


Name of Policy: <u>Sedation/Analgesia by Non-Anesthesiologists</u> Policy Number: 3364-100-53-11 Department: Hospital Administration Medical Staff Approving Officer: Chief Executive Officer - UTMC Responsible Agent: Chief of Staff Scope: The University of Toledo Medical Center and its Medical Staff	 Effective Date: 06/16/2021 Initial Effective Date: 9/12/1990
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

(A) Policy statement

This policy provides a framework for the care and monitoring of patients receiving sedation/analgesia by non-anesthesiologists when undergoing therapeutic or diagnostic procedures. Sedation/analgesia describes a continuum where patients are introduced to medications in any form or given by any route which results in sedation or analgesia. These drugs are expected to cause central nervous system depression with maintenance of adequate cardiopulmonary function and the ability to respond in a purposeful manner to verbal command and/or tactile stimulation. The purpose of administering sedation/analgesia is to allow patients to tolerate unpleasant therapeutic or diagnostic procedures. It is recognized, but not expected, that the administration of sedating drugs may cause the loss of protective airway reflexes and/or cardio-respiratory depression. There exists a need for appropriate and consistent monitoring of patients receiving sedation/analgesia to minimize unexpected consequences of drug administration and maximize patient safety. This policy applies to any patient receiving moderate (conscious sedation) or deep sedation. Minimal sedation is purposely omitted from this policy but addressed in UTM C S.O.C. D16 and D10.

(B) Purpose of policy

To safely provide control of pain, anxiety, and/or apprehension for patients undergoing diagnostic and/or therapeutic procedures.

(C) Procedure

1. ACTIVITIES CONDUCTED OUTSIDE OF INTENSIVE CARE UNITS

a. Pre-Procedural

- 1) The Sedating Licensed Individual Practitioner (“LIP”) utilizing sedation/analgesia assessment form #AN004 will perform the appropriate pre-procedural assessment. The areas to be assessed include but are not limited to medical history, drug history, physical examination (including vital signs and auscultation of the heart and lungs), and evaluation of the airway. The patient's physical status will be evaluated and assigned a classification according to the American Society of Anesthesiology (“ASA”) Physical Status Classification.
- 2) Pre-sedation/analgesia instructions typically include the omission of solid foods or full liquids for 8 hours prior to the scheduled procedure and omission of clear liquids three hours prior to the procedure.
- 3) Pre-sedation/analgesia checklist including NPO status, jewelry, dentures or oral appliances, glasses or contact lenses, allergies, medications, and history of anesthesia complications will be checked and signed by the sedating physician or his/her designee. The Sedating LIP may amend these time intervals after considering the patient's medical condition and urgency of the procedure. These instructions will be confirmed with the patient, legal representative/parent or family.
- 4) The Sedating LIP or designee will explain the risks/benefits of sedation/analgesia and obtain informed consent prior to the procedure.

- 5) Documentation of the patient's baseline vital signs will include heart rate, blood pressure, respiratory rate, oxygen saturation, level of consciousness, and pregnancy status.
- 6) Sedation/Analgesia procedures are to be performed only when necessary personnel and equipment for monitoring and safety are available. Staffing consists of at least one RN or LIP, other than the Sedating LIP, who has demonstrated competency in managing the care of patients receiving sedation/analgesia.
- 7) Emergency equipment: Dedicated areas for sedation/analgesia should be maintained with appropriately sized emergency equipment. Minimal equipment should include advanced airways (endotracheal tubes, LMA, etc.), simple airway management equipment, positive pressure ventilation device, size appropriate facemask. Suction equipment should be available at bedside. ACLS/defibrillator cart should be immediately available in the area. Equipment to administer supplemental O₂ shall be present for all sedation/analgesia cases. Drugs/dosages, including IV reversal agents such as naloxone and flumazenil will be checked and available prior to procedure.
- 8) A patent IV line shall be established and maintained throughout the procedure. In the event an IV is dislodged or infiltrates during the procedure, the procedure should be halted if possible and equipment and personnel capable of re-establishing an IV should be immediately available. Intravenous access shall be discontinued on the order of the Sedating LIP once the danger of re-sedation has passed and discharge criteria are met.
- 9) For patients determined to be ASA III or greater, at extremes of age (very young or very old), morbidly obese, pregnant, or those who have history of previous adverse anesthesia or sedating drug reaction, significant substance abuse, sleep apnea or significant airway findings (formAN004, Mallampati Class III or above), the Sedating LIP should consider consultation with anesthesiology or other specialties prior to administering sedation/analgesia.
- 10) After the patient enters the procedure area and prior to any sedation being given or the procedure starting, the procedure team consisting of the Sedating LIP or designee, the procedure area staff and the monitoring RN or LIP will complete the Universal Protocol Documentation (Policy #3364-100-53-5).

b. Procedural

- 1) Adherence to pre-procedural guidelines as stated above.
- 2) Appropriate patient monitoring shall be completed immediately prior to sedation and will include pulse oximetry/expired CO₂, non-invasive blood pressure monitor, level of consciousness, heart rate, and respiratory rate. EKG monitoring is indicated on all patients receiving moderate or deep sedation. Level of sedation monitoring should be routine. Patients in whom verbal response is not possible, e.g., intra-oral procedure, may be monitored by a "thumbs up" sign or equivalent.
- 3) Availability of staff person dedicated to patient safety: A registered nurse/LIP who is not performing the procedure will be available to monitor the patient on a continuous basis during the sedation/analgesia procedure.
- 4) Recording of monitored parameters: Patient monitored parameters shall be recorded minimally every 5 minutes during the procedure.
- 5) Combinations of more than one sedative/analgesic drugs: It is recognized that using drugs from different categories may be necessary to achieve optimal sedation/analgesia for certain procedures. The potentiating of respiratory depression by combination drug therapy must be appreciated. Small doses of different agents should be slowly titrated to effect with sufficient time between doses to allow for drug absorption and action prior to additional agent administration.
- 6) Patients receiving IV medications for sedation/analgesia should have a patent IV line verified prior to and during the procedure and it should be continued until risk of re-sedation or cardio respiratory depression by the agent has passed. In all cases, individuals skilled at establishing intravenous access and equipment to do so should be available. In the event that the intravenous line fails the procedure should be halted if

possible and new IV access established. The responsible physician shall determine the need to re-establish intravenous access.

- 7) Dosages: The Sedating LIP is ultimately responsible for the patient specific sedation/analgesia prescription. This includes the medication(s), dose, and the route by which it is to be administered. The individualized sedation/analgesia prescription will take into account the type, painfulness and duration of the procedure as well as health of the patient. Pediatric and adult dosing guidelines and reversal agent guidelines are available from Pharmacy. The dosages listed are only guidelines, dosing must be customized to the individual patient and combination of agents being utilized.

c. Post-Procedural

- 1) Post-procedural monitoring is to be done every 5 minutes for the first 15 minutes then every 15 minutes till discharge criteria are met, or more frequently as required. Post-procedural monitoring shall include SpO₂, blood pressure, level of consciousness, heart rate, continuous ECG, and respiratory rate.
- 2) Specific discharge criteria will be followed on the post-sedation/analgesia recovery sheet. Patients may return to routine nursing care or be discharged when he/she is physiologically stable, at baseline, and/or achieved a score of at least 8 on the Modified Aldrete Scale (see form #AN004) or on the specific order of the Sedating LIP.
- 3) Patients will not be released to home after sedation/analgesia unless a responsible adult is in attendance. The responsible adult shall drive the patient home or accompany the patient home. However, in special circumstances and after prolonged monitoring, the Sedating LIP may approve the discharge of the sedation/analgesia patient, when discharge criteria are met, without a responsible adult in attendance.
- 4) Each patient receiving sedation/analgesia should be monitored by the registered nurse or LIP under the direction of the sedating LIP, for adverse reaction to drugs and for physical and psychological changes. The sedating LIP must be accessible by the monitoring personnel until post-procedure monitoring is completed. Drugs administered for sedation/analgesia may cause behavioral changes and rapid, adverse physiological changes. Continual observation of the patient for desired therapeutic drug outcomes, prevention of adverse effects, and accurate documentation of the patient's response are integral components of the drug monitoring process.

2. NON-EMERGENT ACTIVITIES CONDUCTED IN THE INTENSIVE CARE UNIT

Documentation of any sedation and analgesia for patients in the intensive care area will be accurately charted. (In lieu of formAN004)

a. Pre-Procedural:

- 1) Sedation/analgesia pre-procedural checklist is completed.
- 2) The RN will document a physical assessment prior to procedure.
- 3) If multiple sedation/analgesia events occur within a 24-hour period, any changes to the initial pre-procedural assessments are to be documented in the "Progress Notes." The physician should also document an interval note prior to each subsequent sedation event. Consent for procedure(s) is the responsibility of the physician, and may include consent that covers multiple procedures, e.g., dressing changes.
- 4) RN confirms and maintains IV access or seeks assistance from an MD to obtain access.

b. Procedural:

- 1) BP, HR, SpO₂, respiratory rate, EtCO₂ if not intubated and character, level of consciousness, and pain will be documented at least every 5 minutes until return to baseline is established. A note or order from the sedating physician will indicate that the sedation event is complete, and the patient may return to routine ICU care. This monitoring will be used in place of the modified Aldrete Score, since the patient will remain in the ICU post procedure.
- 2) Medications time, dose, and route will be charted.
- 3) EKG rhythm strips are to be posted with other routine EKG recordings.

c. Post-Procedural:

- 1) Reversal/non-reversal of sedation/analgesia will be documented.
- 2) Toleration of procedure and any comments will be recorded.
- 3) Recovery of the sedation/analgesia patient in the intensive care setting will follow the same Standard of Care and Practice regarding the immediate (post-anesthesia) care of the post-op patient.
- 4) RN signature is required by the RN monitoring/documenting the procedure.
- 5) MD signature is required for medications given during the procedure.

3. QUALITY ASSURANCE MONITORING

- a. The Clinical Service Chief of the respective clinical service will be responsible for quality assurance monitoring of all sedation/analgesia cases within that clinical service. The Quality Assurance Monitoring Tool shall be completed for each procedure and forwarded to the Quality Management Department.
- b. Qualification for Administering and Monitoring Sedation/Analgesia - Persons performing sedation/analgesia care are responsible for maintaining skills necessary to provide safe patient care. These personnel are required to be familiar with proper drug dosages, adverse reactions, and interventions for drug reactions, respiratory depression and airway management. Clinical service chiefs are responsible for the regular assessment, evaluation and delineation of privileges to trained members in their respective areas.
- c. Only a licensed physician, or dentist is qualified to prescribe, order and select the medications to be used to achieve sedation/analgesia. RNs or LIPs with appropriate education may administer IV drugs for the purpose of producing sedation/analgesia under direction of a qualified LIP consistent with Ohio Board of Nursing Rules. Monitoring and discharge must be performed by qualified personnel under the direction of the qualified sedating LIP.
- d. A minimum of 5 charts will be audited yearly, 10 charts total during the two-year credentialing period for compliance and quality assurance. Quality metrics will be SaO₂, EtCO₂, respiratory rate, use of reversal agents (naloxone, flumazenil), and intubation. Adherence to sedation dosing guidelines as set forth by the moderate sedation competency will also be assessed

(D) Definitions

1. Minimal sedation (anxiolysis) - - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, respiratory and cardiovascular functions are unaffected
2. Moderate sedation/analgesia ("conscious 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/analgesia - - A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
4. General Anesthesia - - General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory 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.

(F) Prerequisites

1. Attending physicians who wish to administer moderate sedation to adults and/or pediatric patients must be properly privileged through the Medical Staff Office. Residents can only provide moderate sedation under the supervision of a properly privileged attending physician.

2. Areas within the clinical delivery site are designated and equipped for sedation/analgesia. The areas include, but are not limited to, the Emergency Department, radiology sites (RT, MRI, CT, main radiology), catheterization lab, endoscopy, and the operating rooms.

Approved by:		Review/Revision Date:	
<u>/s/</u>	<u>06/16/2021</u>	1/9/91	4/27/2011
Rick Swaine	Date	6/9/93	5/1/2014
Chief Executive Officer - UTMC		5/8/96	2/1/2017
		10/4/96	4/1/2020
		7/14/99	6/1/2021
		9/8/99	
		6/14/00	
<u>/s/</u>	<u>06/16/2021</u>	4/11/01	
Andrew Casabianca, MD, DMD	Date	1/9/02	
Chief of Staff		5/8/02	
		9/10/03	
		9/8/04	
		6/8/05	
		3/14/07	
<i>Review/Revision Completed By:</i>		Next Review Date: 6/1/2024	
HAS			
Clinical Service Chief - Anesthesia			
Chief of Staff			
Policies Superseded by This Policy: 7-53-11			