

Quality Management Committee-February 27, 2006

ADDITION TO CURRENT RULES AND REGULATIONS

DEEP SEDATION POLICY FOR NON-ANESTHESIA STAFF

Purpose

The purpose of this policy is to set forth standards and expectations for all patients receiving “deep sedation” conducted by non-anesthesiologists at Methodist Le Bonheur Healthcare hospitals. This policy applies to all areas where deep sedation might be administered by non-Anesthesiologists; Emergency Departments, Critical Care Areas, Radiology, Operating Rooms, and Starlight Room.

Focus

It is recognized that certain drugs, may be used for brief periods of sedation as might be needed for the conduct of a diagnostic or therapeutic procedure. Unfortunately, these drugs are accompanied by a higher risk of production of “deep sedation”, from which the patient is not easily aroused, and accompanied by loss of protective reflexes. Thus, this policy applies to the use of these agents, as defined by the department(s) of anesthesia.

Definition

A patient under sedation can convert into deep sedation and/or loss of consciousness because of the unique characteristics of the drugs as well as the physical status and sensitivities of the individual patient. The level of sedation planned will determine the level of qualified personnel and monitoring requirements.

Levels of Sedation and Anesthesia are defined as:

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 functions are unaffected. The lowest dose expected to produce this degree of sedation should be administered.
2. Moderate sedation/analgesia (“conscious sedation”)
A medically controlled state of depressed consciousness that (1) allows protective reflexes to be maintained; (2) retains the patient’s ability to maintain a patent airway independently and continuously, and (3) permits age-appropriate response by the patient to physical stimulation or verbal command, e.g., “open your eyes.”
3. Deep sedation/analgesia
Deep sedation: A medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused. It may be accompanied by a partial or complete loss of protective reflexes, and by the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command.

4. Anesthesia

General anesthesia: A medically controlled state of unconsciousness accompanied by a loss of protective reflexes, including the inability to maintain a patent airway independently and respond purposefully to physical stimulation or verbal command. (American Academy of Pediatrics)

Responsibilities/Oversight

The P&T Committee, through its Sedation Subcommittee (with Anesthesiology representations), as delegated by the Medical Executive Committee is responsible for the development of standards of practice for moderate and deep sedation in collaboration with other departments that provide the service, and with the Drug Information Center at University Hospital.

The Department(s) of Anesthesia will define appropriate agents for moderate and deep sedation. This information will be maintained in the Drug Information Center and on MOLLI.

The Medical Director of each department administering sedation will be responsible for ensuring that the standard is followed.

The Pharmacy & Therapeutics Committee will be responsible for overseeing the continuous quality improvement process for assessing outcomes in patients receiving moderate sedation.

Patient Selection Criteria

This policy is applicable to all ages served. The American Society of Anesthesiologists (ASA) classification system will be used as a guideline in the selection criteria. Patients appropriate for sedation will have an ASA classification of I - III. Patients with an ASA classification of IV or greater may require evaluation by Anesthesiology, depending on the setting.

The physician is responsible for assigning the patient an ASA classification, and for airway assessment.

ASA Classification

STATUS	DEFINITION
I	A normal healthy patient
II	A normal patient with mild systemic disease
III	A patient with a severe systemic disease that limits activity but is not incapacitating
IV	A patient with an incapacitating systemic disease that is a constant threat to life.
V	A moribund patient not expected to survive 24 hours with or without the procedure

Airway Assessment

The following findings may increase the likelihood of airway obstruction during spontaneous ventilation and should be recognized:

- Habitus: significant obesity (especially involving the neck and facial features)
- Head & Neck: short neck, limited neck extension, decreased hyoid-mental distance (<3cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation

- Mouth: small mouth opening, edentulous, protruding incisors, loose or capped teeth, high arched palate, macroglossia, tonsillar hypertrophy, nonvisible uvula
- Jaw: micrognathia, retrognathia, trismus, significant malocclusion

If any of the following findings is present by history or exam, the physician should strongly consider anesthesia consultation:

- Previous problems with anesthesia or sedation
- CPAP-dependent sleep apnea
- Dysmorphic facial features (e.g. Pierre-Robin syndrome, Trisomy 21)
- Advanced Rheumatoid Arthritis

Criteria for Administration

Agents likely to produce deep sedation must be administered only by a qualified physician. This physician must be specifically and solely focused on the administration of the medication and monitoring of the patient's response to the medication.

Maintenance of IV access is required for patients receiving IV sedation.

Location for Administration

Deep sedation may be administered only in an appropriately equipped diagnostic unit, limited to:

- Emergency Department
- Critical Care
- Radiology
- Operating room
- Starlight room

Appropriate monitoring equipment will be immediately available, including:

- Cardiac monitor, including defibrillator
- Oxygen availability by a system with positive pressure delivery
- Pulse oximetry
- Non-invasive blood pressure monitoring equipment
- age-specific Emergency equipment
- Crash cart, with appropriate intubation equipment
- Suction apparatus
- Emergency drugs, including flumazenil and naloxone

Pre-Procedure Assessment Responsibilities

Physician

Obtain baseline history. Assess the airway, including mouth and neck, and note ASA status.

An airway assessment and ASA classification must be present prior to the administration of sedation

Document plan for sedation (i.e. sedation with monitoring).

Obtain and document appropriate informed consent

Address NPO status per guidelines (see Appendix II).

The patient will be reassessed by the physician immediately prior to the procedure, and the reassessment will be documented in the record.

- A. Physician
- B. Qualified Personnel
- C. Verify informed consent
- D. Verify presence of H&P
- E. Verify presence of ASA classification by MD
- F. Verify physician pre-sedation plan
- G. Ensure availability and working condition of Age specific Emergency equipment
- H. Crash cart with Ambu bag
- I. Cardiac monitor including defibrillator
- J. Oxygen availability by a system with positive pressure delivery
- K. Suction apparatus
- L. Pulse oximetry
- M. Emergency drugs including flumazenil (Romazicon™) and naloxone (Narcan™)
- N. Non-invasive blood pressure monitoring equipment
- O. Confirm presence of venous access as indicated
- P. Perform and document age-specific, procedure-pertinent assessment to include:
- Q. Current medication
- R. Drug allergies or adverse reactions
- S. Procedure-pertinent history
- T. NPO status (see attached NPO guidelines: Appendix II)
- U. Baseline Vital signs (blood pressure [may be excluded if it interferes with care of the pediatric patient], heart rate, respiratory rate, heart rhythm, oxygen saturation, temperature)
- V. Level of Consciousness(pediatric patients will be evaluated according to developmental and age appropriate responses)
- W. Baseline Aldrete score

Intra-procedure Monitoring

Qualified personnel will be present in the room throughout the conduct of all cases requiring deep sedation.

The minimum number of personnel available for all cases requiring deep sedation shall be two; the operator (physician) and the qualified personnel administering and monitoring sedation. The qualified personnel administering and monitoring sedation is to be independent of the practitioner performing the procedure. Only physicians qualified by privileging and competencies may administer deep sedation.

The qualified personnel monitoring the patient during deep sedation shall have no other responsibilities except for the monitoring.

Standards for Patient Monitoring

Assessment of Level of Consciousness

The conscious patient will receive continuous age- and procedure-appropriate reassurance during the procedure. The qualified personnel will continuously assess the patient's level of comfort and tolerance during the procedure.

Oxygenation

During all procedures a quantitative method of assessing oxygenation (e.g. pulse oximetry), shall be employed. Supplemental oxygen shall be administered as needed.

Ventilation

During all procedures the adequacy of ventilation shall be evaluated by at least the continual observation of qualitative signs and the use of a stethoscope when needed.

Circulation and Rhythm

Every patient shall have their heart rate continuously monitored by pulse oximetry and electrocardiogram. Blood pressure will be monitored every 5 minutes during the procedure. In the patient 13 years old or younger, blood pressure will be monitored if the patient is hemodynamically unstable.

All patients: continuous heart rate monitoring by pulse oximetry and electrocardiogram. Blood pressure (BP) shall be monitored every 5 minutes during the procedure. In the patient 13 years old or younger, BP will be monitored if the patient is hemodynamically unstable.

Documentation

At a minimum, level of consciousness, oxygen saturation, respiratory rate, blood pressure and heart rate and rhythm shall be determined and recorded:

Before the beginning of the procedure

After administration of each dose of the sedative/analgesic. During prolonged procedures, monitoring shall be continuous, and documentation shall occur every 5 minutes.

Upon completion of the procedure.

During initial recovery.

At the time of discharge.

Documentation shall include medication(s) given with the dosage, route, time, and person administering.

Post-Procedure Care

Patient's post-procedure status will be assessed on admission to and before discharge from the post sedation or post anesthesia recovery area. Qualified Personnel will assess and document vital signs every 15 minutes or more frequently if the patient's condition warrants. Discharge from recovery will occur upon the direct order of a physician, following documentation of a level of consciousness that is consistent with that prior to the procedure, or based upon specific assessment criteria.

Qualified Personnel will observe and document any unusual events or post-procedural complications and the patient's response.

Inpatients will be transferred to their units and outpatients will be discharged home in the company of a responsible adult or parent.

Discharge Criteria

Patient will be discharged from the post sedation or post anesthesia recovery area upon the written order from a qualified licensed independent practitioner or attainment of Aldrete score within two (2) points of pre-sedation assessment score (see Appendix I). Patient cannot be discharged with a score of “0” in any category, unless the pre-procedure score in that category is zero (0).

Patients receiving reversal agent(s) must be monitored for a minimum of one (1) hour after last dose of reversal agent.

Documentation of time and condition of patient prior to discharge. Documentation that discharge criteria has been met.

Documentation of the name of the individual that will be responsible for transportation of the outpatient.

Provides report to the patient care staff receiving the patient.

Provide outpatients and/or significant other with written discharge instructions.

Credentialing and Competency

A. Qualified Physicians

Physician Privileges for Deep Sedation shall be granted by the Credentials Committee and are limited to Emergency Medicine, Pulmonary (Critical Care), or Critical Care physicians. Qualified physicians will also have privileges for Moderate Sedation as defined in the Moderate Sedation policy.

In addition, physicians qualified for administration of deep sedation will have intubation as part of core privileges and will successfully complete (as demonstrated by “passing” grade on an exam) a review of the pharmacology and adverse effects, administration, dosage, and emergency interventions of the sedative drugs used within the area.

B. Qualified (Non-physician) Personnel

These individuals are qualified for monitoring deep sedation (not for administration). Personnel shall meet the following requirements. These requirements are consistent with regulatory standards.

- 1) BLS training and
- 2) Successful completion of advanced certification (PALS or ACLS) or resuscitation management review (for Moderate sedation)

- 3) Successfully complete (as demonstrated by “passing” grade on an exam) a review of the pharmacology and adverse effects, administration, dosage, and emergency interventions of the sedative drugs used within the area.
- 4) Review equipment setup, troubleshooting, and monitoring parameters.

C. Compliance with Guidelines

Compliance with guidelines will be monitored by the Sedation Subcommittee of the P&T Committee.

Appendices

Performance improvement will be addressed as outlined in the attached appendix (Appendix III).

Appendix I: ALDRETE SCORE

Assessment	<u>Score</u>
Activity	
Able to move 4 extremities voluntarily or on command	2
Able to move 2 extremities voluntarily or on command	1
Not able to move extremities voluntarily or on command	0
Respiration	
Able to deep breathe and cough freely	2
Dyspnea, shallow, or limited breathing	1
Apneic	0
Circulation (Note: For baseline, automatically assign a score of 2)	
Blood pressure +/- 20% of pre-sedation level	2
Blood pressure +/- 20-50% of pre-sedation level	1
Blood pressure +/- 50% of pre-sedation level	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
O2 Saturation	
Able to maintain SaO2>92% on room air	2
Needs O2 to maintain SaO2>90%	1
SaO2 <90% even with O2 supplement	0

Appendix II: NPO Guidelines

Patients undergoing elective procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before the procedure. If NPO requirements have been violated the physician will decide to proceed, delay, or cancel the procedure. This decision will be documented in the medical record

Ingested Material	Minimal Fasting Period Before Procedure
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Solid food	8 hours

Appendix III: Performance Improvement

The P&T Committee will be responsible for monitoring patient outcomes associated with the administration of moderate or deep sedation. Pertinent data will be collected and reported for review through the Pharmacy & Therapeutics Committee.

Patient outcomes will be monitored using the following criteria:

- A. Hypoxia: drop in oxygen saturation to <90% for ≥ 2 minutes
- B. Unplanned admission or transfer to a higher level of care
- C. Administration of reversal agents
- D. Hypotension: drop of ≥ 20 mm Hg in systolic and/or diastolic blood pressure, requiring medical intervention(s). For the pediatric population, episodes of bradycardia will be assessed instead of this parameter.
- E. Requirement to place airway support (oral airway or ET tube).
- F. Requirement for assisted ventilation.
- G. All episodes of medical emergency (i.e. "Emery House" or "Harvey Team") related to the procedure.