SAINT JOSEPH Regional Medical Center JOSEPH dical Center

Title: Sedation Performed by Non-Anesthesia Provider Version #: 7

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POLICY:

1. The purpose of this policy is to guide clinicians in providing their patients the benefits of sedation/analgesia within the parameters of sedation while minimizing the risks associated with drugs used to achieve the desired effect. This policy applies whenever medications are administered with the plan of either anxiolysis, moderate or deep sedation in the absence of an anesthesia consult.
2. **Exclusion Statement**: This policy does not apply in the following situations:
   A. When sedation medications are given in a critical care setting to patients on full ventilatory support.
   B. Sedatives given in the course of a rapid sequence intubation (RSI).
   C. Sedative medication given for the purpose of anxiolysis outside the procedural setting
3. The identified benefits of sedation are as follows:
   A. It allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort or pain through the administration of different medications or higher doses of medications than are routinely used for pain relief.
   B. It expedites doing procedures that are not particularly uncomfortable, but during which the patient must not move.
4. The identified adverse effects of sedation are as follows:
   A. Excessive sedation/analgesia may result in cardiac or respiratory depression.
   B. Inadequate sedation/analgesia may result in undue patient discomfort, or actual patient injury, either from lack of cooperation or an adverse physiological/psychological response to stress.
5. This policy applies to any procedural sedation in which the intent is moderate or deep sedation. Anxiolysis is defined and addressed in the policy to acknowledge the Continuum of Depth of Sedation.

6. Authority and oversight of sedation is the responsibility of the Chair of the Department of Anesthesia or their designee. The Anesthesia Chair participates in the development of policy, case review and resolution of any policy issues.
7. Departments in which moderate or deep sedation are used are responsible for assuring that a quality monitoring process is in place which allows for positive patient outcomes through the analysis of data and implementation of interventions. The Department of Anesthesia has responsibility for reviewing all quality data. The use of reversal agents must always be tracked and reported. Other events that may require reporting and review are an unplanned admission, cardiac arrest, use of assistance with ventilation (bag-valve-mask ventilation or laryngeal or endotracheal airways, prolonged periods of oxygen desaturation (< 85% for 3 minutes), and failure to return patient to 20% of preprocedure vital signs.
8. Sedation will be defined according to American Society of Anesthesiologists Standard (ASA) as follows:

CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

	Minimal Sedation Anxiolysis	*Moderate Sedation/ Analgesia "Conscious Sedation"*	*Deep Sedation/ Analgesia*	*General Anesthesia*
Responsiveness	Normal Response to verbal stimuli	Purposeful** response to verbal or tactile stimuli	Purposeful** response following repeated or painful stimuli	Unarousable even with painful stimuli
Airway	Unaffected	No intervention required	Intervention may be requited	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA* ***(continued)***

Committee of Origin: Quality Management and Departmental Administration

(Approved by the ASA House of Delegates on October 27, 2004, and amended on October 21, 2009)

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia ("Conscious Sedation") is 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/Analgesia 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.

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 function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

* Monitored Anesthesia Care does not describe the continuum of depth of sedation; rather it describes "a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure."

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

9. **Medications:**
   A. Refer to addendum 1 of this policy, Sedation Medication Administration Guidelines for the pharmacokinetics, dose and administration, precautions, contraindications, and side effects of these medications.
   B. The physician will determine the medication and dosage to be administered.
   C. Medications administered for sedation will be determined through patient assessment and will take into consideration medication allergies, current medication regime, any documented medication intolerances, and the patient's ability to maintain a patent airway.
   D. All medications administered for the purpose of sedation will be titrated to desired effect.
   E. Reversal agents will be kept readily available in every area in which sedation is administered or patients are recovered.
      1) Reversal agents should only be given in the event of an over-sedation.
      2) All instances of reversal agent use should be reported through the hospital reporting system. Data will be reviewed by the Department of Anesthesia.
   F. Anxiolysis Medications include:
      1) Diazepam (Valium)
      2) Lorazepam (Ativan)
      3) Midazolam (Versed)
   G. Moderate Sedation Medications include:
      1) Lorazepam (Ativan)
      2) Midazolam (Versed)
      3) Morphine
      4) Fentanyl (Sublimaze)
      5) Hydromorphone (Dilaudid)
      6) Ketamine (Ketalar)

H. Deep Sedation Medication only to be used by practitioners credentialed for deep sedation or anesthesia include:
   1) Methohexital (Brevital)
   2) Etomidate
   3) Propofol (Diprovan)
      a) Indications: Propofol is used for brief painful procedures, e.g. joint/fracture reductions, dislocations, cardioversions.
   4) Dexmedetomidine (Precedex)
   5) Ketamine (Ketalar)

I. Reversal Agents include:
   1) Naloxone (Narcan)
   2) Flumazenil (Romazicon)

10. **Approved Clinical Sites:**
   A. Moderate Sedation: Surgical Services, Emergency Department, Cardiac Catheterization Lab/Interventional Radiology, CIU, Diagnostic Radiology, MRI Center, GI/Endoscopy Lab, Pediatrics, NICU, and Critical Care.
   B. Deep Sedation: Emergency Department, Cardiac Catheterization, Critical Care, CIU.

11. **Credentialing, privileging, education, and competency of staff:**
   A. **Physicians:**
      1) Physicians performing sedation will practice within the guidelines outlined in this policy including Addendum 1, Sedation Medication Administration Guidelines.
      2) Sedation must be administered under the direct supervision of a privileged physician. Privileging is achieved by fulfilling the requirements established by the Medical Staff. Monitoring of the privileging status of physicians is the responsibility of the Medical Staff.
         a) Anxiolysis (minimal sedation)—No specific credentialing requirements
         b) Moderate sedation –credentialing is attached to procedure credentialing. If a physician is credentialed to perform a procedure, they are also credentialed in administration of the associated moderate sedation.
         c) Deep sedation –specific specialties, by merit of their core competency, will qualify to have deep sedation added as a line item credentialed privilege. Examples include Emergency Physicians and Cardiologists.
         d) General anesthesia is a core privilege for Anesthesiologists.
      3) Administration means overseeing the process of sedation.
      4) Direct Supervision for administering moderate and deep sedation is defined as having a privileged physician physically present in the room and prepared to provide emergent airway and ventilatory support as needed.
   B. **Nursing:**
      1) Registered Nurses are deemed competent in sedation upon completion of the annual competency requirements as defined below:

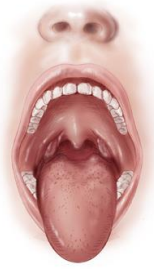
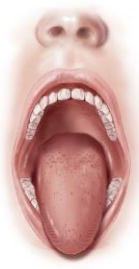
2) Completion of I-Learn Module entitled: Sedation Moderate/Analgesia (Conscious Sedation).
3) Completion of a written test on medications. There is a specific test for each level of competency:
    a) Moderate sedation
    b) Deep sedation
    c) Pediatric sedation
4) Demonstration of skills:
    a) In clinical setting w/preceptor or
    b) In simulation lab (unit based)
5) Current certification in ACLS and/or PALS and/or NRP as appropriate.
6) In addition, a competent nurse is able to:
    a) Operate and troubleshoot all necessary equipment.
    b) Demonstrate an understanding of the pharmacology (use, side effects, and complications) of sedative agents and their antagonists.
7) Identify EKG changes from baseline on the monitoring strips.
8) Establish a patent airway and positive pressure ventilation.
9) Registered Nurses may give meds under direction of credentialed MD who is present at the bedside.
10) A competent RN shall be assigned to monitor the patient throughout the sedation procedure. The level of qualification must be appropriate to the planned level of sedation
11) This nurse may assist others with interruptible ancillary tasks of short duration during the procedure if appropriate.

12. **History and Physical:**

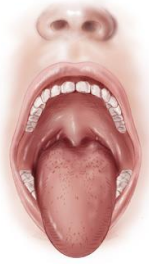
A. A complete history and physical examination (as defined in Medical Staff policy) shall be on the medical record prior to any patient receiving moderate sedation in either the inpatient or outpatient setting.

B. Appropriate candidates for conscious or deep sedation should be determined after a thorough history and examination that includes an airway assessment.

C. An airway assessment using the Mallampati Airway Classification system is required.
    a) Anesthesia is consulted if the physician planning to administer sedation has concerns about the ability to manage the patient airway due to anatomic or physiologic considerations.


Example of Mallampati Class I
- patient sits upright
- head in neutral position
- open mouth as wide as possible
- protrudes tongue
- soft palate
- anterior, posterior tonsillar pillars are visible
- uvula visible - all of it



Example of Mallampati Class II
- tonsillar pillars and tip of uvula hidden by base of tongue

http://vdmtc.org/module01/anatomy/mod01-fig06.jpg

Example of Mallampati Class III
- only the soft palate is visible
- a difficult intubation is predicted
- consider awake intubation

Example of Mallampati Class IV
- the soft palate is not visible
-a difficult intubation is predicted
-consider awake intubation

D. Assignment of a risk classification using ASA Physical Status Classification.

1) The physician who orders the sedation is responsible for assigning the patient an ASA classification.

2) Members of the sedation team must be in agreement with the classification prior to proceeding with the sedation/procedure.

3) Any member of the sedation/procedural team may request anesthesia evaluation/input prior to the procedure if there is a lack of consensus on ASA status and patient fitness for sedation. The procedure will not take place until a consensus is reached.

4) ASA Class P4 and P5 must receive an Anesthesia consult prior sedation/procedure unless the situation is deemed emergent. This will require supporting documentation of the nature of the emergency by the sedating physician.

ASA Physical Classification System

ASA Physician Status 1 - A normal healthy patient

ASA Physician Status 2 - A patient with mild systemic disease

ASA Physician Status 3 - A patient with severe systemic disease

ASA Physical Status 4 - A patient with severe systemic disease that is a constant threat to life

ASA Physician Status 5 - A moribund patient who is not expected to survive without the operation

ASA Physician Status 6 - A declared brain-dead patient whose organs are being removed for donor purposes

These definitions appear in each annual edition of the ASA Relative Value Guide.® There is no additional information that will help you further define these categories.

PROCEDURE:

A. **Informed Consent**:

1) The patient/guardian must be informed about the risks, benefits and alternatives of sedation as a component of the planned procedure.

2) Consent for Procedures/Sedation and Other Medical Services (form #6002) must be completed and signed prior to initiation of the sedation/procedure.

B. **Pre-Procedure Requirements**:

1) Clinicians administering sedation shall be familiar with and document relevant aspects of the patient's medical history to include:

a) Abnormalities of the major organ systems, including a neurological, cardiac, and respiratory assessment. (The sedating physician must complete and document)

b) Previous adverse experience with sedation, as well as general and regional anesthesia

c) Current medications and drug allergies

d) Actual weight unless medical status prohibits this measurement. An exact weight is required for pediatric patients.

e) The patient shall typically be seen in the preop area rather than the procedural suite thereby allowing adequate access for evaluation should anesthesia involvement be determined necessary.

1) Review and documentation of the following is also required:

a) Any pertinent pre-procedure diagnostic tests. Pre-procedural testing is driven by the patient's pre-existing medical conditions and by the likelihood that the results will affect the management of sedation.

b) Nothing by mouth (NPO) status. For elective cases, see for ASA recommendations. In emergent situations, the risks associated with recent oral intake must

ASA Guidelines for Preoperative Fasting

Ingested Material	Minimum Fasting Period [2]
Clear liquids[3]	2 h
Breast milk	4 h
Infant formula	6 h
Non-human milk[4]	6h
Light meal[5]	6h

1 These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee complete gastric emptying.
2 The fasting periods noted below apply to all ages.
3 Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.
4 Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
5 A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Additional fasting time (*e.g.,* 8 or more hours) may be needed in these cases. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

2) Prior to procedure a baseline assessment of the following parameters is measured and documented:

a) Respiratory rate and pattern

b) Oral/temporal artery temperature

c) Oxygen saturation

d) Skin color and temperature

e) Level of consciousness/orientation (age appropriate)

f) Blood pressure (Optional for pediatric patients)

g) Heart rate and rhythm-- A baseline EKG strip is placed in the medical record. (Optional for pediatric patients)

3) IV access is established. Exception: pediatric patients for whom sedation is accomplished with oral medications.

4) Pre-procedure education is documented

5) For elective outpatients, availability of a responsible adult to drive patient home and care for them is documented. Failure to establish this requirement will result in the procedure being rescheduled at a time when this resource is available.

6) All pre-procedural components of Universal Protocol policy, Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.

B. **Intra-Procedure Requirements:**

1) The following equipment will be used on every patient:

a) Pulse oximetry

b) Suction will be readily available at the bedside

c) EKG monitor (Optional for pediatric patients)

d) Blood pressure monitor (Optional for pediatric patients)

e) Capnography

2) Optional equipment dependent upon setting, procedure performed, physician order, patient positioning:

a) Pre-oxygenation with 2 lpm nasal cannula or as ordered by the sedating physician

3) The following equipment/supplies will be available in the immediate area during administration of sedation:

a) Oxygen delivery devices

b) Ambu bags and airways

c) IV supplies/equipment

d) Crash cart with cardiac monitor/defibrillator (Pediatrics: Braselow cart)

e) Pulse oximeter

f) Continuous EKG monitoring

g) Blood Pressure monitor

h) Suction

i) Reversal Agents

j) Means for summoning assistance

4) Medication Management:

a) All medications used for sedation will be ordered electronically using physician computerized order entry (CPOE). Depending on the area, individual doses may be charted on a specialty flow sheet at the time of administration and the total dose of each medication recorded on the electronic medication administration record (eMAR) at the end of the procedure.

b) Reversal agent for each type of sedation administered will be immediately available.

c) Use of oxygen will be ordered using CPOE and documented.

d) IV access will be maintained until the patient is no longer at risk for cardio/respiratory depression. IV access will be re-established if needed due to loss of access or premature discontinuation.

5) Patient Monitoring:

a) Perform and document all components of Universal Protocol policy, Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery.

b) The sedating nurse will document baseline values of all parameters: heart rhythm, pulse, respirations, blood pressure, oxygen saturation, ETCO2, skin color/temp, Ramsay score, and Aldrete score.

c) The patient's ventilatory and oxygenation status and vital signs will be monitored continuously during the sedation procedure and documented every 5 minutes.

d) Ramsay score and skin color/temp will be monitored through the procedure and documented every 15 minutes.

e) EKG rhythm will be documented post procedure only if there is a change from baseline.

f) Document each dose of medication, dose, route, and effect.

g) Document responses to all interventions.

h) Document the start and stop time of procedure and sedation.

i) The use of reversal agents at any point during procedure should be communicated to the next level of care and documented as follows:

(1) eMAR

(2) Significant Events notes

(3) Handoff form

6) Post-Procedure Requirements:

a) At the end of the procedure, the following criteria must be met to terminate the sedation procedure:

(1) Arousable, easily re-oriented, neurologically stable or baseline

(2) Airway, breathing, and circulation have returned to baseline

(3) Patient is comfortable and pain is managed

(4) Aldrete I score must be assessed and documented at the end of the procedure.

(a) If > 8 or pre-procedure value, patient may return to their pre-procedure setting or Postop/Phase II for ambulatory patients.

(b) If < or equal to 8, patient must remain monitored in the procedural setting until score allows transfer or patient must be taken to PACU. If decision is made to transfer to PACU:

[1] PACU must be alerted to patient arrival and complete handoff given upon arrival.

[a] The sedating physician must write PACU orders in addition to post–procedure /discharge orders as applicable.

[b] Patients who have received reversal agents during or immediately following the procedure should be placed in a setting that allows close observation and monitoring for a minimum of 2 hours post procedure.

[2] Plymouth Campus - If Aldrete I score is < or equal to 8, the patient will be transferred to the Critical Care Unit.

C. **Post Procedure Requirements:**

1) Upon return to the inpatient or ambulatory postop/phase II unit, vital signs, oxygen saturation and Aldrete II are documented as outlined in Nursing Policy, Assessment.
2) Outpatients may be discharged when criteria are met:
   a) Vital signs stable for at least ½ hour prior to discharge (2 hours if reversal agent given)
   b) Swallows and coughs
   c) Maintains respiratory function
   d) Minimal nausea, dizziness, or vomiting
   e) Effective pain management
   f) Oriented to person, place, and time
   g) Ambulates consistent with age and surgical procedure
   h) Minimal bleeding or drainage from surgical site
   i) Return of normal sensation (spinal/ epidural anesthesia)
   j) Voids spontaneously (spinal/ epidural anesthesia)
   k) Extremities pink and warm; pulses, sensation and movement present (extremity procedures).
   l) Abdomen soft, no severe abdominal pain, no covert bleeding (sigmoid / colonoscopy procedures)
   m) Swallows, no epigastric pain (EGD procedures)
   n) Patient and/or significant other adult given verbal and written discharge instructions

Related Documents:

- Sedation Monitoring Flowsheet (downtime Form)

Definitions:

- See definitions in body of policy

References/Standards:

- ASA House of Delegates. Continuum of depth of sedation: definition of general anesthesia and levels of sedation/analgesia. (2009).
- ASA House of Delegates. Statement on granting privileges for deep sedation to non-anesthesiologist sedation practitioners. (2010).
- ASA House of Delegates. Statement on granting privileges to nonanesthesiologist practitioners for personally administering deep sedation or supervising deep sedation by individuals who are not anesthesia professionals. (2006).
- ASA House of Delegates. Statement on safe use of propofol. (2009).
- Comprehensive Accreditation Manual for Hospitals, January 2010. Provision of Care, Treatment, and Services Standards PC.03.01.01-PC.03.01.05.

- Department of Health & Human Services, Centers for Medicare & Medicaid Services. (2010). *Revised hospital anesthesia services interpretive guidelines*.
- Gross, J.B. (2002, et al. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology, 96*(4), 1004-1017.
- Odom-Forren, Jan and Watson, Donna, Practical Guide to Moderate Sedation/Analgesia, 2nd ed., Elselvier Mosby, St. Louis Missouri, 2005.
- 2015-2017 Perianesthesia Nursing Standards and Practice Recommendations, American Society of Perianesthesia Nurses, Cherry Hill, New Jersey, 2010.
- 2015 Perioperative Standards and Recommended Practices, Association of Perioperative Registered Nurses, Inc., Denver, CO 2011