is prudent. Never give as a single large bolus dose. Rapid or excessive IV doses may result in respiratory depression or arrest. If not recognized and treated promptly, death or hypoxic encephalopathy may result.

The initial IV dose may be as little as 0.5-2.0mg, but should not exceed 2.5mg in a healthy adult. It should be titrated to the desired effect. Slurred speech is an excellent indicator of an adequate dose. Lower doses should be used for patients over 60 years of age, debilitated patients, or patients receiving narcotics.
Sedation after IV injection is usually achieved within 3 to 5 minutes. The duration of effect ranges from 1 to 6 hours after IV injection. The half-life ranges from 1.2 to 12.3 hours.

Midazolam should not be used on patients with known benzodiazepine hypersensitivity or acute narrow-angle glaucoma. Adverse reactions from IV administration include hiccups, nausea, vomiting, over sedation, headache, coughing, and pain at the injection site.

Diazepam (Valium) has been replaced for the most part by midazolam but still used occasionally for moderate sedation and as a premedication for non-painful procedures. Like midazolam, diazepam is indicated for moderate sedation prior to short diagnostic or surgical procedures, either alone or with a narcotic. It may be administered IV, IM, or PO, although IM administration is very painful and not recommended.

The IV dose may range from 2-20mg in a healthy adult, although 10mg or less is usually sufficient. It should be administered in 1-2mg increments every 2 minutes until the desired effect is achieved. As with midazolam, slurred speech is an excellent indicator of an adequate dose. Lower doses should be used for elderly or debilitated patients. Sedation after IV injection is usually achieved within 3-5 minutes. The half-life ranges from approximately 32-90 hours. Diazepam is extremely irritating to the tissue and should be injected through a large vein. This drug cannot be mixed with other medications or diluted due to precipitation. It should be injected as close to the IV cannula as possible. Adverse reactions include venous thrombosis, phlebitis, apnea, and hypotension.

Diazepam can be given orally as a premedication prior to many non-painful surgical procedures. It is very effective as an anxiolytic. Generally patients less than 50 years of age can be given 10 mg of Valium PO (orally) for premedication. Patients older than 50 years of age should be given 5 mg or less of Valium PO for premedication. Specifically these medications should be used with caution in elderly, chronically ill or debilitated patient.

**Opioids**

Narcotics are naturally occurring or synthetic opioids that act to provide analgesia, sedation, and elevate the pain threshold. They may be classified as agonists, mixed agonists-antagonists, or partial agonists by their activity at the opioid receptors.

Fentanyl (Sublimaze) is a synthetic opioid. It is indicated for analgesic action of short duration in procedures such as endoscopies. If given alone, dosage should begin at 0.5 -2 mcg/kg given incrementally. If given in conjunction with a benzodiazepine a smaller dose should be used. The average patient usually requires 25-100mcg given incrementally. Fentanyl has an immediate response and provides excellent analgesia. The half-life is 2-4 hours.
Rapid IV administration can lead to a rigid chest wall and difficulty breathing. This effect may be reversed with naloxone (Narcan) or may require a depolarizing muscle relaxant and intubation.

<table>
<thead>
<tr>
<th><strong>MEPERIDINE (Demerol)</strong></th>
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<tbody>
<tr>
<td><strong>Dose &amp; Route of</strong></td>
<td><strong>Adults –</strong></td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td><strong>IV/IM: 1-3 mg/kg (50-150 mg)</strong></td>
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<tr>
<td></td>
<td><strong>Children –</strong></td>
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<tr>
<td></td>
<td><strong>IV/IM: 1-3 mg/kg (Max. 4-5 mg/kg)</strong></td>
</tr>
<tr>
<td><strong>Time to Peak Effect</strong></td>
<td><strong>Intravenous: 1 to 3 minutes</strong></td>
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<tr>
<td></td>
<td><strong>Intramuscular: 30 to 90 minutes</strong></td>
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<tr>
<td></td>
<td><strong>Rectal: 120 minutes; Not recommended</strong></td>
</tr>
<tr>
<td></td>
<td><em>(onset 1 to 2 minutes with IV, and 10 to 15 minutes with IM or oral)</em></td>
</tr>
<tr>
<td><strong>Duration of Action</strong></td>
<td><strong>2 to 4 hours</strong></td>
</tr>
<tr>
<td><strong>Adverse Reactions</strong></td>
<td><strong>Respiratory depression – more common in infants, with rapid infusion and co-administration with other CNS depressant medications.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Seizures- May precipitate seizures in patients with underlying seizure disorders. Its metabolite, normeperidine, may cause seizures. Not recommended to be administered on a chronic basis or as a continuous infusion.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Delirium</strong></td>
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<tr>
<td></td>
<td><strong>Nausea</strong></td>
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<td></td>
<td><strong>Vomiting</strong></td>
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<td></td>
<td><strong>Urinary retention</strong></td>
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<td></td>
<td><strong>Pruritus</strong></td>
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<td></td>
<td><strong>Dysphoria</strong></td>
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<td></td>
<td><strong>Smooth muscle spasm</strong></td>
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<tr>
<td></td>
<td><strong>Hypotension- Most common in patients with hemodynamic instability and/or hypovolemia; may in part be histamine related.</strong></td>
</tr>
<tr>
<td><strong>Drug Interactions</strong></td>
<td><strong>Concomitant administration of other respiratory depressants, including benzodiazepines, increases the risk of respiratory depression.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Concomitant administration with phenytoin may decrease the analgesic effect.</strong></td>
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<tr>
<td></td>
<td><strong>Naloxone or nalmefene may precipitate normeperidine-induce seizures.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>CNS toxicity potentiated by concomitant administration with tricyclic antidepressants and phenothiazine.</strong></td>
</tr>
</tbody>
</table>
**Special Concerns**

- Half-life 3 to 59 hours in neonates; elimination may be prolonged. **Not recommended for use in neonates.**
- Oral absorption may be increased and elimination prolonged in patients with liver disease.
- Rectal administration is associated with delayed absorption and therefore potential for delayed respiratory depression.
- Use with caution in patients at risk of biliary cholelithiasis.
- Seizures are caused by normeperidine, the main metabolite. Should only be used on a short-term basis to avoid accumulation of toxic metabolite.
- Not recommended for use in patients with seizure disorders.
- Normeperidine may accumulate in neonates and in patients with decreased renal clearance, or patients receiving prolonged therapy. **Should not generally be administered on a chronic basis or as continuous infusion.**

**Contraindications**

- Hypersensitivity to meperidine
- Patients taking monamine oxidase inhibitors.

**Antagonist**

- Naloxone---may precipitate normeperidine- induced seizures
- Nalmefene---may precipitate normeperidine- induced seizures

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**MORPHINE**

<table>
<thead>
<tr>
<th>Dose &amp; Route of Administration</th>
<th>Adults – IV: 0.05-0.1 mg/kg (1-15mg), repeat q 15 mins-4 hrs as indicated; or by continuous IV (1 mg/ml) in ICU setting IM: 2-20 mg</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Children: IV/IM: 0.05-0.3 mg/kg</td>
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</tbody>
</table>

| Time to Peak Effect | Oral: 60 minutes  
|                     | Intravenous: 3 to 5 minutes (CNS effect delayed compared with synthetic opioids due to low fat solubility)  
|                     | Intramuscular: 10 to 30 minutes.  
|                     | Rectal: 30 to 60 minutes: Not recommended. |

<table>
<thead>
<tr>
<th>Duration of Action</th>
<th>3 to 5 hours</th>
</tr>
</thead>
</table>

| Adverse Reactions | Respiratory depression- More common in infants, with rapid infusion, and co-administration with other CNS depressant medications.  
|                   | Circulatory depression  
|                   | Dysphoria |

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<table>
<thead>
<tr>
<th>Delirium</th>
<th>Nausea</th>
<th>Vomiting</th>
<th>Smooth muscle spasm</th>
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<tr>
<td><strong>Drug Interactions</strong></td>
<td></td>
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<td></td>
<td>Concomitant administration of other respiratory depressants, including benzodiazepines, increases the risk of respiratory depression and prolongs the period of sedation.</td>
</tr>
<tr>
<td><strong>Special Concerns</strong></td>
<td></td>
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<td></td>
<td>• Dose should be decreased in high-risk or debilitated patients.</td>
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<td></td>
<td>• Elimination may be prolonged in neonates.</td>
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<td></td>
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<td></td>
<td></td>
<td>• Rectal administration is associated with delayed absorption and therefore potentially delayed respiratory depression.</td>
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<td>• Use with caution in patients at risk of biliary cholelithiasis.</td>
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<td></td>
<td>• Use with caution in patients with asthma.</td>
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<tr>
<td><strong>Antagonist</strong></td>
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<td></td>
<td></td>
<td></td>
<td>• Naloxone</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Nalmefene</td>
</tr>
</tbody>
</table>

### MIDAZOLAM (Versed)

#### Dose & Route of Administration

- **Adults:**
  - IV: 0.5-2 mg over 2 mins, repeat q 2-3 mins until desired effect, or, by continuous IV in ICU setting
  - IM: 0.02-0.1 mg/kg (1-7.5 mg)
  - PO: 0.5-0.8 mg/kg (Max. 50 mg)

- **Children:**
  - IV/IM: 0.025-0.08 mg/kg over 2 mins (max. 2.5 mg)
  - PO: 0.25-0.75 mg/kg (Max. 20 mg)

#### Time to Peak Effect

- **Oral:** 10 to 30 minutes
- **Sublingual:** 10 to 15 minutes
- **Intravenous:** 3 to 5 minutes
- **Intranasal:** 10 to 15 minutes
- **Rectal:** 10 to 20 minutes

#### Duration of Action

- **Intravenous:** 20 to 60 minutes (dose related)
- **Elimination half-life:** 1.5 to 2.5 hours
- **Oral and Rectal:** 60 minutes (dose related)

#### Adverse Reactions

- Respiratory depression- Dose and rate related, more pronounced with IV route; more likely when co-administered with other CNS
**Depressant medications.** Reduce initial dose by at least 25% to 33% when co-administered with an opioid.

**Ataxia**

Paradoxical excitation

Hypotension- Rapid administration in neonates, co-administration of fentanyl in neonates.

Myoclonic, seizure-like activity- Rapid administration in neonates

Nasal burning- Following nasal administration.

### Drug Interactions

- Concomitant administration with opioids, barbituates, or other CNS depressant medications increases the risk of respiratory depression and apnea. When administered with opioids, the initial dose should be reduced by at least 25% to 33%.
- Use with other CNS depressant medications prolongs the recovery time.
- Erythromycin and calcium channel blockers delay metabolism through cytochrome p450 enzyme inhibition.
- Neonates are particularly susceptible to hypotension with rapid IV administration or concomitant of fentanyl.

### Special Concerns

- Dose should be decreased in high risk or debilitated patients.
- Nasal administration is associated with burning sensation; potential for direct neurotoxicity (theoretic concern.)
- Elimination may be prolonged in patients with congestive heart failure, in neonates, and in patients receiving vasopressors.
- Midazolam is known to cause airway obstruction by reducing hypopharyngeal airway patency.

### Antagonist

Flumazenil (10g/kg over 15 seconds every 1 to 2 minutes up to 1 mg); observe at least 2 hours for resedation.

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| **DIAZEPAM**  
<table>
<thead>
<tr>
<th><strong>(Valium)</strong></th>
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<tbody>
<tr>
<td><strong>Dose &amp; Route of Administration</strong></td>
</tr>
</tbody>
</table>
| Adult:  
IV/IM/PO: 2-10 mg (up to 20 mg may be used for procedures after careful patient assessment)  
Children: (Rarely used)  
IV/PO: 0.05-0.25 mg/kg |
| **Time to Peak Effect** |
| Oral: 60 minutes  
**Intravenous:** 1 to 2 minutes |
| **Duration of Action** |
| **Intravenous:** 2 to 6 hours—dose related (elimination half-life 20 to 40 hours) |
| **Adverse Reactions** |
| Respiratory depression- Dose and rate related, more pronounced with IV route; may be exacerbated by rapid administration and co-administration of other CNS depressant medications.  
Ataxia  
Paradoxial excitation |
Pain and phlebitis at injection site—Slow administration, preferable in largest possible vein. Hypotension—Increased risk of hypotension with rapid IV administration.

### Drug Interactions
- Concomitant administration with opioids, barbiturates, or other CNS depressant medications increases the risk of respiratory depression and apnea. When administered with opioids, the initial dose should be reduced by at least 25% to 33%.
- Use with other CNS depressant medications prolongs the recovery time.
- Clearance can be delayed when administered in association with cimetidine (Tagamet).

### Special Concerns
- Elimination prolonged (half-life as long as 100 hours) in premature neonates; prolonged sedation may result.
- Because of the possibility of impaired metabolism, caution should be used in patients with severe hepatic dysfunction.
- Pharmacologically active metabolite, desmethyldiazepam, has a half-life of 30 to 219 hours.
- Dose should be decreased in high risk or debilitated patients.

### Contradictions
- Patients with known sensitivity to benzodiazepines.
- Patients with acute narrow-angle glaucoma or those with open-angle glaucoma who are not receiving therapy.

### Antagonist
Flumazenil (10g/kg over 15 seconds every 1 to 2 minutes up to 1 mg); observe at least 2 hours for resedation.

****See attached Drug Table for additional information

### Ketamine

**NOTE:** Ketamine use for moderate sedation is restricted to anesthesiologists and ED physicians and may only be administered by a physician.

Ketamine is a short-acting, hallucinogenic, "dissociative" anesthetic. In large doses ketamine can induce general anesthesia, but in smaller doses the patient has the sensation of being "dissociated" and "removed from their body," enough to tolerate surgical procedures. It also has direct analgesic properties. Ketamine is related to phencyclidine (PCP) and has the potential to cause hallucinations.

### Reversal Agents

Reversal agents are drugs that counteract the effects of other drugs. The reversal agent used for benzodiazepines is flumazenil (Romazicon), and the reversal agent used for narcotics is naloxone (Narcan).

**Flumazenil** (Romazicon) is a benzodiazepine antagonist. It competes for receptor sites thereby reducing or reversing the effects of the benzodiazepine. The dosage is 0.1-0.2 mg every 30 seconds until the desired effect is achieved or until 2 mg is given. The
effect lasts for about 1 hour. The effects of the benzodiazepine can return because of the disparity in the half-lives of the two drugs. Patients should be observed for resedation for at least 2 hours after administration.

Patients receiving benzodiazepines chronically are at risk for grand mal seizures with the use of flumazenil. Also, patients with a history of seizures should receive this medication with extreme caution. Seizures have occurred after the reversal of benzodiazepines even with patients not dependent on their use. For this reason, flumazenil should not be used as a matter of routine. If needed, it should be administered slowly and the patient should be carefully and continuously monitored.

**Naloxone** (Narcan) is a pure narcotic antagonist. It competes for the receptor sites thereby reversing the effect of the narcotic. It is important to note that all opioid effects are reversed in parallel. This means that rapid injections of naloxone not only reverse sedation and respiratory depression, but analgesia as well. This sudden unmasking of pain may result in significant sympathetic and cardiovascular stimulation, which in turn can cause hypertension, stroke, tachycardia, arrhythmias, pulmonary edema, congestive heart failure, and cardiac arrest.

Naloxone can be given in 0.1-0.2 mg dose and repeated every 2-3 minutes until the patient is alert with adequate ventilation yet without significant pain or discomfort. The effects are seen in 1-2 minutes and last from 1-4 hours. The half-life of Naloxone is 60-90 minutes. Because of this short half-life, patients can become re-narcotized after the effects of naloxone have worn off. Patients should be closely monitored to watch for resedated

**Post-procedure Physician Responsibilities**

Responsibilities of the physician include:

- Directing and providing of emergency interventions as necessary
- Dictation of operative note as per hospital policy

**Documentation**

Documentation should include:

- Dosages, route, time and effect of all drugs used
- Type and amount of fluids administered, including blood and blood products, monitoring devices or equipment used
- Heart rate, rhythm, blood pressure, respiratory rate, oxygen saturation, and level of consciousness
- Interventions and the patient’s response to the interventions
- Untoward or significant patient reactions and their resolution or outcome
Patient Monitoring by Nursing

The patient must be continuously monitored from the start of moderate sedation until the time discharge criteria are met. Baseline vital signs, oxygen saturation level, heart rate, rhythm, and level of consciousness are the minimum assessment parameters obtained and documented prior to sedation. The patient should be monitored continuously during the procedure with vital signs recorded at 5-minute intervals (more frequently if patient condition warrants) and at 15-minute intervals during the recovery phase, and at any significant event in either phase. **THE RN MONITORING THE PATIENT MAY NOT BE ENGAGED IN ANY OTHER ACTIVITY DURING THE PERIOD OF MODERATE SEDATION!** The nurse should immediately report any unexpected response by the patient to the physician. These include, but are not limited to variations from baseline in BP or pulse; cardiac dysrhythmias (continuous); variations in baseline of oxygen saturation (continuous monitoring); dyspnea, apnea, or hypoventilation; diaphoresis (may signify myocardial ischemia); inability to arouse the patient; or the need to maintain the patient’s airway mechanically. Post-procedure monitoring may be discontinued when the patient reaches an Aldrete score within 1 point of original score. This timeframe will be at least 30 minutes. Monitoring equipment may be removed at this time. A score within 1 point of original score indicates a return to patient’s pre-procedural status for the following:

a. Oxygen saturation greater than 92% on room air/return to pre-procedural baseline.
b. Level of consciousness
c. Color
d. Blood pressure within 20% of baseline
e. Ability to move 4 extremities on command consistent with pre-procedural assessment

Emergency Interventions

Overdose or adverse drug reactions may cause respiratory depression, hypotension, and impaired cardiac function. The Physician and the RN must be ready to intervene if these complications arise. Emergency interventions include, but are not limited to, airway management, reversal of sedating medications and other measures such as basic and advanced cardiac life support.

Respiratory Depression and Hypoventilation

Decreased or shallow respiration and decreased oxygen saturation demonstrate respiratory depression, which can progress to respiratory arrest. Respiratory depression should be treated with oxygen and airway management. **The most effective way to open the airway is the head tilt-jaw lift.** Often this maneuver alone is enough to improve ventilation and oxygen saturation. Every patient should have supplemental oxygen throughout the procedure. If the patient is breathing and the oxygen saturation is low, the flow of nasal oxygen may be increased. Encourage the patient to take deep breaths. If the patient is breathing but the oxygen saturation remains low, change the nasal oxygen to a 100% non-rebreathing facemask. If efforts remain unsuccessful, bag-mask
ventilation of the patient is necessary. Continue to mask ventilate the patient until the oxygen saturation improves. If the condition does not improve, consult an anesthesia provider promptly.

**Cardiac Complications and Hypotension**

Hypotension is another complication of moderate sedation. Hypotension may sometimes be corrected by placing the patient in the Trendelenburg (head down) position and giving IV fluids. If this intervention does not improve the blood pressure, more aggressive drug therapy is needed. If problems continue, call for help before the situation gets worse.

Another potentially lethal complication of conscious sedation is cardiac arrhythmias. Cardiac arrhythmias must be recognized and treated quickly for positive patient outcomes. **REMEMBER: IF YOU ARE IN DOUBT IT IS SAFER TO CALL FOR HELP!** If your patient arrests, begin CPR immediately and have your tech or nurse call a “Dr. Leo” code.

**Discharge Criteria**

Patients who have received moderate sedation must go to the PACU or another recovery area with comparable monitoring capabilities post procedure. Monitoring will be continued at 5-15 minute intervals. The patient must meet specific discharge criteria for the recovery area before returning to the floor or being discharged. Patients receiving reversal agents will be monitored for 2 hours post-procedure to ensure that they do not re-sedate prior to discharge.

**Nursing Responsibility**

Responsibilities of the RN include:

- Knowledge of the goals of IV sedation
- Administration of medications per physician’s orders
- Uninterrupted observation and monitoring of the patient from time of moderate sedation until time of discharge
- Documentation
- Provision of appropriate emergency intervention as necessary
For ED physicians only

Ketamine

NOTE: Ketamine use for moderate sedation is restricted to anesthesiologists and ED physicians and may only be administered by a physician.

Ketamine is a short-acting, hallucinogenic, "dissociative" anesthetic. In large doses ketamine can induce general anesthesia, but in smaller doses the patient has the sensation of being "dissociated" and "removed from their body," enough to tolerate surgical procedures. It also has direct analgesic properties. Ketamine is related to phencyclidine (PCP) and has the potential to cause hallucinations, which at times are discomforting to patients. It may be prudent to precede ketamine doses with a benzodiazepine in selected pediatric patients. Increased oral secretions is a common side effect.

An IM dose of 2-4 mg/kg produces adequate sedation in most children. A suggested dose of IV ketamine is 0.5-1mg/kg. Benzodiazepines reduce the incidence of hallucinatory emergence reactions and should be considered if risk factors are present; these include age greater than 10 years, rapid IV administration, excessive noise or stimulation or a baseline of frequent dreaming. Routine administration of benzodiazepines to children under the age of 10 years is of questionable benefit owing to the low incidence of emergence phenomena and the prolongation of recovery time. Administration of a concurrent anticholinergic is recommended by some to reduce the hypersalivation seen with ketamine. Atropine 0.01 mg/kg (maximal total dose of 0.5 mg) and or glycopyrrolate 0.005 mg/kg (maximal total dose of 0.25 mg) can be combined with ketamine in a single IM injection.

Adverse effects include marked salivation, skeletal muscle hyperactivity, tonic-clonic movements and increased heart rate, blood pressure, and intracranial pressure. Respiratory depression is rare but has been reported with rapid IV push. Laryngospasm, presumed to be secondary to the heightened gag reflex, is the most dangerous potential complication, but this occurs in fewer than 2% of cases in the doses described above and is usually transient, rarely requiring intubation. Emesis and a transient hyperemic rash can occur after recovery.

Contraindications: hypersensitivity to ketamine or conditions where a significant elevation of blood pressure is hazardous

Precautions: < 3 months old; active upper and lower respiratory infections; increased ICP; hypertension; CVS disease; h/o airway instability or tracheal stenosis; oral procedures; psychoses; glaucoma; thyroid disease; intermittent prophyria.