Supportive Data

Sedation/Analgesia allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, and/or pain associated with these therapeutic, diagnostic, invasive, and/or noninvasive procedures. Sedation/analgesia may also be used to perform procedures that are not particularly uncomfortable but require that the patient be kept still during the procedure.

A collaborative effort by the American Society of Anesthesiologists (ASA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has produced comprehensive standards for safe sedation practices. The new guidelines stress the level or score referring to the patient’s level of sedation is independent of drug choice, route of administration, or the intended level of consciousness. Rather, patient’s are to be sedated and then continuously evaluated with respect to their actual (not intended) level of consciousness, presence or absence of protective reflexes, and response to painful stimuli.

Purpose

The purpose of this policy is to delineate hospital-wide guidelines for the administration of sedation/analgesia by Non-Anesthesiologist Licensed Independent Practitioners in order to provide their patients the benefits of sedation/analgesia during procedures while minimizing the associated risks. This policy provides guidelines for the appropriate pre-procedure, intra-procedure and post procedure assessment and monitoring of the patient undergoing sedation/analgesia for procedures.

Important Note: It is NOT the medication, dose of medication, or route of administration that determines the application of this policy. The level of sedation achieved and/or intended for the procedure solely drives application of this policy to a given patient situation!

Policy Statement

These guidelines apply to sedation/analgesia administered by ANY ROUTE. Evaluation of Mallampati airway classification and ASA classification are the ultimate responsibility of the sedating physician.

Policy Exclusions: Guidelines in this policy DO NOT APPLY to the following situations:

- Patients who are not undergoing a diagnostic or therapeutic procedure
- Control of seizures
- Alcohol withdrawal
- Therapeutic management of pain
- Sedation/Analgesia of mechanically ventilated patients *** (see special note for monitoring criteria)
- Physiologic emergencies
- Rapid sequence intubation for emergency airway management
Locations where sedation/analgesia may be administered for procedures

- Radiology Departments
- Georgia Heart Center to include: Cath Lab, EP Lab, Peripheral Vascular Lab, Non-Invasive
- Level IV & Level V Telemetry units
- Endoscopy Departments: Ambulatory Surgery Center, Inpatient Endoscopy
- Emergency Department
- Adult Critical Care Units to include: STICU, NICU, MSICU, CVICU

Definitions

1. **Minimal Sedation (anxiolysis/analgesia)** ~ a drug-induced state during which patients will respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

2. **Moderate Sedation** ~ 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.

3. **Deep Sedation** ~ 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. **Deep Sedation/Analgesia is covered under the Pediatric Deep Sedation Policy and only Pediatric Intensivist’s and Anesthesia providers are credentialed to administer deep sedation.**

4. **Pediatric Patient** ~ Patients 16 years of age or younger or those patients, up to age 21, who receive their primary or specialty care from a pediatric care provider.

5. **Adult Patient** ~ Patients over the age of 16 years.

QUALIFICATIONS/INITIAL COMPETENCIES

1. **Registered Nurse:**

The Registered Nurse responsible for the monitoring the patient during the procedure will be ACLS certified. In addition, initial training will include a demonstrated understanding of the pharmacological agents administered for moderate sedation as well as the antagonists for opioids and benzodiazepines as evidenced by a passing score of 80% on an MCCG designated Moderate Sedation training module. **This will be an annual competency requirement in high risk/low volume areas or at the discretion of the area director.**

2. **Resident Staff:**

Refer to Department specific Resident staff policies for training and experience related to the performance of Sedation/Analgesia Administration for Procedures. Residents must have privileging through their Department.

**Physician Staff**

The practitioners responsible for the treatment of the patient and/or administration of drugs for sedation/analgesia shall be trained and have the appropriate credentials to manage the patient receiving sedation/analgesia. **Credentialing for the administration of sedation/analgesia is granted through the MCCG Credentials Committee, MEC and the MCCG Board.** Refer to MCCG Privilege Delineation Criteria for Adult Moderate Sedation.
**Pre-Procedure Patient Evaluation and Preparation**

* Please Note: The literature supports the use of supplemental oxygen during moderate sedation to reduce the frequency of hypoxemia. There is agreement that supplemental oxygen decreases patient risk during moderate sedation. Supplemental oxygen should be considered for moderate sedation, unless contraindicated by patient diagnosis/condition.

**Normothermic** is best defined as a core temperature range between 36.5°C and 37.5°C (97.7°F – 99.5°F). Hypothermia prolongs drug action by decreasing metabolism, causes protein wasting, impairs platelet and clotting-cascade enzyme function, and triggers shivering and thermal discomfort. More importantly, core temperatures only 1-2°C below normal are associated with adverse patient outcomes.

Clinical Practice Guidelines developed by the American Society of Peri-Anesthesia Nurses recommends the following interventions:

Institute preventive warming measures for patients who are normothermic: 36.5°C - 37.5°C [97.7°F – 99.5°F]. A variety of measures may be used, unless contraindicated. Passive insulation may include warmed cotton blankets, limited skin exposure, circulating water mattresses and increase in ambient (room) temperature to 20°C – 23.8°C [minimum 68°F - 75°F].

Institute active warming measures for patients who are hypothermic 35.3°C [95.9°F or below]. Active warming is the application of a forced air convection warming system (i.e. Bair Huggar).

**Pre-Procedure History & Physical Examination:**

Baseline history and physical examination performed by Physician, Advanced Practice Registered Nurse (APRN), or Physicians Assistant (PA), to include, but not limited to:

1. Abnormalities of the major organ systems
2. Evaluation of patient’s airway using Mallampati Airway Classification [See Addendum B]
3. Evaluation of respiratory risk factors
   a. History of neck surgery
   b. History of heavy snoring
   c. History of sleep apnea
   d. Current CPAP or BiPAP
   e. Protruding or large tongue
   f. Protruding or recessed jaw
4. Previous adverse experience with sedation/analgesia, local anesthesia, regional anesthesia or general anesthesia.
5. **Review and acknowledgement of current medications**
7. History of alcohol, tobacco or substance abuse.
8. Focused physical examination, including careful auscultation of heart and lungs
9. **Fasting History:**
   a. For elective procedures the patient will be NPO for 6-8 hours, except for clear liquids up to 2 hours before the procedure.
   b. For emergency procedures, when fasting has not been assured, the increased risks of sedation must be weighed against the benefits, and the lightest effective sedation should be used. An emergency patient sometimes requires protection of the airway prior to sedation.
Physician Responsibilities

A. Documentation on Sedation/Analgesia Record (E 5098), will include the following:
   1. MD signature, date and time indicating patient has been evaluated immediately prior to sedation
   2. Assignment of an ASA classification [See Addendum A]

B. Informed consent
   1. Risks, benefits and possible alternatives to the procedure will be discussed with the patient or legal
      guardian and/or significant other (if procedure not emergently necessary) by the physician and
      appropriate consent form signed
   2. Risks, benefits and possible alternatives of sedation will be discussed with the patient, legal
      guardian and/or significant other (if procedure not emergently necessary).

C. Formulate a plan for sedation/analgesia

   **Important Note: Department of Anesthesia should be consulted for patients when the MD
   procedurist feels there may be problems with sedation. Emergency conditions sometimes mandate
   the initiation of a procedure prior to being able to obtain a consult on such patients.

Nursing Responsibilities:

1. Facilitate/assure pre-sedation history/physical is complete prior to start of procedure.
2. Review presence of ANY respiratory risk factors with sedating physician prior to start of procedure.
3. ALERT Respiratory Therapy Supervisor @ extension 3 - 6750 PRIOR to sedation of a patient with
   Class IV Airway and/or 2 or more risk factors for respiratory compromise.
4. Sedating RN to review current medications with MD prior to sedation
5. Baseline patient assessment to include: temperature, blood pressure, heart rate, respiratory rate,
   oxygen saturation, level of consciousness as defined by University Hospitals of Cleveland Sedation
   Scale [Addendum C]
6. Note pre-procedure temperature and institute temperature-warming interventions as appropriate.
7. Assure patent intravenous access.
8. For sedatives administered by routes other than intravenous ~ the sedating MD will determine need for
   IV access on a case by case basis.
   Assure “TIME OUT” prior to ALL invasive procedures.

Equipment

1. Emergency resuscitative equipment is immediately accessible to every location where
   sedation/analgesia is administered and where patients are recovered, including but not limited to:
   defibrillator, suction, airway equipment, oxygen, ambu and ambu bag, code cart, ECG, monitor and
   reversal agents (Narcan, Romazicon).
2. Personnel skilled in airway management are immediately available.
3. Personnel skilled in establishment of intravenous (I.V.) access are immediately available.
4. Equipment to administer supplemental oxygen should be present when sedation/analgesia is
   administered.
**Medications**

1. Physician selects and orders the medications and dosage(s).
2. The attending physician will be present for the administration of the sedating medication(s), and for assistance regarding any untoward effect of the medication(s). Intravenous sedative/analgesic drugs should be given in small, incremental doses that are titrated to the desired endpoints of analgesia and sedation. Sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by non-intravenous routes (e.g., oral, rectal, intramuscular), allowance should be made for the time required for drug absorption before supplementation is considered.
3. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (e.g., additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The propensity for combinations of sedative and analgesic agents to potentiate respiratory depression emphasizes the need to appropriately reduce the dose of each component as well as the need to continually monitor respiratory function.
4. Use of medications classified as “anesthetic agents” (i.e. Ketamine, Sodium Pentothal, Diprivan (Propofol), Etomidate) is prohibited for Moderate/Procedural Sedation. Use of these medications requires special privileging.

**Intra - Procedure Monitoring, Management and Documentation**

_Special Note:_ Patients who receive Minimal sedation (anxiolysis/analgesia) prior to a procedure will be assessed by the RN following the administration of the anxiolytic/analgesic to ensure that the patient continues to respond normally to verbal commands. If, at any time, level of consciousness becomes diminished, RN will follow documentation and monitoring criteria for moderate sedation!

**Moderate Sedation**

1. The minimum number of personnel available during procedural sedation/analgesia shall be two ~ the physician performing the procedure and the physician or ACLS Certified Registered Nurse administering the medications and monitoring the patient.
2. The Registered Nurse monitoring the care of the patient receiving sedation shall have no other responsibility that would leave the patient unattended or compromise continuous monitoring. Monitoring of the patient is to be continuous throughout the procedure.
3. Continuous assessment and monitoring of oxygen saturation (pulse oximetry), heart rate and cardiac rhythm throughout the procedure.
4. Heart Rate, respiratory rate, oxygen saturation, LOC, and blood pressure will be documented a MINIMUM of every 5 minutes during the procedure or more frequently if patient condition warrants.
5. Document all medications administered including: dose, route and exact time of administration.
6. At the completion of the procedure, document heart rate, respiratory rate, oxygen saturation, blood pressure, temperature, color, airway, respiratory effort and LOC as defined by University Hospitals of Cleveland Sedation Scale.
7. Document any unusual events during the procedure.

**Post Procedure Monitoring and Documentation**

1. The patient’s condition shall be evaluated continually for a MINIMUM of 30 minutes after the last dose of sedation is administered, during the post sedation recovery. An individual trained in recognition of post procedure/post sedation complications may monitor the patient during the recovery period.
2. A Registered Nurse will evaluate the patient to determine when discharge criteria have been satisfied. _Note: Particular attention is given to monitoring oxygenation, ventilation, circulation and temperature._
Post Procedure Monitoring and Documentation (continued)

3. During the recovery phase O2 saturation shall be continuously monitored by pulse oximetry.
4. Vital signs will be monitored and recorded at the beginning of the recovery period and at least every 15 minutes until return to pre-sedation status. **Vital signs include:** heart rate, respiratory rate and blood pressure. **Level of consciousness** will also be monitored and documented every 15 minutes until return to pre-sedation status.
5. Body temperature should be recorded at the beginning of the recovery period and prior to discharge.
6. **If the patient receives a reversal agent, the patient will be recovered/monitored for a minimum of two hours.**
7. The patient may be transferred to the receiving unit and/or discharged when the following discharge criteria have been met:
   a. Vitals signs return to pre-sedation status
   b. Level of consciousness returns to pre-sedation status
   c. SaO2 > 92% on room air or supplemental oxygen to maintain SaO2 >90% or a return to patient baseline
8. Any deviations from these discharge criteria must be cleared by the physician prior to discharge.

**Special Note: Monitoring of Ventilated Patients**

Ventilated patients are monitored continuously. With the understanding that sedation can cause physiologic changes, those ventilated patients, who require additional sedation/analgesia for procedures, will have the following documentation in the medical record:

1. Heart rate, respiratory rate, blood pressure, oxygen saturation every 5 minutes during the procedure.
2. Heart rate, respiratory rate, blood pressure, and oxygen saturation every 15 minutes at the end of the procedure until the vitals return to pre-sedation baseline.

**References:**

ADDENDUM: A

Physical Status Classification of the American Society of Anesthesiologists
Status Definition

I A normal healthy patient

II A normal patient with mild systemic disease

III A patient with 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 operation

E A classification used in conjunction with the scores above denoting an emergency situation.

NOTE:
Anesthesiology Department will be consulted for patients when the MD proceduralist feels there may be problems with sedation. Emergency conditions sometimes mandate the initiation of a procedure prior to being able to obtain an anesthesiology consultation on such patients.
Mallampati Airway Classification

Mouth: □ OK □ Small

Neck: □ Free ROM □ Decreased ROM

Indicate airway evaluation below:

Class 1: The soft palate, fauces, uvula and anterior and posterior tonsillar pillars can be seen.

Class 2: All of the above (class 1) features can be seen except the tonsillar pillars, which are hidden by the tongue.

Class 3: Just the base of the uvula is visible.

Class 4: Not even the uvula can be visualized.

NOTE: Anesthesiology Department will be consulted for patients when the MD proceduralist feels there may be problems with sedation. Emergency conditions sometimes mandate the initiation of a procedure prior to being able to obtain an anesthesiology consultation on such patients. If a patient presents with an unstable physiologic condition and/or a difficult airway, an anesthesiology consult should be considered.
ADDENDUM: C

University Hospitals of Cleveland Sedation Scale

1 = Awake

2 = Drowsy, anxiety free

3 = Sedated, but wakes to voice

4 = Sedated, arousable to pain

5 = Sedated, not arousable to pain

 Conscious/Moderate Sedation = Level 3

Deep Sedation = Level 4

For purposes of this policy, patients Level of Consciousness should not stay beyond Level 3