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Tier 1: Procedural Sedation/Analgesia (Moderate Sedation; Adult, Pediatric) by Non-Anesthesiology Personnel Outside of the Operating Room

Background

This policy will guide non-anesthesia clinicians in the safe administration and documentation of moderate sedation and analgesia for procedures occurring outside the operating room environment when anesthesiology personnel are not involved.

This policy **does not** apply to:

- Any member of the anesthesia care team.
- Patients on full mechanical ventilator support in critical care areas.
- Deep sedation.

Definitions

Procedural Sedation is a technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows the patient to tolerate procedures while maintaining cardiorespiratory function.

Procedural Sedation and Analgesia is intended to allow patient comfort while maintaining ventilation, oxygenation and airway patency without significant intervention.

ASA Physical Classification System is designed by the American Society of Anesthesiologists (ASA) to preoperatively assess the overall physical status of the patient. ***(Attachment 1)***

Mallampati Classification is used to indicate the potential ease or difficulty of intubation. It is determined by looking at the anatomy of the oral cavity; specifically, it is based on the visibility of the base of uvula, faucial pillars and soft palate. Scoring may be done with or without phonation. A high Mallampati score (class 4) may be associated with a more difficult intubation, as well as higher incidence of sleep apnea. ***(Attachment 2)***

Faucial Pillars are the arches in front of and behind the tonsils

Obstructive Sleep Apnea Assessment (STOP/BANG) Loud **S**noring, **T**iredness, **O**bserved apnea, high blood **P**ressure (STOP)-**B**ody mass index (BMI), **A**ge, **N**eck circumference, and **G**ender (Bang) questionnaire

is a validated screening tool for identifying obstructive sleep apnea in surgical patients. For identifying severe OSA, a STOP/BANG score of 4 has a high sensitivity (88%) for confirming severe OSA; a score of 6 is more specific. ***(Attachment 3)***

Minimal Sedation or Analgesia is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Either a sedative or an analgesic is usually chosen, but not both. Minimal sedation is used to decrease the stimulus of a minimally invasive procedure. The amount of either medication starts with the smallest amount, titrated slowly, never reaching a level of moderate sedation. ***(Attachment 4)***

Moderate Sedation and Analgesia is a drug-induced depression of consciousness during which the patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. ***(Attachment 4)***

Deep Sedation/Anesthesia is a drug-induced depression of consciousness during which patients cannot be easily aroused, but may respond purposefully after 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. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner privileged in the administration of deep sedation. ***(Attachment 4)***

Ramsey Sedation Scale is a tool that is designed to focus on the depth of sedation and is used in situations where application of sedation is the desired endpoint. ***(Attachment 5)***

Richmond Agitation-Sedation Scale (RASS) is a clinical scale used to measure the agitation or sedation level of a patient and is frequently used in critical care areas where patients may be agitated or sedated for various reasons. **(Attachment 5)**

Pediatric Sedation State Scale (PSSS) is a 6 – point scale that is a valid measure of the effectiveness and quality of procedural sedation in children. **(Attachment 5)**

Aldrete Score A tool to guide patient readiness for discharge from the sedation episode and return to the floor or home. The Aldrete score assesses level of consciousness, respiratory status, circulatory status, pain, and nausea. ***(Attachment 6)***

Advanced Practice (Midlevel) Providers includes physician assistants and advanced practice nurses.

Direct Supervision: means that the Medical Staff member must be "immediately available" and "interruptible" to provide assistance and direction throughout the performance of the procedure; however, he or she does not need to be present in the room when the procedure is performed.

Provider means Medical Staff member or Advanced Practice (Midlevel) Provider

Policy

Oversight of Sedation Practices

In order to assure safe and consistent care across all clinical service**s**, the System Chair of Anesthesiology, Medical Director of Anesthesia Services, or designee, oversees and participates with the chairs and medical

directors of his/her departments/services in establishing the institutional policy for the administration of sedation by non-anesthesia personnel outside of the operating room.

Policies specific to the use of sedation in focused areas may be designed to meet or exceed this policy; however, no policy may be designed which does not meet the standards contained herein.

The director of the department/service (Service Chief, Chair, or Department Head) in which sedation services are provided is responsible for monitoring of compliance with the health system policy for sedation/analgesia.

Each Department Director is responsible for:

A. Recommending privileges to prescribe sedative / analgesia for diagnostic and therapeutic procedures.

B. Compliance with policies and procedures including that all required equipment and personnel are present.

C. Appropriate documentation of the pre-sedation/analgesia evaluation, intra-procedure monitoring and post-sedation/analgesia care.

D. Implementation of a system for monitoring adverse outcomes.

    1. Quality improvement measures related to procedural sedation.

    2. Provider specific performance data regarding sedation/analgesia outcomes will be reviewed as part of the appointment and reappointment process.

Training and Privileging

Any provider who prescribes **and/or** supervises the administration of medications with the intention of moderate sedation/analgesia must successfully:

A. Complete competency-based education and training specific to moderate sedation/analgesia every two (2) years. This may include completion of a HFHS University Course on moderate sedation or a formal external training course on techniques of sedantion and analgesia, successfully completed and documented, as approved by anesthesiology leadership.

B. Demonstrate of skills in airway management, arrhythmia recognition and treatments as demonstrated by Advanced Cardiac Life Support (ACLS) or Pediatric advanced life support (PALS) certification (for those caring for pediatric patients) training and certification or equivalent, as approved by the anesthesiology chair or his/her designee.

Privileges to provide moderate sedation/analgesia must be reviewed and granted through standard medical staff approval processes **which have been approved** by the Chair of Anesthesiology or his/her designee.

Provider Competency-based education, training, and experience for moderate sedation/analgesia is required in:

A. **Pre-Sedation/Pre-Analgesia Assessment** for proper patient selection:

    1. Training in professional standards and techniques to administer pharmacologic agents to predictably achieve desired levels of sedation and to monitor patients carefully to maintain them at the desired level of sedation.

    2. Fasting state. ***(Attachment 8)***

3. ASA score. ***(Attachment 1)***
4. Mallampti score. ***(Attachment 2)***
5. Pre-procedural medication use.
6. Performing sedation/analgesia including methods and techniques required to rescue patients who unintentionally move to a deeper than desired level of sedation/analgesia.
7. Knowledge of patient characteristics that may increase:
    a. Patient sensitivity to sedation/analgesics.
    b. Risk of cardiac or respiratory complications.
    c. Difficulty in managing cardiac and respiratory complications.
8. Applied clinical pharmacology of medications used for sedation/analgesia and antagonists to opioids and benzodiazepines ***(Attachment 7)***

B. **During Procedure**

1. Monitoring and recognition of major abnormalities in oxygenation, ventilation, cardiovascular function, and knowledge of their appropriate treatment. Monitoring includes blood pressure, respiratory rate, oxygen saturation by pulse oximetry, ECG, depth of sedation, and capnography, if indicated.
2. Basic airway management (head and jaw positioning, oral/nasal airways, bag/mask ventilation).
3. Documenting the drugs administered, the patient's physiologic condition and depth of sedation at regular intervals throughout the period of sedation and analgesia, using the electronic health record.

C. **Post-Sedation/Analgesic Assessment**:

1. Aldrete Score. ***(Attachment 6)***
2. Monitoring and reporting adverse outcomes.

Specific Requirements for Disciplines

Advanced Practice Providers (Midlevels)

- The Advanced Practice Provider (Midlevel), who administers **or orders (pursuant to delegated authority) administration of** sedative and analgesic drugs, will be under the direct supervision of a **Medical Staff Member** privileged in procedural (moderate) sedation.

Pharmacists

Competency determination is completed every **two (2) years.**

- A licensed pharmacist, in the Emergency Department, with the required competency and experience in medication administration for sedation/analgesia can administer such agents **only when the ordering provider is present at the bedside when the pharmacist administers the medication.**
- Completion of a HFHS University Course and competency in procedural sedation using moderate and deep sedation/analgesia that includes the pharmacology of medications used for moderate and deep sedation.
- ACLS and/or PALS Certifications (depending on clinical needs) will be required every two (2) years.

Registered Nurses

- Education in assigned HFHS University course including those focused on sedation/analgesia and that include information regarding medications for procedureal (moderate) sedation/analgesia every **two (2 years).**
- ACLS &/or PALS certifications (depending on clinical needs) will also be required every two (2) years.

Procedure

Pre-Procedure

Informed consent for the procedure and sedation/analgesia is done by a **provider involved** with the procedure (drugs, monitoring and potential effects, risks, benefits and **alternatives). [See** Tier 1 HFHS Informed Consent Policy**]**

Confirm documentation in the Electronic Medical Record

A. Current history and physical.
B. Pregnancy testing (as indicated, see Peri-operative Pregnancy Testing Policy).
C. Allergies.
D. Current Medications.
E. Time and nature of last oral intake.
F. Tobacco, alcohol or substance abuse history.
G. Examination specific to the procedure to be performed.
H. Examination/assessment of heart and lungs by auscultation.
I. Assessment of level of consciousness using an age appropriate sedation scale. ***(Attachment 5)***
J. Patient's weight or approximation of weight.
K. Baseline vital signs and oxygen status.
L. Identify any adverse effect/response to previous sedation, regional or general anesthesia.

Assessment of patient and plan

A. Time out.
B. Indication/symptoms for procedure requiring sedation.
C. Assessment of the patient's ability to tolerate sedation.
D. ASA Classification score. ***(Attachment 1)***
E. Mallampati Classification. ***(Attachment 2)***
F. STOP-BANG assessment. ***(Attachment 3)***
G. Sedation plan of care discussed with registered nurse.

Key Point

Patients with ASA score 3 or higher, STOP BANG score 6 or higher, Mallampati score 3 or 4, a history

of anesthetic problems and pediatric patients have an elevated risk during procedures; therefore, an anesthesiology consultation should be considered.

Provider/Registered Nurse assisting with pre-procedure care

Prepare Patient

Establish intravenous access.

Prepare Environment

Monitoring Equipment

A. Cardiac Monitor
B. Pulse Oximetry
C. End Tidal CO_2 (or alternative respiratory monitor)

Confirm presence of the following or document them the electronic health record (EHR)

A. Assessment of baseline level of consciousness
B. Patient's weight or approximation of weight
C. Ventilation and oxygenation status: baseline pulse oximetery and end-tidal CO2 (or alternative respiratory monitor)
D. Hemodynamic monitoring: baseline blood pressure, heart rate, and electrocardiogram (ECG).
E. Baseline Sedation scale score ***(Attachment 5)***
F. Allergies
G. Current medications
H. Time and nature of last oral intake
I. Tobacco, alcohol, or substance abuse history

Emergency Equipment that should be readily available

A. Supplemental Oxygen
B. Airway management devices including oral and nasal airways
C. Bag Valve Mask (BVM) with appropriate size face mask
D. Equipment for intubation (e.g., endotracheal tube, stylets, laryngoscopes, etc.)
E. Emergency Medications for resuscitation & rapid sequence intubation
F. Pharmacologic antagonists (Naloxone, Flumazenil) ***(Attachment 7)***
G. Suction set up
H. **Defibrillator**

During Procedure

Personnel Required for Moderate Sedation/Analgesia

A. A Provider privileged for moderate sedation/analgesia

B. Registered Nurse with education in sedation/analgesia

Provider

A Provider privileged for moderate sedation/analgesia prescribes the medications.
A Provider privileged for moderate sedation/analgesia shall be present during the administration of the sedation/analgesia.

Pharmacists

In areas where pharmacists administer moderate sedation/analgesia, a privileged provider is required to be at the bedside during sedation/analgesia administration.

Registered Nurse

A. Medications are administered and documented based on the Provider order performing or assisting with procedure.

B. Medications are documented in the electronic health record

C. End tidal CO2 (if ordered), heart rate, blood pressure, respiratory rate, and O2 saturation monitored and documented every 5 minutes during the procedure

D. Sedation scale score documented every 5 minutes during the procedure

1. The patient should have a purposeful response to verbal commands after the sedation/analgesia medication is given.

E. Pain assessment as appropriate

F. Notify Provider performing procedure of any unexpected outcomes such as:

1. A variation of plus or minus 20% in Blood Pressure or Heart Rate
2. Serious arrhythmia
3. Oxygen desaturation
4. Dyspnea
5. Apnea
6. Diaphoresis
7. Inability to arouse the patient
8. The need to maintain the patient's airway mechanically
9. Hypo/hypercapnic (normal end-tidal CO2 = 35-45 mmHg)
10. Notify Provider if patient transitions to deep sedation

G. Intravenous access should be maintained

H. Supplemental oxygen shall be readily available and used as appropriate.

I. The registered nurse must primarily focus on monitoring the patient, but may assist the Provider with

procedural tasks only if they are: interruptible, of short duration, at the bedside (once the patient's level of sedation and vital signs have stabilized) and adequate monitoring is maintained throughout the procedure.

Post Procedure

A **Registered Nurse** will be present until baseline Sedation scale score ***(Attachment 5)*** is achieved or until appropriate discharge Aldrete score is achieved.

A. Monitor and document heart rate, blood pressure, pulse oximetry immediately post procedure and every 15 minutes until pre-procedure vital signs are returned.

B. Sedation scale score assessed and documented immediately post procedure and every 15 minutes until pre-procedure sedation is returned.

C. Aldrete Scores (Attachment 6) will be Discharge Criteria where applicable

   1. Score ≤ 7 = continue to monitor patient
   2. Score ≥ 8 = consider completing sedation episode

D. Pain assessment should be performed immediately post-procedure and as indicated.

E. Notify provider for any decline in vital signs or sedation for possible reversal agent administration.

F. If reversal agents are used the patient must be:

   1. observed for a minimum of one (1) hour to ensure respiratory depression does not occur,
   2. seen by Provider before discharge.

Rescue/Emergency Management

- In all instances of sedation/analgesia, at least one individual capable of establishing a patent airway and positive pressure ventilation, as well as means for summoning additional assistance must be present.
- An emergency response team or an individual with both advanced airway management skills (including endotracheal intubation) and ACLS or equivalent must be available to respond if needed.
- If deep sedation occurs, the procedure should stop if possible.
- Procedures, necessary equipment and medications must be available to rescue patients whose level of sedation becomes deeper than intended.

Patient and Family Education

Discharge planning and/or patient/family education must be provided and documented as appropriate. For outpatients, written discharge education/planning should include:

A. Limitations of food/alcoholic intake, operating machinery, driving, active playing (if pediatric patient) and decision-making for a minimum of 24 hours (these guidelines do not preclude variations deemed appropriate by the physician).

B. 24-hour emergency contact and phone number.

C. Procedure-specific assessment parameters (movement, sensation, dressing, bathing).

D. Drug-specific side effects that may be experienced (nausea, itching, amnesia, drowsiness).

E. Cautions to support head and neck in young child on car ride home.

F. Provider follow-up appointment date/time.

G. Discharge instructions that include information regarding the procedure and sedation are printed and given to the patient prior to discharge.

Discharge Criteria

A. Aldrete score ***(Attachment 6)*** of 8 or greater (or equivalent of pre-procedure score if less than 8) must be achieved prior to discharge (if applicable).

B. If a score of 8 or greater is not met, a provider's order for discharge must be obtained.

C. Outpatients will be discharged into the care of a responsible adult unless alternative plans (e.g., 23 hr. observation) have been made or the patient, if competent, signs out against medical advice.

D. A patient may be discharged with an individual who has not reached the legal age of majority (Adult = 18 in MI) if deemed appropriate and documented by a provider.

Documentation

Sedation/Procedure monitoring documentation should occur in the electronic health record.

Related Documents

None

References/External Regulations

A. American Society of Anesthesiologists: Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018. *Anesthesiology*, 2018; 128:437-79.

B. American Society of Anesthesiologists: Practice Guidelines for Preoperative Fasting and the Use of Pharmacologic Agents to Reduce the Risk of Pulmonary Aspiration: Application to Healthy Patients Undergoing Elective Procedures. *Anesthesiology*, 2017; 126:376-393.

C. *The Joint Commission Standards*, 2018. Program: Hospital; Chapter: Provision of Care, Treatment, and Services. PC.03.01.01: The hospital provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.

D. Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department. *Ann Emerg Med* 2014; 63:247-258.

E. Validation of the Pediatric Sedation State Scale. Pediatrics, 2017; 139:2019-2897.

F. American Society of Anesthesiologists: Continuum of Depth of Sedation & General Anesthesia and Levels of Sedation/Analgesia (2009).

G. ASA statement of granting privileges for administration of moderate sedation to practitioners who are not anesthesia professionals 2011

H. ASA advisory on granting privileges for deep sedation to non-anesthesiologist sedation practitioners 2010 (amended 2012)

I. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Memorandum Summary: Revised Hospital Anesthesia Services Interpretive Guidelines- 4th Revision,

February 14, 2011

All revision dates: 10/18/2018

Attachments

7: Medications for Moderate Sedation Analgesia
8: Fasting & NPO Guidelines
2: Mallampati Classification
3: Stop-Bang Sleep Apnea Questionaire
4: Continuum of Depth of Sedation as Defined by the American Society of Anesthesiologists (ASA)
5: Tools for Assessing Level of Consciousness
6: Aldrete Scoring System
1: ASA Physicial Classification System

Applicability

Henry Ford Allegiance Health, Henry Ford Behavioral Health Services, Henry Ford Community Care Services, Henry Ford Health System, Henry Ford Hospital, Henry Ford Kingswood Hospital, Henry Ford Macomb Hospital, Henry Ford Medical Group, Henry Ford West Bloomfield Hospital, Henry Ford Wyandotte Hospital