I. Title

*Moderate Sedation (Conscious Sedation)*

II. Policy

A. The following policy sets uniform requirements and minimum standards for the use of moderate sedation for therapeutic, diagnostic, or surgical procedures performed at UTMB.

B. All UTMB patients who receive moderate sedation for a procedure will be provided a safe and comparable level of care consistent with, or in excess of, the minimum recognized standards for such procedures.

C. UTMB respects the diverse cultural needs, preferences, and expectations of the patients and families it serves to the extent reasonably possible while appropriately managing available resources and without compromising the quality of health care delivered.

III. Exclusions

A. This policy applies to the use of moderate sedation in all healthcare areas except as stated below.
   1. This policy does not apply to:
      a) Sedation provided by an anesthesiologist/Certified Registered Nurse Anesthetists (CRNA);
      b) Mechanically ventilated patients in the Intensive Care Unit (ICU), ER or Post-Anesthesia Care Unit (PACU) with EKG, B/P and SaO2 monitoring; or
      c) Administration of anxiolytic or analgesic agents when administered routinely to alleviate pain and agitation (e.g., sedation for treatment of insomnia, pre- or post-operative analgesia).

B. *Anesthetic Agents Ketamine, Propofol, Etomidate, and Methohexital*: Refer to Pharmacy Policy 7.71 Administration of Anesthetic Agents by Non-Anesthesiologists for additional requirements for use of anesthetic agents for sedation.

C. The use of these agents for non-procedural sedation by continuous drip is addressed in Pharmacy Policy 07.49 Preparation and Administration of Medications via Continuous Intravenous Infusion (Adult).

IV. Privileges

A. Anesthesiologists/CRNAs are privileged to provide all levels of sedation, including moderate sedation with no additional requirements.
B. Licensed Independent Practitioners (LIP), including MD, DO, DDS, Podiatrist, PA, or APRN, not privileged to provide anesthesia will need to be privileged by UTMB to direct and administer moderate sedation based on UTMB Moderate Sedation Education Requirements, as follows:

1. The LIP must maintain at least one current Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS), or Neonatal Resuscitation Program (NRP) certification, as appropriate to the population served.

2. The LIP must successfully complete the online Moderate Sedation course and final assessment every two (2) fiscal years.

3. The LIP must be familiar with this policy.

4. The LIP must be granted the moderate sedation privilege by the credentialing office.

5. Those who have met these criteria are privileged to direct and administer moderate sedation with no additional supervision requirements.

V. Personnel

A. Moderate sedation directed by someone other than an anesthesiologist/CRNA, requires use of a Credentialed Monitoring Assistant.

B. The practitioner privileged to direct moderate sedation is responsible for the safety and wellbeing of the patient, and will ensure that this policy is observed. In either elective or emergent procedures, if circumstances warrant deviation from this policy, the reason will be documented in the patient’s medical record. Additional responsibilities include:

1. Completion of informed consent for both the procedure and the use of sedation;
2. Ordering medication (including dosage and route of administration); and
3. Directing and providing emergency interventions as necessary.

C. A Credentialed Monitoring Assistant will be credentialed by UTMB through completion of the UTMB Moderate Sedation Education Requirements:

- The Credentialed Monitoring Assistant must maintain at least one current certification described below as appropriate to the population served.
  i. ACLS;
  ii. PALS or ENPC (Emergency Nursing Pediatric Course);
     Or
  iii. NRP certification.

D. Departmental approval for participation as a Credentialed Monitoring Assistant is evidenced by request for assignment of the online Moderate Sedation course.

E. The Credentialed Monitoring Assistant must successfully complete the online Moderate Sedation course and final assessment every two (2) fiscal years.

F. The Credentialed Monitoring Assistant must be familiar with this policy.

G. The Credentialed Monitoring Assistant’s responsibility is to monitor physiologic parameters and assist in any supportive or resuscitative measures, as required. The Credentialed Monitoring Assistant...
Assistant must also:
1. Be familiar with the effects of the drugs used;
2. Know how to recognize an airway obstruction and correct it;
3. Know how to monitor required parameters, recognize abnormalities in the required parameters, and intervene as needed;
4. Be able to manage ventilation with a self-inflating bag valve mask; and
5. Be familiar with this policy

H. Medication may be administered only by individuals permitted to do so by their licensure and UTMB.

VI. Equipment
Monitoring equipment detailed herein will be available, including:
1. Device to measure blood pressure;
2. Pulse oximeter;
3. Continuous ECG will be used for patients requiring continuous ECG monitoring;
4. Oxygen, including a positive pressure oxygen delivery system;
5. A functional suction apparatus;
6. Emergency medication and equipment, including emergency airway equipment; and
7. Appropriate reversal agents located in the procedure room.

VII. Informed Consent
A. Each patient, parent, or guardian must receive an explanation regarding the risks and alternatives of moderate sedation.

B. Appropriate informed consent for both the procedure and sedation will be obtained prior to sedation. Refer to the following related policies: IHOP Policy 9.3.17 Patient Consent - Overview and Basic Requirements and IHOP Policy 9.3.18, Consent – Treatment of a Minor.

VIII. Dietary Precautions
A. Sedation may reduce airway protective reflexes, thus allowing pulmonary aspiration of gastric contents in the event of emesis. The use of sedation will be preceded by an evaluation of food and fluid intake.

B. Elective: Before elective sedation, oral intake will be curtailed as appropriate for age.
   Clear liquid: 2 hours
   Breast milk: 4 hours
   Infant Formula: 6 hours
   Non-human milk: 6 hours

C. Light meal: 6 hours Administration of intravenous fluids should be considered for patients experiencing prolonged fasting or who are at risk for dehydration.

D. Certain radiological procedures require the administration of oral fluids in conjunction with sedation and analgesia. Risk of aspiration during these procedures must be weighed against the benefits of sedation and analgesia.

E. Emergency: For non-elective sedation when proper fasting has not been assured, the increased risks of sedation will be weighed against its benefits. If possible, such patients may benefit from
delaying the procedure and administering appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH. These patients may require protection of the airway before sedation or anesthesia consultation.

IX. Pre-Procedure Assessment and Plan

A. Because sedation carries risks, administration of sedation must be planned. A sedation plan should be developed to meet each patient’s needs identified through a pre-sedation assessment. A pre-sedation assessment is required prior to administration of sedation. The pre-sedation assessment will be documented in the patient’s medical record.

B. The pre-sedation assessment must be reviewed prior to administration of sedation. A pre-sedation assessment includes but is not limited to:
   1. Physical status assessment (review of systems, vital signs, airway, cardiopulmonary reserve, past and present drug history including drug allergies);
   2. Previous adverse experience with sedation and analgesia, as well as with regional and general anesthesia;
   3. Results of relevant diagnostic studies;
   4. Verification of patient NPO status; and
   5. Assignment of physical status classification using

C. The American Society of Anesthesiologists (ASA) Physical Status Classifications as follows:
   1. Class I a normal healthy patient
   2. Class II a patient with mild systemic disease
   3. Class III a patient with severe systemic disease
   4. Class IV a patient with severe systemic disease which is a constant threat to life
   5. Class V a moribund patient who is not expected to survive with or without the operation

D. Candidates for sedation must 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) consultation with an anesthesiologist or attending physician specializing in the primary disease process affecting the patient is recommended but not required.

E. Immediately prior to moderate sedation, baseline values of blood pressure, heart rate, respiratory rate, oxygen saturation, and responses to verbal stimuli or level of consciousness will be recorded.

XI. Intravenous Access

IV moderate sedation requires continuous IV access until the patient has recovered. This can be accomplished with an indwelling catheter or needle, with or without IV fluid administration. For patients receiving moderate sedation by non-intravenous routes or whose intravenous access has become nonfunctional, the practitioner directing the moderate sedation will determine the advisability of establishing or reestablishing intravenous access. In all circumstances, an individual capable of establishing intravenous access should be readily available.

XII. Intra-Procedure

A. The patient must be reevaluated immediately prior to administration of sedation. Sedated patients must never be left alone during or immediately after sedation.
B. A Credentialed Monitoring Assistant must be present to continuously assess patient wellbeing and facilitate patient safety and comfort. The Credentialed Monitoring Assistant will have no other responsibilities that will leave the patient unattended or compromise continuous monitoring. Exception: moderate sedation provided by an anesthesiologist or CRNA does not require a Credentialed Monitoring Assistant.

C. Medications will be administered only under the direction of an LIP privileged to order and direct moderate sedation.

D. Loss of consciousness for patients undergoing moderate sedation should not be the goal.

E. Heart rate and oxygen saturation will be monitored continuously. Continuous ECG monitoring will be considered for patients who are ASA Physical Status Class II or higher. Use of supplemental inspired oxygen is beneficial for those rare instances where a safety cushion might provide one or two minutes of oxygenation to a patient whose airway was compromised. Supplemental oxygen will be considered for an oxygen saturation of less than 96% at any time during the procedure.

F. The following items will be monitored and recorded at five minute intervals or more frequently, if indicated, on a time-based record:
   1. Blood pressure, heart rate, respiratory rate, and oxygen saturation;
   2. Responses to verbal stimuli or level of consciousness; and
   3. Medications and dosages.

G. Excluded from the monitoring requirements are instances where:
   1. The use of conventional monitors would be unsafe, as in hyperbaric atmospheres, in water, or in an MRI;
   2. The use of conventional monitors would preclude imaging procedures because they would:
      b. Distort the image;
      or
      c. Stimulate movement and produce artifact (e.g., BP cuffs in children, verbal stimulation, or responses during head CT or MRI).

H. Documentation Requirements: Total fluids will be recorded, and any unusual, unanticipated, or adverse events will be described. The patient’s condition at the conclusion of the procedure must also be assessed and documented.

XIII. Post Procedure

A. The patient will not be left alone during the recovery period, and a medically qualified individual will monitor and record the following items immediately post-procedure and frequently until stable and adequate function is restored (see Discontinuation of Monitoring):
   1. Blood pressure, heart rate, respiratory rate, and oxygen saturation;
   2. Responses to verbal stimuli or level of consciousness;
   3. Medications and dosages, fluid types and volumes; and
   4. Unusual, unanticipated, or adverse events.

B. Infants less than 48 weeks Post Conceptual Age (PCA) and premature infants less than 60 weeks must be monitored for a minimum of 12 hours prior to discharge.
C. Prior to discharge, the responsible physician will reexamine the patient and enter a note in the chart documenting post-procedure recovery status and return of adequate function (e.g., level of consciousness, ambulation, etc.). Alternatively, specific discharge criteria may be applied by qualified personnel to facilitate safe discharge (see Guidelines for Discharge Post Sedation). If the patient is to go home the day of the procedure, the patient will be accompanied at discharge by a responsible adult, with written post-discharge instructions (see Criteria for Discharge Post Sedation).

XIV. Warning on the use of Reversal Agents
The routine use of narcotic antagonists and/or benzodiazepine antagonists is not recommended. The duration of action of the sedatives and/or narcotics may exceed that of the antagonist(s). Patients who receive narcotic antagonists and/or benzodiazepine antagonists require extended post-procedure observation.

XV. Criteria for Discontinuation of Procedural Monitoring
A. During this immediate post sedation period, in addition to the Credentialed Monitoring Assistant or recovering RN, there will be at least one other staff member in the unit. This additional staff member should be able to directly hear a call for assistance in the case of an emergency.

B. Patients will be monitored until the following criteria are met:
1. Modified Aldrete score of ≥ 9 or a return to the patient’s baseline;
2. Protective reflexes are intact;
3. No evidence of procedural complications (including bleeding from the wound site);
4. Pain adequately controlled; and
5. A minimum of 15 minutes has elapsed after the end of the procedure.

XVI. Criteria for Discharge Post Sedation
A. The patient may be discharged once discharge criteria are met. If discharge criteria are not met, exceptions may be made by a qualified LIP.

B. Discharge criteria:
1. Modified Aldrete score of ≥ 9 or a return to the patient’s baseline;
2. Protective reflexes are intact and the patient exhibits no signs of respiratory distress;
3. The patient is not suffering from nausea, vomiting or dizziness;
4. A minimum of 30 minutes has elapsed since the end of the procedure; and
5. The patient is accompanied by a responsible adult.

XVII. Post-Discharge Instructions
Written post-discharge instructions will be provided to the patient and the responsible adult accompanying the patient. Information will include:
1. Relevant dietary and medication instructions;
2. Post-discharge activity instructions;
3. Requirement that a responsible adult accompany the patient home post-discharge;
4. Steps to follow in the event of a complication, including a phone number to call; and
5. What to do in event of an emergency.

XVIII. Patient Safety & Risk Management
A. In all instances, patients who receive moderate sedation must be monitored by a Credentialed
Monitoring Assistant whose principal role is patient safety and monitoring. Such individuals must exercise prudent clinical judgment in determining which patients do, and do not, meet criteria for receiving moderate sedation.

B. The chain of command must be followed if orders are contraindicated by professional standards of practice.

XIX. Quality of Care
  A. All moderate sedation procedures will be documented on a UTMB Moderate Sedation Usage Record or the electronic medical record. Sentinel events will be reviewed by the Department of Anesthesiology. Significant events will be reported and discussed through a departmental quality management program and/or the UTMB Sedation Committee.

  B. Adverse Drug Event cases involving moderate sedation are tracked, trended and reported through the quality structure.

XX. Definitions

  Credentialed Monitoring Assistant: An MD, DO, DDS, Podiatrist, RN, APRN, PA, Respiratory Therapist, or Radiological Technician responsible for providing sedation monitoring during the procedure.

  Privileges: The process whereby the specific scope and content of patient care services (that is, clinical privileges) are authorized for a health care practitioner by a health care organization based on evaluation of the individual’s credentials and performance. See also licensed independent practitioner

  Licensed Independent Practitioner (LIP): Any individual permitted by law and UTMB Bylaws to provide care and services without direction or supervision within the scope of the individual’s license and consistent with individually granted clinical privileges.

  Minimal Sedation (Anxiolysis): A drug-induced state during which a patient responds normally to verbal commands. Cognitive functions and coordination may be impaired, but ventilatory and cardiovascular functions are unaffected.

  Moderate Sedation (Conscious Sedation): A drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by physical stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Sedation is a continuum, and it is not always possible to predict how an individual patient will respond. However, in general, one should consider the effect on the patient to be that of moderate sedation/analgesia under the following circumstances: The prescribing LIP’s intent is to produce a depression of consciousness that exceeds simple reduction of anxiety or simple relief of pain. For example, the sedation/analgesia may be intended to, among other things, produce amnesia of a short duration

Or,

Administration by any route of sedatives and/or narcotics in doses that are reasonably expected to produce a moderate sedating and analgesic effect for this individual patient in order to allow the patient to tolerate unpleasant procedural therapies of a short duration.

  Deep Sedation: A drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to
independently maintain ventilatory function may be impaired. The patient may require assistance with maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Refer to Pharmacy Policy 7.71 Administration of Anesthetic Agents by Non-Anesthesiologists for information about deep sedation, including requirements and privileges.

XXI. Related UTMB Policies and Procedures
Pharmacy Policy 7.71 Administration of Anesthetic Agents by Non-Anesthesiologists.

Pharmacy Policy 07.49 Preparation and Administration of Medications via Continuous Intravenous Infusion (Adult)

XXII. Additional References

American Society of Anesthesiologists: Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals (last amended Oct. 19, 2011)

Minimum staffing requirements for the performance of GI endoscopy Gastrointestinal Endoscopy, V 72, No.3: 2010

How to best approach endoscopic sedation. Gastroenterology & Hepatology V8, September 2011
Board of Nurse Examiners for the State of Texas, Position Statement #15.8 The Role of the Nurse in Moderate Sedation.

American Society of PeriAnesthesia Nursing- Nursing Standards, Practice Recommendation 1 -Patient Classification/ Staffing Recommendations Reviewed and updated October 2011

XXIII. Dates Approved or Amended

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XXIV. Contact Information
Department of Quality & Healthcare Safety
(409) 772-0590