Introduction

Procedural sedation is a state of reduced excitement or anxiety induced with medication that allows patients to tolerate unpleasant procedures. It occurs on a continuum from minimal sedation to general anesthesia. As it is difficult to predict how individual patients will respond, practitioners intending to produce a given level of sedation should be able to recognize the level of sedation and rescue patients whose level of sedation becomes deeper than intended.

Scope

This policy refers to the provision of sedative and analgesic medications administered to adult patients for procedures outside of the operating room. The policy does not apply to sedation of intubated patients in critical care units.

Definitions

Ramsey Sedation Scale (RSS). The RSS scores sedation at six different levels. It is easy to interpret and replicate and it has specifically defined endpoints. (See Appendix A)

Minimal Sedation (RSS 2-3). 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 (RSS 3-4). 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 (RSS 5). A drug-induced depression of consciousness during which the patient 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 inadequate. Cardiovascular function is usually maintained.

Dissociative sedation: Dissociative sedation is a trance-like cataleptic state characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability. Ketamine is commonly administered to evoke dissociative levels of sedation.

Staffing and Credentials

1. A minimum of two personnel are required to perform procedural sedation:
   - The clinician performing the procedure, and
   - An appropriately trained regulated health care professional (RHP) whose sole responsibility is to monitor the patient during the procedure. Exception: For stable patients with minimal to
moderate sedation, the regulated health care professional may briefly assist in minor, interruptible tasks as long as appropriate monitoring of the patient is maintained.

2. Registered Nurses and Respiratory Therapists who administer physician-ordered sedative and analgesic drugs and monitor patients are restricted to moderate procedural sedation (RSS 3-4) and may not administer medications to provide deep sedation. They must successfully complete sedation-specific learning as determined by their respective disciplines.

3. Physicians require specific hospital privileges to 1) administer or supervise moderate sedation or 2) administer deep sedation.

4. Credentialing for moderate procedural sedation (RSS 3-4) will be restricted to physicians with formal training in the safe administration of sedative and analgesic drugs and the rescue of patients who exhibit adverse physiologic consequences of sedation. This training may be part of a residency or fellowship program or separate educational program. The Department Head is responsible for ensuring the physician requesting privileges has the appropriate training with knowledge and competence in:
   - Identifying patients at high risk for sedation-related adverse events
   - Pharmacokinetics of commonly used medications and reversal agents
   - Determining the depth of sedation using the Ramsay sedation scale
   - Management of sedation-related adverse events
   - Recognizing the adequacy of ventilatory function
   - Basic airway management skills including bag-mask ventilation
   - Knowledge of ACLS guidelines

5. For procedures requiring deep (RSS 5) or dissociative sedation, two physicians must be present. Privileges for deep and dissociative sedation are restricted to anesthesiologists, emergency medicine physicians, and adult intensivists. The physician providing this level of sedation must meet the following additional criteria:
   - Ability to perform and interpret capnographic monitoring
   - Proficiency in advanced airway management including endotracheal intubation

6. The prescribing of propofol is restricted as per the KGH Drug Formulary, Section 1. During the administration of propofol for procedural sedation, the ongoing presence of a physician authorized to prescribe it is required.

Equipment

Equipment that is required at the bedside includes the following:
- Oxygen source and administration equipment
- Suction source and equipment
- Basic airway equipment, (resuscitation bag, face mask, oral airways)
- Intravenous equipment
Medications, including reversal agents
Pulse oximeter
Cardiac monitor
Non-invasive blood pressure
Capnography – recommended for moderate sedation where available.
   – required for deep sedation

Equipment that must be readily available includes the following:
• Advanced airway equipment, (laryngoscope and endotracheal tubes);
• Resuscitation cart with defibrillator.

Consent

Informed consent for the procedure (including sedation) will be obtained and recorded by the
physician prior to sedation. Either a verbal or written consent will be recorded in the patient record,
except as provided in sections 5.1 (Emergency) and 5.5 (Overriding a Substitute Decider’s
Decision) of the KGH Administrative Consent to Treatment Policy #06-040.

Pre-procedure

1. Confirm that all emergency and procedure equipment is available and functioning

2. The physician is responsible for the assessment of the patient prior to administration of medications
   for procedural sedation. The assessment and documentation will include the following:
   • Present medical history and indication for the procedure
   • Current medications
   • Adverse reactions
   • Fasting status
   • ASA classification (Appendix B)
   • Weight and baseline vitals signs
   • Physical examination including an airway assessment

3. The physician will identify patients at high risk of complications from procedural sedation and
   consider an Anesthesiology consultation before the administration of medications. Conditions that
   increase the risk of sedation include but are not limited to:
   • ASA class > 3
   • Morbid obesity
   • Obstructive sleep apnea
   • Pregnancy
   • Severe neurologic impairment
   • Severe cardiovascular or pulmonary disease
   • Known or suspected difficult intubation or ventilation
   • Invasive or prolonged procedures
• Patients at high risk for aspiration (e.g. small bowel obstruction)

4. All members of the interdisciplinary team involved with the procedure will complete the procedural sedation safety checklist brief (Appendix C). The team will discuss the target depth of sedation required for the procedure.

Intra-procedure

1. The physician performing the procedure and the RHP providing sedation will remain in constant attendance with the patient throughout the procedure. Continuously monitor vital signs and depth of sedation throughout the procedure. Required monitors include pulse oximeter, cardiac monitor, and blood pressure. Capnography is required for deep sedation.

2. The RHP providing sedation will document all medications, dosages, and the time of administration and any adverse events (e.g., desaturation, apnea, hypotension, emesis etc) and interventions.

3. The RHP providing sedation will document vital signs (heart rate, blood pressure, respiratory rate), RSS level, oxygen saturation before the procedure and at least every 5 minutes during the procedure.

4. When the procedure is finished, the team will complete the debrief section of the safety checklist.

Post Procedure

1. Post-procedure care of the sedated patient may be delegated to an appropriately trained and qualified individual once the patient has recovered to a RSS 2 (awake, cooperative, and oriented) and meets an Aldrete score of > 9 (Appendix D).

2. The attending physician must be available to attend to the patient until discharge criteria are met.

3. Monitor and document vital signs (heart rate, blood pressure, respiratory rate), RSS level and continuous oxygen saturation
   • Every 15 minutes until discharge criteria are met
   • Patients must remain in the recovery area for at least 30 minutes after the last dose of sedative or analgesic medication.
   • Patients must remain in the recovery area for at least 120 minutes if opioid or benzodiazepine reversal agents have been administered
   • Intravenous access must be maintained until discharge criteria are met
   • Prior to discharge or transfer to another patient care area

4. A registered nurse may, with a physician order, discharge a patient from hospital or to another patient care area when the following discharge criteria are met:
   • A Modified PADSS score ≥ 9 or greater (Appendix E)
   • At least 30 minutes since the last sedative and 120 minutes since reversal agents
A responsible adult is present to transport the patient home and remain with the patient for at least 12 hours.

Verbal and written discharge instructions have been given to the patient and caregiver.

Patients must be instructed to refrain from driving or operating heavy machinery for 24 hours.

Documentation/Audit

1. Documentation of all aspects of care during procedural sedation is required (see example, Appendix F). The clinical record will contain the following:
   - Details of the pre-procedure assessment
   - Procedural sedation safety checklist
   - Record of all medications administered
   - Record of all observations; baseline, intra and post-procedure
   - Record of all adverse events
   - Record of discharge process; criteria, instructions, escort

2. Serious adverse events and critical incidents related to sedation must be documented in Safe Reporting for auditing purposes. Examples of reportable adverse events include:
   - Administration of sedation without the appropriate equipment or human resources
   - Suspected aspiration of gastric contents
   - Prolonged oxygen desaturation (SpO2 < 85% for 3 minutes)
   - Use of reversal agents
   - Need for unplanned endotracheal intubation
   - Unplanned admission due to complications from sedation
   - Cardiac or respiratory arrest

Authorizing Signature

Leslee F. Thompson
President and Chief Executive Officer
References:


