


SUBJECT: Adult Moderate Sedation by Non-Anesthesia Personnel	Policy #
DEPARTMENT: Anesthesia	
EFFECTIVE: May 2013	
APPROVED BY: Ashok Kewalramani, DO, Medical Director Anesthesia Joseph Liewer, MD, Medical Director ETOPD MEC 5.20.13	


Purpose:

To provide guidelines for the management of adult patients who are undergoing invasive, manipulative, diagnostic, surgical or therapeutic procedures with intravenous (IV) sedation and analgesia administered by non-anesthesia personnel.

Definitions:

Moderate sedation is defined as a depressed level of consciousness but retention of the ability to independently and continuously maintain a patent airway and respond appropriately to verbal commands. Sedation occurs on a continuum from minimal sedation to general anesthesia. These levels are defined and described as follows:

1. **Minimal Sedation (Anxiolysis):** A drug induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular function are unaffected.
2. **Moderate sedation/analgesia:** 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 patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
3. **Deep sedation/analgesia:** A drug induced depression of consciousness during which patients cannot be easily aroused, but responds 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 adequate. Cardiovascular function is usually impaired.
4. **Anesthesia:** Consist of general anesthesia and spinal or major regional anesthesia. It does not include local anesthesia. 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 support is often impaired. Patients often require assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed

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5. spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

Licensed Individual Practitioner: Refers to Physicians, Registered Nurses (RNs), and anesthesia personnel trained in Moderate Sedation/Analgesia as set forth in this policy.

Policy:

Site specific guidelines may be more, but not less restrictive than the intuitional guidelines. This policy does not apply to care of patients receiving sedation for the purpose of:


- Ventilatory management
 - Pain management
 - End of life/palliative care sedation
 - Management of delirium tremors or seizures
 - Pre-operative pre-medications administered under the direction of the Department of Anesthesia.
 - Anxiolysis
1. IV moderate sedation/analgesia is ordered by a physician credentialed in administering moderate sedation/analgesia to be utilized for patients undergoing invasive, manipulative, diagnostic, surgical or therapeutic procedures.
 2. A physician evaluates the patient to determine appropriateness for moderate sedation/analgesia. Assessment should include allergies, current medications, health problems, previous experience with sedation/analgesia or anesthesia, vital signs, and use of tobacco, alcohol or other substances of abuse.
 - A physician shall perform a focused physical examination to include, at a minimum, auscultation of heart and lungs and airway assessment.
 - Sedation options, benefits and risks should be discussed with patient/care providers.
 - A sedation plan should be developed based upon the physician’s assessment and communicated between healthcare team members.
 3. Procedures performed throughout the hospital that require Moderate Sedation/Analgesia without the use of Anesthesia Services are done in the presence of a physician who has attained privileges to perform the procedure. In all cases, sedation or analgesia is administered by or under the direct supervision of the physician, who must have active moderate sedation privileges.

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4. Individuals administering Moderate Sedation /Analgesia should be able to rescue the patient who enters a Deep Sedation/Analgesia level.
5. Administration of Deep Sedation is restricted to the Anesthesia Providers or those credentialed for deep sedation

The Specific type and dosage of medication administered should remain at the discretion of the physician.

- Dosages should be titrated to the sedative/analgesic endpoint for each individual patient.
 - No ‘standard dosing’ is recommended.
 - In general medication is given in small titrated increments:
 - Additional doses of medication should be given based upon the patient’s response to the initial dose given.
 - The specific type and dosage of the medication is determined at the discretion of the physician performing the procedure.
 - Dosing beyond the guidelines indicated changes the care of the patient from Moderate Sedation/Analgesia to Deep Sedation, which should be administered under the direction of a physician credentialed for Deep Sedation or an Anesthesia provider.
6. A licensed Individual Practitioner trained in Moderate Sedation/Analgesia should be in attendance (one to one [1:1] practitioner/patient ratio) during any procedure requiring Moderate Sedation/Analgesia in order to provide continuous clinical assessment of the patient. The practitioner administering the medication should monitor the patient.
 - If during performance of the procedure, the practitioner detects through his/her clinical assessment or mechanical monitoring, any significant (20%) deviations from baseline vital signs or reassessment for the purpose of airway management, he/she informs the physician who is responsible to decide and implement the necessary corrective measures.
 7. All licensed Individual Practitioners and Physicians directly administering or monitoring in moderate sedation complete a biennial re-certification in airway management, pharmacology and emergency intervention and maintain current Advanced Cardiac Life Support (ACLS and /or Pediatric Advanced Life Support (PALS) training.


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8. Moderate Sedation/Analgesia may be performed in any clinical area provided that the criteria set forth in this policy are adhered to:

The means for notifying additional support services such as respiratory therapy, practitioners skilled in tracheal intubation (i.e.: anesthesia personnel) and activating emergency response "code" pages should be clearly identified and posted in procedure/sedation areas. Training/Credentialing of Physicians

The practitioner responsible for the treatment of the patient and/or the administration of medications for Moderate Sedation/Analgesia shall be appropriately trained:

- A. The minimum number of available personnel shall be two-the operator (who performs the invasive or diagnostic procedure) and the monitor (an assistant trained to monitor appropriate physiologic variables and to assist in any support or resuscitation measures that may be required), each assigned to their specific roles in patient care for the purpose of the planned procedure. Such personnel are to be available to the patient from the time of administration of the sedative medication until recovery is judged adequate or the care of the patient is transferred to personnel performing recovery care.
- B. The chairman of the department/division performing the procedure shall certify that all physicians administering sedative medications are trained in airway management, IV access, and trained in safe use of these medications:
 - 1). Physicians with privileges for moderate sedation/analgesia are trained and competent to manage compromised airway and to provide adequate oxygenation and ventilation. Including positioning the airway, use of Oropharyngeal and nasopharyngeal airways and the application of positive pressure ventilation utilizing a bag-valve-mask.
 - 2). Physicians with privileges for moderate sedation/analgesia are trained in the administration of pharmacologic agents to predictably achieve desired levels of sedation and in techniques to monitor patients in order to maintain them at a desired level of sedation.

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- a. Educational requirements may be achieved through annually successfully completing the Moderate /Deep Sedation self learning module with post test.
- b. The department of anesthesia may participate in the organization of a hospital wide educational program to inform physicians of guidelines for the use of sedating medications and monitoring modalities. It would be appropriate for such a program to be accredited for continuing education in risk management.


Training of the Licensed Individual Practitioner Administering/ Monitoring IV Moderate Sedation Analgesia.

- A. The Licensed Individual Practitioner managing the care of patients receiving IV Moderate Sedation/Analgesia should:
 1. Demonstrate the acquired knowledge of anatomy, physiology, pharmacology, cardiac dysrhythmia recognition, and complications related to IV Moderate Sedation/Analgesia.
 - a. Education and competency validation includes evaluation and documentation of the individual’s demonstration of knowledge, skills and abilities to related management of the patient receiving IV Moderate Sedation/Analgesia.
 - b. Evaluation and documentation of competency should occur annually via a self learning packet and post test, and maintaining ACLS certification.

Considerations in Medicating During IV Moderate Sedation/Analgesia

The type of IV Moderate Sedation/Analgesia to be used for a procedure is determined by the physician performing the procedure. The patient’s medical diagnosis, age and any complicating medication conditions are considered. It is the responsibility of the physician to discuss the choice of sedation/analgesia with the patient and obtain consent prior to the procedure.

- A. Administration of IV moderate sedation drugs will be done by an anesthetist, an RN, or physician who has been credentialed in moderate sedation and who is under direct supervision of a physician,

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- B. All drugs must be titrated to patient response and health status.
- C. All patients scheduled for elective moderate sedation must be NPO at least 6 hours for solids and 2-3 hours for clear liquids before the scheduled procedure. In unscheduled or emergency situations, NPO status is at the discretion of the physician.
- D. All patients must have a patent IV access. Strongly consider running fluid for cases requiring multiple-dose-titration. IV access should be maintained until cardio respiratory depression from the medications no longer poses a risk to the patient

Commonly Used Drugs:

- 1. Benzodiazepines: Midazolam
Diazepam
- 2. Opiate Agonists: Morphine
Fentanyl
- 3. Anti Emetics: Droperidol/Metoclopramide
- 4. Anti Histamine: Diphenhydramine


EQUIPMENT/SUPPLIES:

The following minimum equipment must be present, in working order, and be **ready for use in the room:**

- A. Oxygen and oxygen delivery devices
- B. Suction equipment
- C. Emergency airway- equipment
- D. Noninvasive BP monitor or manual BP cuff
- E. Pulse oximeter and end-tidal CO2 monitor
- F. Medications for moderate sedation as ordered by physician
- G. Reversal agents as appropriate for moderate sedation medications used, i.e., Naloxone for opiates and Flumazenil for Benzodiazepines.
- H. Other emergency drugs such as Epinephrine, Ephedrine, Diphenhydramine, Atropine, and Lidocaine will be immediately available.
- I. A cardiac arrest cart with defibrillator must be located in close proximity to the procedure/sedation site.

PROCEDURE:


- A. Pre-Procedure:

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1. The physician or his/her physician designee must discuss the risks and benefits of conscious sedation and obtain consent prior to the procedure.
2. Document on Patient record:
 - a. Allergies/adverse drug reactions
 - b. Current medications (doses and time of last dose when necessary)
 - c. NPO status and time of last food/drink
 - d. Pertinent medical history and assignment of American Society of Anesthesiologists (ASA) physical status
(Refer to addendum I)(H&P and ASA status by physician)
 - e. Pertinent lab results
 - f. Pregnancy status
 - g. Previous anesthesia experience/problems
 - i. Baseline Aldrete Score (Refer to Addendum II): Obtain immediately prior to the procedure
3. Physical examination to include:
 - a. *Vital* signs; lung sounds, cardiac (heart and lung exam to be done by physician): Obtain immediately prior to procedure
 - b. Weight
 - c. Mental status/level of consciousness
4. Establish IV access per physician order.
5. Document patient teaching/discharge instructions.
6. Obtain and document baseline scoring of the patient using the Modified Pre/Post Sedation Score (Aldrete Score) on their ability to:
 1. Move extremities on command;
 2. Ability to breathe freely;
 3. SBP (+) or (-) twenty (20)% pre-sedation level;
 4. Respond appropriately to verbal stimuli; and
 5. Oxygen saturation

Modified Pre/Post Sedation Score (Aldrete):

Activity:	Scoring
Able to move 4 extremities voluntarily or on command	2

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	Able to move 2 extremities voluntarily or on command	1
	Able to move 0 extremities voluntarily or on command	0
Respiration:		
	Spontaneous, unassisted respirations	2
	Airway in place, dyspneic	1
	Mechanically assisted respirations	0
Circulation:	(Systolic Blood Pressure = SBP)	
	SBP +/-20% of pre-sedation level	2
	SBP +/- 20-50% of pre-sedation level	1
	SBP +/- 50% of pre-sedation level	0
Consciousness:		
	Answers questions and acknowledges location appropriately	2
	Responds when called by name	1
	Failure to elicit a response upon auditory stimulation	0
SaO2:		
	93-100%	2
	90-92%	1
	89% or less	0

B. Intra-Procedure:

1. Licensed Individual Practitioner (L.I.P.): Administer/monitor sedation as directed by physician.
2. **All patients** will have oxygen administered at beginning of procedure unless specifically contraindicated by clinical status or procedure, e.g., cardiac catheterization.
3. Licensed Individual Practitioner: Administers Medication and monitors levels of sedation/analgesia under the direction of the physician performing the procedure.

Document:

- a. BP, pulse, respirations, **SpO₂**, and **EtCO₂** at least every 5 minutes throughout the procedure. This must be performed immediately before and immediately after the procedure.

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- b. Level of consciousness - at least every 5 min. through out the procedure.
- c. Electrocardiogram monitoring (rate and rhythm) on all patients.
NOTE.- Manual and concurrent recording of these data ensure that the individual caring for the patient is aware of any changes in vital signs in a timely manner. The L.I.P./monitor may assist with interruptible, ancillary tasks of short duration, once a stable level of sedation is achieved.
- d. Appearance of any undesired effects, along with notification of physician and treatment, if any.

C. Post-Procedure:

- 1. Vital signs: BP, P, R, SpO2, and Aldrete score on arrival then vital signs every 10 minutes x 3 (more frequently depending on clinical status), then every 15 minutes until return to baseline status. **If the patient has already returned to baseline status on arrival**, vitals will be recorded every 15 minutes x 2 and just prior to discharge.
- 2. Level of consciousness: Note changes and notify physician as necessary.

D. Discharge Criteria:


- 1. After analgesia/sedation, patients should be observed until they are no longer at risk for cardio respiratory depression for at least 30 min.
- 2. 2 hours should have elapsed after the last administration of reversal agents to ensure that patient does not become resedated after reversal effects have abated.
- 3. Aldrete discharge criteria must be met and score recorded. Score must be 9-10 or return to baseline. (*Refer to Addendum II*)
- 4. Notify physician if baseline status is not regained.
- 5. Outpatients must be discharged in the presence of a responsible adult who will accompany them home.
- 6. Outpatients will be provided with written instructions regarding post procedure diet, medications, activities, and course of action if a complication develops.
- 7. Inpatients will be transferred to the nursing unit when stable. Report to receiving unit to include:
 - a. Medications patient received for conscious sedation.
 - b. If reversal agent was used.
 - c. Findings and/or new physician orders.

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- d. Receiving nurse to:
 - 1) Meet patient at bedside
 - 2) Compare vital signs, LOC to baseline assessment.

RISK MANAGEMENT AND QUALITY ASSESSMENT:


- A. Quality assessment will be ongoing with concurrent and/or retrospective monitoring of anesthesia established criteria by the manager of any department where conscious sedation is used.

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ADDENDUM 1

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) Physical Status

- 1 Normal healthy patient
- 2 Patient with mild systemic disease that results in no functional limitation, e.g., HTN, DM, chronic bronchitis, morbid obesity, extremes of age
- 3 Patient with severe systemic disease that results in functional limitation e.g., poorly controlled HTN DM with vascular complications, angina pectoris, prior myocardial infarction, pulmonary disease that limits activity
- 4 Patient with severe systemic disease that is a constant threat to life, e.g., congestive heart failure, unstable angina, advanced pulmonary, renal, or hepatic dysfunction
- 5 Moribund patient who is not expected to survive without the operation, e.g., ruptured abdominal aneurysm, pulmonary embolus, and head injury with increased intracranial pressure
6. Emergency operation is required


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Physical status classification is based on physical condition of the patient only and is intended to serve as a “common language” across different departments and institutions for subsequent examination of morbidity and mortality.

ADDENDUM II

Modified Pre/Post Sedation Score (Aldrete)

Activity:		Scoring
	Able to move 4 extremities voluntarily or on command	2
	Able to move 2 extremities voluntarily or on command	1
	Able to move 0 extremities voluntarily or on command	0
Respiration:		
	Spontaneous, unassisted respirations	2
	Airway in place, dyspneic	1
	Mechanically assisted respirations	0
Circulation:	(Systolic Blood Pressure = SBP)	
	SBP +/-20% of pre-sedation level	2
	SBP +/- 20-50% of pre-sedation level	1
	SBP +/- 50% of pre-sedation level	0
Consciousness:		
	Answers questions and acknowledges location appropriately	2
	Responds when called by name	1
	Failure to elicit a response upon auditory stimulation	0
SaO2:		
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	89% or less	0

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ADDENDUM III

Example of Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with atypical airway anatomy. Also, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors which may be associated with difficulty in airway management are:


History:

- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Dysmorphic facial features (e.g. Pierre-Robin syndrome, trisomy 21)
- Advanced rheumatoid arthritis

Physical Examination:

- Habitus: Significant obesity (especially involving the neck and facial features)
- Head and Neck: Short neck, limited neck extension, decreased hyoid-mental distance (<3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation
- Mouth: Small opening (<3 cm in an adult); edentulous; protruding incisors, loose or capped teeth; big, arched palate, macroglossia; tonsillar hypertrophy; non-visible uvula
- Jaw: Micrognathia, retrognathia, truisms, significant malocclusion

Minimal physical airway assessment should include mouth opening, neck extension, and size of jaw (thyro-mental distance more than 2.5 finger breadths)

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ADDENDUM IV

Example of 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 upon 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, 22 gauge]
- Intravenous tubing [pediatric 'microdrip' - 60 drops/ml]
- Intravenous fluid
- Three-way stopcocks
- Assorted needles for drug aspiration, IM injection [intraosseous bone marrow needle]
- Appropriately sized syringes
- Tape

Basic Airway Management Equipment:

- Source of compressed O₂ (tank with regulator or pipeline supply with flowmeter)
- Source of suction
- Suction catheters [pediatric suction catheters]
- Yankauer-type suction
- Face masks [infant/child face masks]
- Self-inflating breathing bag-valve set [pediatric bag-valve set]
- Oral and nasal airways [infant/child size airways]
- Lubricant


Advanced Airway Management Equipment (for practitioners with intubation skills):

- Laryngoscope handles*
- Laryngoscope blades [pediatric laryngoscope blades]*
- Endotracheal tubes:*
- Cuffed 6.0, 7.0, 8.0 mm i.d.

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[Uncuffed 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0 mm i.d.]
 Stylet [appropriately sized for endotracheal tubes]*

* Refer to Nursing Policy, Crash Carts

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ADDENDUM V

Example of Emergency Equipment for Sedation and Analgesia

Pharmacologic Antagonists:

Naloxone
Flumazenil

Emergency Medications:

Epinephrine
Diphenhydramine
Ephedrine
Hydrocortisone
Methylprednisolone
Atropine or dexamethasone
Lidocaine
Diazepam or Midazolam
Glucose (50%) [10% or 25% glucose]