TITLE: Moderate Sedation Policy for Diagnostic, Therapeutic, and Invasive Procedures	**SEARCH WORD:** sedation
DEPARTMENT: All departments administering sedation	
VP APPROVAL: Jason Smith, MD, CMO	**DIRECTOR/MANAGER APPROVAL:** Terri Sartain, Medical Staff Services Director
EFFECTIVE DATE: 02/10/2003	**REVIEWED DATE(no changes):** 11/19/2015, 12/21/2018, 12/21/2021
LAST REVISED DATE: 12/12/2017	**REVISION HISTORY:** 01/10/2012, 9/11/2012, 8/12/2014, 7/11/2017, 12/12/2017

PURPOSE:
To establish appropriate standards for administering and monitoring sedation and analgesia.

POLICY STATEMENT:
Sedation occurs in a dose-related continuum, is variable, and depends on each patient's response to various drugs. The definitions listed below progress on a continuum from a high state of consciousness to unconsciousness. This policy addresses only practices for moderate sedation.

PROCEDURE:

CONTINUUM OF DEPTH of SEDATION
(Developed by the American Society of Anesthesiologists)

Note: Any Sedation on this continuum exceeding Moderate must be performed by a provider holding Deep Sedation privileges. Consult Anesthesia with any questions.

	Minimal Sedation (Anxiolysis)	Moderate Sedation Analgesia (Conscious)	Deep Sedation Analgesia	General Anesthesia
RESPONSIVENESS	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation	Purposeful response following repeated or painful stimulation	Unarousable, even with painful stimuli
AIRWAY	Unaffected	No intervention required	Intervention may be required	Intervention often required
SPONTANEOUS VENTILATION	Unaffected	Adequate	May be inadequate	Frequently inadequate
CARDIOVASCULAR FUNCTION	Unaffected	Usually maintained	Usually maintained	May be impaired

DEFINITIONS:

Minimal Sedation (anxiolysis)	A drug-induced state during which patient responds normally to verbal commands. Cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
Moderate Sedation/Analgesia	A drug-induced depression of consciousness during which patients respond purposely 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	A drug-induced depression of consciousness during which a patient cannot be easily aroused but respond purposely following repeated and 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.
Anesthesia	Consists of general anesthesia, and spinal or major regional anesthesia. It does ***not*** include local anesthesia. Drug induced loss of consciousness during which a patient 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.
Appropriately Trained Personnel	Registered nurses, physician assistants and paramedics whose competency to administer and monitor patients receiving moderate sedation has been assessed as satisfactory
Competency in Moderate Sedation	Appropriately trained personnel are able to: • Administer a medication to produce desired level of sedation and identify adverse reactions • Assess patient care requirements prior, during moderate sedation, and recovery. • Identify and report abnormalities to physician • Understand the principles of oxygen delivery, identify data from the oximeter and the use oxygen delivery devices • Demonstrate skill in airway management and resuscitation • Anticipate and recognize potential complications of moderate sedation and possess the requisite knowledge and skills to access and intervene in the event of complications or undesired outcomes. Institute appropriate interventions in compliance with physician orders
Procedural Sedation	• Begins with administration of sedation medication and concludes when procedure is complete
Post-Procedural Sedation (Phase 1 & 2)	• Begins when the procedure ends and continues until discharge criteria is met

Pediatric Patient	All patients from birth through 12 years
Licensed Independent Practitioner (LIP)	A physician who has a current license to practice and is approved to administer sedation. This does not include Advanced Practice Registered Nurses (APRN's) or Physician Assistants (PA's)
Diagnostic Procedure	This includes but is not limited to diagnostic radiology, including computerized tomography (CT), nuclear magnetic resonance (MRI), and echocardiography
Therapeutic Procedure	This includes but is not limited to orthopedic manipulations, and radiation therapy
Invasive Procedure	A procedure involving puncture or incision of the skin or insertion of an instrument or foreign material into the body including but limited to percutaneous aspiration and or biopsy, cardiac or diagnostic catherization, endoscopy, trans-esophageal echocardiography, angioplasty, central venous catheter placement, and percutaneous placement of long-term intravenous catheter (PICC)

This policy applies to the use of sedation and analgesia in all hospital departments and areas except as stated below:

1. This policy does not apply to patients who have Anesthesiologist, Anesthesia PA/AA or nurse anesthetist providing sedation because they are governed by the standards of care established by the Department of Anesthesiology. This includes patients receiving monitored anesthesia care (MAC), deep sedation, and general anesthesia.

2. This policy does not apply to patients in the Intensive Care Unit (ICU) or the Post Anesthesia Care Unit (PACU) under a 1:2 nurse to patient ratio who are mechanically ventilated.

3. This policy does not cover patients who receive anxiolytic or analgesia agents that are administered routinely to alleviate pain or agitation (e.g., sedation for treatment of insomnia, pre-operative anxiolysis, post operative analgesia) because they are not at significant risk.

PRE-SEDATION PROTOCOL:

1. Factors Affecting Candidacy for Sedation

A. Candidates for sedation and analgesia shall be in good general medical health and have adequate ventilatory reserve. For patients who have significant medical problems (e.g., severe systemic disease, morbid obesity, sleep apnea, upper or lower structural airway abnormalities) consideration shall be given for consultation with an anesthesiologist or an attending physician specializing in the primary disease affecting the patient.

B. For severely compromised or medically unstable patients, or if it likely that sedation to the point of unresponsiveness will be necessary to obtain adequate condition, practitioners not trained in administration of general anesthesia should consult an anesthesiologist.

Recommendations for consultation are:

1. All ASA class IV and V
2. Patients that have a family history of anesthesia complications
3. Patients that have had an episode of malignant hyperthermia
4. Patients that have an abnormal airway evaluation
5. Patients that have established barriers to intubation

C. Satisfactory arrangement for transportation after the procedure must be made before the patient is sedated.

2. Pre-sedation Assessment

A. A pre-sedation assessment by a Licensed Independent Practitioner, or a designated appropriate staff member under the direct supervision of the LIP, is required prior to administration of sedation and analgesia. The pre-sedation assessment will be documented in the patient's medical record. The pre-sedation assessment must be reviewed with respect to patient condition prior to administration of sedation and analgesia by the Licensed Independent Practitioner supervising the sedation who will sign the pre-sedation form.

B. A pre-sedation assessment includes but is not limited to:

a. Physical status assessment (review of systems, vital signs, cardiopulmonary reserve)
b. Assessment of the airway utilizing the Mallampati criteria
c. Previous adverse experience with sedation and analgesia as well as with regional and general anesthesia
d. Results of relevant diagnostic studies
e. History of tobacco, alcohol, and substance use/abuse
f. Verification of patient NPO status
g. Plan and choice of sedation
h. Transportation arrangements for patients who are expected to be discharged from the facility

C. Multiple Administration of Sedation and Analgesia

In patients who are undergoing procedures that require sedation and analgesia multiple times per day or single / multiple times on successive days, the initial pre-anesthesia assessment is sufficient as long as the physician performing the procedure determines through subsequent evaluation of the patient that no change has occurred in the patient's clinical status that would alter the outcome of administration of sedation and analgesia. A short note will be written in the patient's medical record stating that an evaluation of the patient's clinical status was performed prior to subsequent administration of sedation and analgesia.

3. Consent for Sedation:

A. The patient or the patient's parent / legal representative must be informed about the risks and benefits and must consent to the proposed sedation plan.

B. Documentation of informed consent will be included in the medical record. This may be included with consent for the procedure.

4. NPO Guidelines:

A. Airway reflexes are impaired proportionally to the degree of sedation. Therefore, appropriate pre-procedural fasting is recommended. See below table.

Age	Solids and Non-clear Liquids	Clear Liquids
Adult	6-8 hours or none after MN	2-3 hours
> 36 months	6-8 hours	2-3 hours
6 – 36 months	6 hours	2-3 hours
< 6 months	Breast milk – 4 hours Infant formula – 6 hours	2 hours
Exceptions to these guidelines may be made for unscheduled emergency procedures		

B. Certain procedures require the administration of oral fluids. Also in emergent, urgent, or other situation when gastric empting is impaired, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed or (3) whether the trachea should be protected by intubation.

EQUIPMENT NEEEDED:

Equipment must be available that is appropriate for the size of the child or adult being sedated and must be checked before sedation and analgesia are given. Minimum equipment in the area of the sedated patient **must** include:

1. A self-inflating positive pressure oxygen delivery system capable of administering oxygen at a 10 liter/minute-flow rate for at least 60 minutes or a flow-inflating resuscitation bag system (i.e., Mapleson-D).

2. Appropriate sizes of airway management equipment (e.g., masks, oral airways, endotracheal tubes, and laryngoscopes)

3. A suction apparatus with catheters and Yankauer rigid suction device.

4. Monitors including those capable of measuring:
    a. Oxygenation (pulse oximeter)
    b. Blood Pressure (automated or manual device)
    c. Heart Rate

5. Emergency resuscitation cart or kit as approved by the Hospital Code Blue Committee.

6. Telephone or other device capable of summoning assistance in an emergency.

7. Appropriate reversal agents.

SEDATION MANAGEMENT:

1. Monitoring and Documentation of the Procedure

A. Baseline vital signs shall be recorded in the sedation record before administering sedation and analgesia.

B. During sedation, the following vital signs shall be monitored, and documented contemporaneously in the sedation record at 5 minute intervals:

   a. Heart rate – continuous monitoring. This must be done by EKG on all patients
   b. Respiratory rate – by observation or auscultation
   c. Oxygen saturation (pulse oximeter) – continuous monitoring on all patients
   d. Blood pressure

C. Fluids and medications that are administered must be documented on the sedation record as well as the patient's intake and output.

D. The patient's general appearance and responses to stimulation are extremely important parameters and should be assessed and documented q 5 minutes. Response to commands during the procedure is a guide to level of consciousness (LOC). Additionally special attention should be paid to positioning of the patient after sedation and analgesia since airway obstruction and peripheral neurological injury can occur.

E. Alternative monitors may be used and alternative vital signs measured in situations when:

   a. The use of conventional monitors would be unsafe as in hyperbaric atmospheres and in water
   b. The use of conventional monitors would preclude imaging procedures because they would: distort the image or stimulate movement and produce artifact (BP cuffs on children, verbal stimulation or responses during a head CT or MRI)

2. Monitoring & Documentation Post Procedure

Aldrete Scoring is completed immediately post procedure and upon discharge at a minimum. Scoring may also occur dependent on patient condition or unit criteria.

3. Staff Qualifications

A. The registered nurse/physician assistant ("RN/PA") monitoring sedation and analgesia cannot be the same person who performs the procedure unless the procedure is itself that of monitoring (i.e. EEG). This individual should not have other responsibilities.

B. The RN/PA monitoring and administering sedation and analgesia shall:
   a. Understand the pharmacology of the sedating agents, as well as pharmacological antagonists
   b. Be able to recognize associated complications
   c. Know how to recognize airway obstruction and be capable of establishing a patent airway and delivering positive pressure ventilation
   d. Meet the numerical criteria of a passing score on the moderate sedation exam.
   e. Be ACLS, PALS, or ATLS certified.
   f. Understand that this document does not give them prescriptive privileges for propofol or controlled substances.

4. Physician Qualifications

A. Physician's privileging in accordance with medical staff bylaws will include:
   1. Completing a self-directed learning module, and passing the written exam available via email or hardcopy.

   2. Current certification in ACLS, PALS, ATLS, or board certification (or board eligible) in Emergency Medicine.

B. At the time of recredentialing, the physician must show proof of the following:
   1. Current certification in ACLS, PALS, ATLS, or board certification (or board eligible) in Emergency Medicine.

MEDICATIONS

A. Titration of incremental doses with allowance of adequate time for onset of effect is recommended. See dosage guidelines (Attachment A)
B. The specific sedative drugs used should be at the discretion of the practitioner and appropriate to the procedure and to the experience of the practitioner.
C. Patient's recovery from narcotic reversal agents should be monitored for 90 minutes prior to discharge.

DISCHARGE CRITERIA

A. Discharge will be based upon on the Modified Aldrete Scoring mechanism (see below). For all discharges from Phase 1 a score of 17 or greater or a return to the patient's pre-procedure state must be achieved. For all discharges from Phase 2 the patient must have achieved a score of 18 to 20 or returned to their pre-procedure state.

		Phase I → Phase II								
		Baseline	Minutes post procedure 0	15	30	45	60	75	90	Discharge
ACTIVITY Able to move 4 extremities voluntarily or on command Able to move 2 extremities voluntarily or on command Able to move 0 extremities voluntarily or on command	2 1 0									
RESPIRATIONS Able to breathe deeply and cough freely Dyspnea or limited breathing Apneic	2 1 0									
CIRCULATION ***Pre-op BP_____*** BP ± 20% of preanesthetic level BP ± 20% to 49% of preanesthetic level BP ± 50% of preanesthetic level	2 1 0									
CONSCIOUSNESS Fully awake Arousable on calling Not responding	2 1 0									
OXYGEN SATURATION Able to maintain oxygen saturation >92% on room air Needs oxygen inhalation to maintain O2 saturation >90% O2 saturation < 90% even on oxygen supplement	2 1 0									
DRESSING Dry or N/A* Wet but stationary Wet but growing	2 1 0									
PAIN "Zero to 10" Aldrete equivalents: Pain free 0 to 2 = "2" Mild pain 3 to 6 = "1" Pain requiring parenteral meds 7 to 10= "0"	2 1 0									
AMBULATION Able to stand up and walk straight or N/A* Vertigo when erect Dizziness when supine	2 1 0									
FASTING-FEEDING Able to drink fluids or N/A* Nauseated Nausea and vomiting	2 1 0									
URINE OUTPUT Has voided or N/A* Unable to void but comfortable Unable to void but uncomfortable	2 1 0									
TOTALS										
Signatures	Time ⇒ ⇓ Initials ⇒									

*Any section determined to be N/A (not applicable) will receive a score of 2.

B. A post-procedure note should be completed by the LIP, including a discharge summary.

C. Prior to discharge from Phase II, the person responsible for the patient shall receive written instructions from the facility that will include:
   g. Information about expected behavior
   h. Instructions for eating
   i. Warning signs of complications
   j. Special instructions in case of emergency

D. If a patient is being discharged home:
   a. Ensure that the patient has prescription(s)
   b. Ensure that an adult will drive the patient home, or that an adult will accompany the patient via taxi
   c. Document patient's status and any instructions given on the appropriate flow sheet

Location:

All cases involving moderate sedation will be performed in areas where a properly credentialed Licensed Independent Practitioner (LIP) and trained staff are present. Areas where these criteria are consistently met are Endoscopy Lab, Emergency Center, Intensive Care Unit, Surgical Services, Radiology, Neurodiagnostics, and the Cardiac Cath Lab.

Performance Improvement:

Performance Improvement opportunities are identified through occurrence reporting.

References:

American College of Emergency Physicians (ACEP). Use of Short Courses in Emergency Medicine as Criteria for Privileging or Employment, January 2016. https://www.acep.org/Clinical---Practice-Management/Use-of-Short-Courses-in-Emergency-Medicine-as-Criteria-for-Privileging-or-Employment/. Accessed May 22, 2017.

American Academy of Emergency Medicine (AAEM). Position Statement on the Advanced Cardiac Life Support Course, February 1998. http://www.aaem.org/em-resources/position-statements/1998/acls. Accessed May 22, 2017.