Institutional Handbook of Operating Procedures Policy 09.13.17	
Section: Clinical Policies	Responsible Vice President: Executive Vice President and CEO Health System
Subject: General Clinical Procedures and Care	Responsible Entity: Health System

I. Title

Minimal Sedation (Anxiolysis) of Pediatric Patients

II. Scope

This establishes the policy and standard operating procedure for minimal sedation of pediatric patients for procedures outside of the operating room (OR) such as intravenous line placement, lumbar puncture or other procedures. This policy does not apply to the care of anesthesiology or critical care.

III. Policy

A. The following policy sets uniform requirements and minimum standards for the use of minimal sedation (anxiolysis) for therapeutic, diagnostic, or surgical procedures performed on pediatric patients at UTMB.

B. All UTMB patients who receive anxiolysis 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.

IV. Inclusion

This policy applies to pediatric patients undergoing a procedure for which anxiolysis is required.

V. Exclusion

This policy does not apply to - Any patient that requires or slips into a deeper level of sedation beyond minimal sedation (anxiolysis) falls in the purview of moderate sedation and requires the appropriate level of additional training, equipment and procedures. This SOP is not intended to address these patients. IHOP - 09.13.05 - *Procedural Sedation (Moderate and Deep Sedation)*.

VI. Licensed Independent Practitioner for Minimal Sedation (Anxiolysis)

A. Licensed Independent Practitioners (LIP) for minimal sedation include MD, DO, DDS, Podiatrist,–not privileged to provide anesthesia, deep or moderate sedation. The LIP must be privileged by UTMB to direct and administer anxiolysis based on UTMB anxiolysis for Procedural Sedation Education Requirements, as follows:

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

2. The LIP must be familiar with anxiolysis policy.

B. Responsibilities of the LIP privileged to direct anxiolysis:

1. The LIP is responsible for the safety and well-being of the patient. The prescribing LIP's intent is to produce a mild depression of consciousness in order to obtain a reduction of anxiety and psychological trauma, improve patient safety and compliance with intended procedure, and at times to reduce pain.

2. The LIP is responsible for assessment of patient's risk and documentation in the patient's electronic medical record of medication effect. The LIP is responsible for ordering medication (including dosage and route of administration).
3. The LIP is responsible for directing and providing emergency interventions and initiating rescue as necessary.

4. The LIP will ensure that this policy is observed. In either elective or emergent procedures, if circumstances warrant deviation from this policy, the reason must be documented in the patients' medical record.

VII. Personnel

A. Credentialed Monitoring Assistant is a RN, MD, DO, DDS, Podiatrist, APRN, or PA responsible for providing monitoring during anxiolysis.

B. A Credentialed Monitoring Assistant will be credentialed by UTMB.

1. The Credentialed Monitoring Assistant must maintain at least one current certification described below as appropriate to the population served.
   a) ACLS
   b) PALS or ENPC (Emergency Nursing Pediatric Course)
   c) NRP

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

C. The Credentialed Monitoring Assistant's responsibility:

1. To monitor physiologic parameters.
2. Know how to monitor required parameters, recognize abnormalities in the required parameters and intervene as needed.
3. Administration of medication(s) as permitted to do so by their licensure and UTMB.
4. Be familiar with the effects of the drugs used.
5. Know how to recognize an airway obstruction and correct it.

6. Be able to manage ventilation with a self-inflating bag valve mask.
7. To assist in any supportive or resuscitative measures, as required.
8. To make sure that all equipment (see below) is immediately available and functioning properly.

VIII. Equipment

All necessary equipment will be available and checked for proper function prior to administration of sedative medications. The equipment must be appropriate for the patient's weight and height. Monitoring equipment detailed herein will be available in or in close proximity to the procedure room. The monitor with the patient's vital signs needs to be easily visible to both LIP and monitoring assistant. Equipment includes as needed:

1. Device to measure blood pressure.
2. Pulse oximeter.
3. Heart Rate Monitor (may obtain through pulse oximeter).
4. Oxygen, including delivery system with appropriate supplies and a positive pressure oxygen delivery system.
5. A functional suction device.
6. Thermometer.
7. Reversal agent as appropriate.
8. A code cart that holds a continuous ECG/defibrillator/AED monitor with emergency medications and equipment must be readily available. If not present in the locations the procedure is performed, the staff must know the nearest location and be able to immediately access these items if needed.

IX. Informed Consent

A. Each patient, parent, or guardian must receive an explanation regarding the risks and alternatives of anxiolysis.

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.*

X. Dietary Precautions

A. **NPO status**: There is no requirement for patients to be NPO to receive anxiolysis.

B. If patient slips into a deeper level of sedation, then the provider needs to be on alert and understand the risk for pulmonary aspiration of gastric contents should protective reflexes be compromised. Moderate sedation policy monitoring and procedures then applies.

XI. Pre-Procedure Assessment and Plan

A. Because the use of any sedative medication 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 by the LIP is required prior to administration of anxiolysis. The pre-sedation, baseline assessment will be documented in the patient's medical record.

B. The pre-sedation assessment must be reviewed prior to administration of sedation by both LIP and Monitoring Assistant. A pre-sedation assessment includes but is not limited to:

1. Physical status assessment (vital signs, airway, cardiopulmonary reserve, past and present drug history including drug allergies, review of systems).
2. Previous adverse experience with sedation or anesthesia.
3. Review of relevant diagnostic studies.

C. Children undergoing mild sedation should be in good general health and have adequate ventilatory reserve. Children with complex medical problems, or children with anatomic abnormalities or severe tonsillar hypertrophy carry higher risk and the effects of mild sedation must be considered and may require higher level of sedation care i.e., critical care/anesthesia consultation.

XII. Intravenous Access

A. Administration of mild sedation (anxiolysis) does not require IV access. In all circumstances, an individual capable of establishing access should be readily available.

XIII. Intra-Procedure

A. The child is to be evaluated immediately prior to administration of medication and a set of vital signs is to be documented in the chart.

B. The EPIC order set is used to place the medication order.

1. The EPIC order set has the appropriate weight-based dosage, dose limits, routes of administration and respective concentrations of the prescribed medications.

C. The patient will be placed (at a minimum) on continuous pulse oximetry and monitored intermittently by the monitoring assistant or LIP.

D. The patient will never be left alone until the patient recovers, and the monitoring assistant and LIP should be within reasonable distance to hear monitor alarms.

E. The patient's response and level of consciousness to administered medication is to be observed and documented in the EPIC medical record.

F. The Level of Consciousness is to be intermittently observed and documented by the monitoring assistant or LIP and any transition to a deeper level of sedation should prompt full moderate sedation monitoring as per procedural sedation policy. IHOP 09.13.05 - *Procedural Sedation (Moderate and Deep Sedation)*.

G. In the event of an unexpected event occurring during the administration of anxiolysis, in addition to immediate attention to the matter, prompt documentation into the EPIC medical record is required. Events in particular to be documented include but are not limited to the following;

1. Airway Intervention
2. Administration of Oxygen
3. Any nausea requiring antiemetic or any vomiting

4. Any prolonged level of depressed consciousness that is not responsive to verbal commands beyond expected duration of action of prescribed medication. (Generally > 90 minutes from administration of medication).
5. Any other adverse event

H. The monitoring assistant is to utilize the standard EPIC template to document vital signs, LOC, medication administration time and route, medication dosage, and any events is to be recorded.

XIV. Criteria for Discharge

A. Prior to discharge, the responsible physician will reexamine the patient and enter a note in the chart documenting post-procedure recovery status and the patient's physiological status return to pre-procedure baseline. Alternatively, specific discharge criteria may be applied by qualified personnel to facilitate safe discharge.

B. The patient may be discharged once discharge criteria are met. If discharge criteria are not met, exceptions may be made by a qualified LIP.

C. Discharge criteria:

1. Patient is awake or return to the patient's baseline
2. Protective reflexes are intact and the patient exhibits no signs of respiratory distress
3. Vital signs have returned to the patient's normal baseline
4. The patient is not suffering from nausea, vomiting, or dizziness
5. Pain adequately controlled
6. A minimum of 30 minutes has elapsed since the end of the procedure

D. If the patient is transferred to an inpatient location, the designated nurse on the receiving floor will receive a report about the patient containing information about the procedure including but not limited to the procedure performed, medications administered, any intra-procedure events, post-procedure treatment, adverse events and post-procedure patient status.

E. If the patient is to be discharged home the day of the procedure, the patient will be accompanied at discharge by a responsible adult, with written post-discharge instructions. Written post-discharge instructions will be provided to the patient and the responsible adult accompanying the patient.

XV. Oversight and Responsibility

This procedure applies to clinicians who perform procedures on infants and children in inpatient, outpatient or Emergency Department settings and wish to use anxiolysis to assure procedural success or improve the patient experience.

The Procedural Sedation Committee is responsible to review, revise, update and operationalize this policy to maintain compliance with regulatory or other requirements.

XVI. Definitions

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 light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

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.

Licensed Independent Practitioners (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. Refer to UTMB Policy Term Definition for Privileges.

Monitoring Assistant: AnRN, MD, DO, DDS, Podiatrist, APRN, or PA responsible for providing sedation monitoring during the procedure.

Mild Sedation (Anxiolytic) Agents: These medications are the agents referred to in this policy.

Patient: Any Pediatric patient in the Department of Pediatrics or pediatric setting.

Monitor: Person responsible for assuring patient is in the state of anxiolysis and has not advanced to a more sedate state, an RN who has BLS and PALS/NRP certifications. If RN is not PALS/NRP, they will solicit a PALS/NRP RN to assist.

Rescue: The ability and responsibility to assess and act if patient advances to more sedate state.

Emergency Equipment: Oxygen, BVM, suction, code cart, reversal agent.

XVII. Related UTMB Policies and Procedures

IHOP – 09.13.05 – Procedural Sedation (Moderate and Deep Sedation)

XVIII. Additional References

AAP Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update. American Academy of Pediatrics, American Academy of Pediatric Dentistry, CJ Cote, S Wilson and the Work Group on Sedation. Pediatrics 2019;143 (6);e20191000 DOI: https://doi.org/10.1542/peds.2019-1000

Dexmedetomidine sedation: uses in pediatric procedural sedation outside the operating room. McMorrow SP, Abramov TJ. Pediatr Emerg Care. 2012 Mar;28(3):292-6.doi:10.1097/PEC.0b013e3182495e1b.PMID:22391930 Review.

Intranasal Fentanyl and Midazolam for Procedural Analgesia and Anxiolysis in Pediatric Urgent Care Centers. Williams JM, Schuman S, Regen R, Berg A, Stuart L, Raju J, Mabry W, Kink RJ. Pediatr Emerg Care. 2020 Sep;36(9):e494-e499. doi: 10.1097/PEC.0000000000001782.PMID: 30789872

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Intranasal Fentanyl, Midazolam and Dexmedetomidine as Premedication in Pediatric Patients. Chatrath V, Kumar R, Sachdeva U, Thakur M. Anesth Essays Res. 2018 Jul-Sep;12(3):748-753. doi: 10.4103/aer.AER_97_18. PMID: 30283188

XIX. Dates Approved or Amended

Originated: 05/23/2023	
Reviewed with Changes	*Reviewed without Changes*

XX. Contact Information

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