

ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**Subject: Moderate Sedation/Analgesia- Procedural (“Conscious Sedation”)****No. III.21****Policy**

Safe, consistent care will be provided for all patients receiving moderate sedation/analgesia for therapeutic and diagnostic procedures. All patients receiving moderate sedation/analgesia will receive a comparable level of quality of care and monitoring by appropriately qualified personnel throughout the organization.

The Department of Anesthesiology is responsible for setting guidelines for the administration of medication and setting the guidelines for the monitoring of the patients receiving moderate sedation/analgesia.

The physician administering medication to achieve moderate sedation/analgesia is responsible for the ordering and titration of the medication dosages, based on the patient’s age, weight and medical history. Questions regarding medications may be directed to the Department of Anesthesiology.

Approved administrative sites include: Cath Lab, Critical Care, Emergency Department, Endoscopy Suite, EP Lab, Non-invasive Cardiology, PACU, Pediatrics, NICU, Radiology, and Telemetry.

Exception: Any exception to the approved sites for the administration of moderate sedation/analgesia must have nursing management approval. All other policy criteria must be in place before the administration of the moderate sedation/analgesia.

Definitions

Moderate Sedation/Analgesia (“conscious sedation”) A drug induced depression of consciousness during a procedure 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 (Note: Deep Sedation is not “conscious sedation”) 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. See Anesthesia department policy for additional levels of anesthesia.

Exclusions

This policy is not intended to govern cases of pain control, or anxiety, or sedation of patients on ventilators, or single dose drugs used as anxiolytics (where patient retains a normal response to verbal stimuli and airway/ventilation is unaffected). This policy specifically excludes the administration of regional, deep sedation, general or monitored anesthesia care within or outside the operating room by a credentialed anesthesiologist.

Purpose

To delineate the procedure for administering and monitoring moderate sedation/analgesia during therapeutic, surgical and diagnostic procedures.

Performed by:

1. Moderate Sedation/analgesia may be administered by 1) a physician; 2)a CRNA; or 3) a CRNP, an RN or Physician's Assistant under the guidance of a physician who is physically present in the room during administration.
2. Qualified staff as describe in policy section: Training.

Equipment:

Equipment available is to be age appropriate, i.e. Pediatric, NICU

- Pulse oximetry
- BP monitoring equipment
- ECG monitor, as required
- Supplemental O₂
- Emergency equipment must be immediately accessible to every location where moderate sedation/analgesia is administered, and includes at least the following: intubation equipment, suction device, airways, Bag-Valve-Mask, ECG monitor, emergency Defibrillator should be immediately available for patients with mild to severe cardiovascular disease (e.g. HTN, Ischemia, CHF)
- The means for immediately notifying emergency support services including respiratory therapy and code teams
- Immediate access to specific pharmacological antagonists or reversal agents for the type of sedation used.
- Patent IV access

Procedure

I. Personnel

- A. Minimum number of personnel involved in the care of a patient undergoing moderate sedation/analgesia during the entire procedure shall be two: the operator and the monitor.
 - 1.The operator is defined as the physician, or CRNP, or Physician's Assistant (who are directly supervised by a physician) who performs any procedures. If the operator is a physician, he/she may be involved in the administration of moderate sedation/analgesia.
 - 2.The monitor is defined as trained personnel responsible for monitoring the patient and his or her response to sedation and the procedure. The monitor should be capable of assisting with any supportive or resuscitative measures. The monitor may assist the operator with interruptible ancillary tasks of short duration; however, the monitor shall have no other responsibilities that would leave the patient unattended and/or compromise monitoring.
- B. The physician or CRNA privileged to perform moderate sedation/analgesia must be present during the administration of the sedative medications. The physician, CRNA or monitor must be present and available to the patient until recovery is complete and the patient meets established criteria for discharge, or the care of the patient is transferred to comparable, competent personnel performing recovery care.

II. Training

The personnel responsible for the care and treatment of the patient undergoing moderate sedation/analgesia shall be appropriately trained. All physicians and CRNA's responsible for prescribing moderate sedation/analgesia will have delineated clinical privileges in the procedure being performed.

A. General competency for the qualified physician managing the care of the patient receiving sedation/analgesia includes:

1. The demonstration of knowledge of anatomy, physiology, pharmacological agents, cardiac arrhythmia recognition, and treatment, as well as, the requisite knowledge and skills to assess and intervene in the event of complications or undesired outcomes, and to institute interventions in compliance with orders or institutional protocols and guidelines.
2. The ability to assess total patient care requirements during moderate Sedation/ Analgesia and recovery. Physiological measurements should include, but are not limited to respiratory rate, oxygen saturation, blood pressure, heart rate and rhythm, and the patient's level of consciousness;
3. Understanding the principles of oxygen delivery, respiratory physiology, oxygen transport and oxygen uptake and demonstrate the ability to use oxygen delivery devices;
4. Demonstration of skills in airway management and resuscitation.
5. Evaluation of the operator's competencies will be confirmed during the clinical privileging process.

B. Specific criteria for the monitor managing the care of a patient receiving sedation/analgesia include training related to:

1. Advanced Cardiac Life Support; and/or Pediatric ALS or Emergency Nurse Pediatric Certification; Neonatal Resuscitation Program during the procedure, as appropriate to the particular patient.
2. Training in the recognition of the cardiovascular and respiratory side effects of sedatives, as well as the variability of patient response;
3. Training in airway management, resuscitation and basic cardiac dysrhythmias;
4. Knowledge of the medications administered including actions, side effects, pharmacological antagonists and reversal agents for the type of sedation used, as delineated in Appendix 1.
5. Documented competency compliance as an employee of a MLH hospital or as a credentialed member of the medical or specified health professional staff.

III. Patient Management

Prior to the procedure the patient is determined to be an appropriate candidate for the planned anesthesia.

A. Pre-Procedure Assessment

Prior to physical preparation of the patient, it is necessary to assure that the chart is complete with:

1. Identify patient by asking the patient to verbally state his/her name and DOB. Then verify the patient's name, DOB by checking it with the ID bracelet.
1. Informed Consent- the patient or guardian must be informed about the risks, benefits, and alternatives to sedation as a component of the planned procedure. Documentation of consent should be placed in the medical record prior to the procedure;
2. Identify patient- identification shall be with two identifiers: patient name and either date of birth or medical record number; ensure that an identification bracelet is on the patient's wrist and that information is correct;
3. Documentation of baseline blood pressure, pulse, respiratory rate; oxygen saturation;
4. History and physical exam that is appropriate for the level of intervention, pre-procedure checklist, including an airway assessment using the Mallampati scoring, pre-procedure mental status, current medication, significant medical history, allergies, adverse

reactions to anesthesia or sedation, and Pre-Procedure Fasting Guidelines as referenced below:

<u>Pre-Procedure Fasting Guidelines</u>	
<u>Ingested Material</u>	<u>Minimum Fasting Period</u>
Clear liquids	2 hr
Breast Milk	4 hr
Infant Formula	6 hr
Non-human Milk	6 hr
Light Meal (toast & clear liquids)	6 hr

Reference: ASA, Oct. 2001

These recommendations apply to patients who are undergoing elective procedures

5. Labs/diagnostic studies necessary, or relevant to the patient's health status and the procedure performed;
6. If Mallampati IV and/or ASA class IV, an Anesthesia consult is required.
7. Documentation of post-procedure transportation (outpatients). **The patient may not drive home**; the patient must be discharged with a responsible adult who will accompany them home and be able to report any post procedure complications. In extenuating circumstances, when arrangements cannot be made for a responsible adult to provide transportation and stay with the patient for a few hours, the patient must stay for six (6) hours. At the end of six (6) hours, **the physician should be called to evaluate the patient and determine if they can leave unaccompanied. The patient may not drive.** The department performing the procedure must make arrangements for alternate transportation.
8. Documentation of pre-procedure/pre-op teaching and patient/significant others level of understanding.

B. Assessment Prior to Administration

Reassessment of each patient is performed prior to the administration of the planned moderate sedation/analgesia agents

Requirements:

- Vital Signs: 1) Baseline and
2) Pre-induction/sedation (Taken Immediately Prior to administration of medication)
- Level of Consciousness
- Equipment Availability

Time Out:

The “time out,” must occur in the location where the procedure will be done, immediately prior to starting the procedure. The “time out” may precede induction of anesthesia or may occur after the patient is anesthetized but just before starting the procedure. The timeout will involve the entire procedure team. At a minimum, this includes active participation by the operator/physician, and monitor. Timeout verification will include:

1. Correct patient identity.
2. Correct side, position and site, if applicable
3. Agreement on the procedure to be done.
4. Active communication during the timeout in this context, means an affirmation, orally or by some action, that the patient, procedure, and site are correct.

C. Care during the procedure

1. Administer appropriate moderate sedation/analgesia as per physician order. Documentation will include dosage, route, the time of administration. For procedures requiring moderate sedation/analgesia, IV access must be maintained until discharge criteria are met.
2. In keeping with the recommendations of the American Academy of Pediatrics any child requiring sedation needs to either have an IV in place, or have immediate access to someone who can place an IV in an emergency.
3. Assessing and monitoring of the patient is to be throughout the procedure. Blood pressure, pulse rate, respirations, and oxygen saturation will be monitored and documented every 5 minutes. Level of consciousness and pain assessment will be **documented at minimum at 15 minute intervals.** ECG monitoring is to be used for patients with hypertension and patients with documented cardiovascular disease or dysrhythmias. Monitoring alarms must be set and activated.
4. Monitoring of the pediatric patients during an MRI or CAT scan procedure will include heart rate, O2 saturation and LOC.
5. If moderate sedation/analgesia has not been administered for greater than 60 minutes, AND the patient is stable, documentation may occur at 15 minute intervals for prolonged procedures such as EPS.

IV. Post-Sedation Care

- A. The individual responsible to monitor the patient should ascertain and record the patient’s reaction to the sedation and/or the procedure, the patient’s vital signs, level of consciousness, activity, color and oxygen saturation (every 15 minutes for a **minimum of 30 minutes**) following the last *dose* of sedation administered. Continuous pulse oximetry must be utilized during the procedure until discharge. Outpatients may be discharged home 30 minutes after the completion of the procedure if the room air oxygen saturation has reached baseline and/or is \geq 94% and discharge criteria are met. If these parameters are not met, continue to monitor the patient every 15 minutes, as above, until the discharge criteria are met and/or the patient returns to his/her pre-sedation state.
- B. If an IV reversal agent is administered, the patient must then be monitored for a minimum of two hours before being assessed with discharge criteria, to ensure patients do not become re-sedated after reversal effects have abated.

V. Discharge Criteria

- A. Monitoring
The patient shall be observed and assessed until he/she returns to the **pre-sedation state.** Any patients receiving reversal agents require at least a two hour period of monitoring. The patient may be discharged when the patient has returned to the pre-sedation state with regard to:

1. vital signs and oxygen saturation level;
2. airway, breathing and circulation;
3. level of consciousness;
4. ability to verbalize; and if not clinically contraindicated;
5. ability to sit unaided, if applicable
6. ability to walk with assistance, if applicable
7. ability to take fluids.

B. Documentation

Documentation following moderate sedation/analgesia for diagnostic and therapeutic procedures shall include:

1. the time of discharge;
2. the patient's condition;
3. the discharge plan, written instructions regarding diet, medications, activities and a phone number to use in case of emergency;
4. disposition at the time of discharge;
5. name of responsible party/competent adult, or extenuating circumstances.

C. Education

Patients undergoing procedures performed on an outpatient or ambulatory care basis should receive instructions including:

1. verbal and written instructions regarding diet, medications, activities, and signs and symptoms of complications with course of action to take if any complication develops;
2. information regarding complications and conditions that warrant contacting their physician, and a 24 hour emergency contact;
3. patients should be advised to refrain from operating heavy machinery, driving a car and consuming alcohol for 12 hours.

VI. Transfer Criteria

A. Monitoring

The patient is deemed stable for transfer when the applicable discharge criteria is met and the patient has returned to the pre-sedation state. If the patient is immediately transferred to a cardiac monitored bed post procedure, monitoring of the patient should continue every 15 minutes until the patient has returned to the pre-sedation state.

B. Documentation

Documentation following sedation/analgesia for diagnostic and therapeutic procedures shall include:

1. time of transfer
2. the patient's condition
3. vital signs, respiratory rate, oxygen saturation and level of consciousness
4. physician instructions.

C. Education

Reinforcement of physician instructions and outcomes of the procedure may be needed secondary to amnesic effects of the medications.

VII. Performance Monitors

- A. Periodic evaluation of care processes will be done by departments or units performing moderate sedation/analgesia and reviewed for system-wide process improvements.
- B. Adverse events, including the use of reversal agents, will be reported via an Event Report to Risk Management office and processed for peer review through the Quality Improvement

Department.

References

- Comprehensive Accreditation Manual for Hospitals, JCAHO, 2005.
- Recommended Practices for Monitoring the Patient Receiving Intravenous Conscious Sedation
- Previous Administrative Conscious Sedation Policies Bryn Mawr Hospital, The Lankenau Hospital, Paoli Memorial Hospital
- ASA American Society of Anesthesiologists: Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologist Anesthesiology website Jan. 05
- State Board of Nursing, Chapter 21, No. 266 Jan. 1997

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BENZODIAZEPINE AGENTS						
Medication	Uses	Side Effects	Route	Duration of Action	Adult Dosage Range	Pediatric Dosing
Diazepam (Valium ®)	anti-anxiety, muscle relaxant, control of status epilepticus, acute alcohol withdraw	bradycardia, hypotension, respiratory depression, phlebitis	IV	Onset: 1-5 minutes Peak: 0.5-2 hours Duration: 15 min-4 hours	2-10 mg; Titrate to desired response. Infuse slowly; not to exceed 5 mg/minute. Lower doses should be used in the elderly; Maximum recommended dose: up to 20mg	0.04-0.3 mg/kg/dose q 2-4 hours; Maximum recommended dose: up to 0.6 mg/kg within 8 hrs. Infuse dose slowly over 3 minutes.
			PO	Onset: 30 minutes Peak: 1-2 hours Duration: 6-8 hours	5-10mg. Lower doses should be used in the elderly.	0.1 to 0.5mg/kg (max 20mg)
Lorazepam (Ativan ®)	anti-anxiety, hypnotic, status epilepticus, chemotherapy related n/v, muscle relaxant	dizziness, delirium, disorientation, agitation, respiratory depression	IV	Onset: 1-5 minutes Peak: 1-6 hours Duration: 12-24 hours	0.05 mg/kg at a rate not to exceed 2mg/min; Lower doses should be used in the elderly. Titrate to desired response. Dilute with equal volume NSS or D ₅ W prior to injection. Recommended dose: up to 4 mg	0.02-0.05 mg/kg/dose q 4-8 hrs.
			IM	Onset: 15-30 minutes Peak: 2-6 hours Duration: 12-24 hours	0.05 mg/kg up to a maximum of 4 mg. For optimal effect, administer at least 2 hours before procedure. Inject undiluted, deep into the muscle mass.	N/A
			PO	Onset: 60 minutes Peak: 1-6 hours Duration: 12-24 hours	2.5 - 4 mg.	0.05 – 0.1mg/kg (max 2 mg)
Midazolam (Versed ®)	hypnotic prior to short surgical procedure., epilepsy, anti-anxiety, sedation	prolonged sedation, hypotension, respiratory depression, respiratory arrest, apnea, phlebitis, nausea, vomiting, bradycardia	IV	Onset: 1-2.5 minutes Peak: 10-15 minutes Duration: 2 -6 hours	0.5mg - 2.5mg . Infuse slowly over 2 minutes; Titrate to desired response every 5 min. Lower doses should be used in the elderly; Maximum recommended dose: up to 5mg	0.05-0.15 mg/kg over 2 min.; Repeat prn. Recommended dose: up to 0.2 mg/kg or 2.5 mg
			IM	Onset: 10-15 minutes Peak: 20-60 minutes Duration: 1-6 hours	0.07 to 0.08 mg/kg IM (injected deep in a large muscle mass) approximately 1 hr prior to procedure; lower doses may suffice in debilitated patients or in patients > 60 yrs	0.1 to 0.15 mg/kg IM. Doses up to 0.5 mg/kg IM have been used. The total dose usually does not exceed 10 mg.
			PO	Onset: 10-15 minutes Peak: 10-15 minutes Duration: > 2 hours	N/A	0.2 –0.5mg/kg (max 15mg)
			Intra-nasal	Onset: 5-10 minutes Peak: 10-15 minutes Duration: > 2 hours	N/A	0.2-0.3 mg/kg

REVERSAL AGENT FOR BENZODIAZEPINE AGENTS						
Medication	Uses	Side Effect	Duration of Action	Adult Dosage Range	Pediatric Dosing	
Flumazenil (Romazicon ®)	complete or partial reversal of benzodiazepine induced sedation	Resedation- benzodiazepine dependent.	Onset: 1-2 minutes Peak: 6-10 minutes Duration: 1-4 hours	0.2 mg initial over 30 seconds; May repeat 0.2 mg – every 60 seconds until awake Total max. dose 1-3 mg.	0.01 mg/kg initial dose (max. 0.2 mg); then, 0.005 mg/kg (max. 0.2 mg) given every minute to a maximum total dose of 1 mg.	

NARCOTIC ANALGESICS						
Generic	Uses	Side Effects	Route	Duration of Action	Adult Dosage Range	Pediatric Dosing
Fentanyl (Sublimaze ®)	analgesia; pre-medication sedation	respiratory depression, bradycardia, apnea, hypotension, seizures, diaphoresis, chest wall rigidity after rapid iv infusion	IV	Onset: 5-8 minutes Peak: 5-15 min Duration: 30-60 minutes	0.05-0.1/mg/kg slowly over 1-2 min. May repeat dose q30-60 min.	1-4 mcg/kg/dose q 2-4 hrs. prn
Hydromorphone (Dilaudid ®)	alleviates moderate to severe pain, sedation	hypotension, respiratory depression, nausea, vomiting	IV	Onset: 15-30 min. Peak: 30-60 min. Duration: 4-5 hrs.	Recommended dose: up to 4mg IV slowly over 2-5 minutes	Not usually used in young children
Meperidine (Demerol ®)	treatment of moderate to severe pain, sedation	hypotension, nausea, vomiting, respiratory depression	IV	Onset: 10-45 min. Peak: 30-60 min. Duration: 2-4 hrs.	25 mg over 5 min. preferably diluted Recommended dose: up to 100mg	1-1.5 mg/kg/dose q3-4 hr prn Recommended dose: up to 100 mg
Morphine (Astramorph PF ®, Duramorph PF ®)	treatment of moderate to severe pain, sedation	respiratory depression, bradycardia, hypotension, hallucinations, nausea, constipation	IV	Onset: 15-60 min. Peak: 30-60 min. Duration: 3-7 hrs.	2 - 5mg slowly over 5 minutes Recommended dose: up to 15 mg	Neonates: 0.05-0.2 mg/kg/dose q 4 ^o <u>slowly</u> prn Children: 0.1-0.2 mg/kg/dose q 2-4 ^o <u>slowly</u> prn. Recommended dose: up to 15 mg

REVERSAL AGENT FOR NARCOTIC ANALGESICS						
Medication	Uses	Side Effect	Duration of Action	Adult Dosage Range	Pediatric Dosing	
Naloxone (Narcan ®)	complete or partial reversal of narcotic depression	resedation - narcotic dependent	Onset: 1-2 min. Peak: 4-5 min. Duration: 45 min-4 hrs. (dependent on dose and duration of narcotic)	0.1 mg - 0.2 mg IV repeat doses at 2-3 min. intervals until desired response Recommended dose: up to 10 mg	Children < 20 Kg: 0.01-0.1 mg/kg/dose IV. Repeat as necessary q 2-3 min. Children > 20 Kg or > 5 yrs: 2 mg/dose IV. Repeat q 2-3 min. prn	

MISCELLANEOUS AGENTS						
Generic	Uses	Side Effects	Route	Duration of Action	Adult Dosage Range	Pediatric Dosing
Chloral Hydrate (Noctec ®)	sedation	N/V	PO/PR	Onset: minutes Peak: minutes Duration: minutes	N/A	50 - 100 mg/kg