Policy Title: Care of Patients Requiring Procedural Sedation Administered by Non-Anesthesia Personnel
Addendum Title: Procedure for Patients Requiring Procedural Sedation Administered by Non-Anesthesia Personnel
Addendum Letter: A
Date: 6/16/2021

Procedure Description:
Criteria for Selecting Patients for Moderate or Deep Sedation

1. American Society of Anesthesia (ASA) classification Addenda D
2. **Physical Exam** Inclusion Criteria:
    a. All weight categories except morbidly obese (greater than 40 BMI).
    b. Stable oxygen saturation greater than 92% on room air (in a patient with no chronic hypoxic problems).
    c. No evidence of airway obstruction.
    d. No patients with uncontrolled gastroesophageal reflux (GER) at high risk of aspiration (i.e., loss of gag reflex).
    e. No alterations in mental status which would compromise the patient's ability to follow commands.

*Additional Physical Exam Considerations for the Pediatric Population**

- If the patient has an underlying chronic hypoxemic condition (e.g. cyanotic heart disease, other chronic hypoxemic condition), oxygen saturation should be within 10% of their pre-sedation or baseline saturation.
- Children who have an acute airway obstruction or abnormal airway anatomy (e.g. tonsillar hypertrophy, mid-facial hypoplasia, macroglossia, etc.) present special concerns that require consultation with the department of anesthesiology.
- Children under the age of 6 and children with developmental disabilities are particularly vulnerable to sedating medication's effects on respiratory drive, airway patency, and protective airway reflexes.
- Children with a history of obstructive sleep apnea may be more sensitive to the effects of opioids and lower titrated doses should be used.
- Infants less than 2.5 months of age and former preterm infants less than 50 weeks post conceptual age are at increased risk for apnea and special plans are needed for extended observation following sedation. For infants in these age categories, admission and observation for a minimum of 12 hours is mandatory after sedation. For this period of time, monitoring will at a minimum include continuous pulse oximetry and apnea monitoring.

3. **NPO guidelines**

    a. Patients undergoing sedation should meet the NPO fasting guidelines (Addenda E) ***NOTE**: The NPO guidelines for Pediatric Sedation are different.

b. For the patient undergoing a truly emergent diagnostic or therapeutic procedure, the physician must weigh the increased risks of an unprotected airway in patients with a “full stomach” against the benefits of sedation to perform the procedure. If a physician wishes to proceed with a procedure involving Moderate or Deep Sedation when the patient has been NPO for less than the recommended guidelines, it is the responsibility of the physician to explain to the patient the risks and benefits of undergoing sedation in such a situation. This explanation is to be provided as part of the patient’s informed consent and documented in the medical record.

EXCEPTION: Certain radiologic procedures (abdominal CT) may require the administration of clear oral fluids before sedation has been given.

Consulting the Department of Anesthesiology

1. If the patient does not meet the above criteria, a consultation with the Department of Anesthesiology may be warranted. **NOTE:** *If after consultation the non-anesthesiologist and the anesthesiologist cannot agree whether the patient meets criteria for sedation by the non-anesthesia provider, the anesthesiologist will have overall authority to decide the timing, route, sedating personnel and location for sedation administration. The procedural physician will determine the timing of the procedure.*
2. Patients with the following conditions require a consultation with the Department of Anesthesiology prior to any sedation:
    a. If a patient has had a paradoxical response to sedation or anesthesia.
    b. A patient with a personal or family history of Malignant Hyperthermia must be referred to the Department of Anesthesiology.
    c. Patients with abnormal airway anatomy present special concerns that require consultation with the Department of Anesthesiology.
    d. For patients who are not able to be successfully sedated using Deep Sedation.

Patient Evaluation Prior to Procedure

1. An evaluation of the patient to assess the suitability for sedation will be completed and signed by a Medical Staff Member prior to the procedure. Documentation of the assessment may be delayed in cases of an emergency. This must include but is not limited to:

    a. A general "History and Physical Examination" which is documented in the medical record.
    b. Past medical and surgical history and treatments.
    c. An airway evaluation: Multiple physical or airway parameters can be used, but at a minimum the exam must include either a Mallampati classification Mallampati Classification (Addenda H) In Pediatric patients, the Mallampati may not be possible due to the age and cooperation of the patient
    d. Past and present drug history including names of medications, both prescription and self-administered (i.e. alcohol, tobacco, over-the-counter, illicit) and time of last administration.
    e. Allergies and adverse drug reactions, including latex allergy
    f. Pre-procedure diagnosis.
    g. Results of relevant diagnostic studies.
    h. American Society of Anesthesiology (ASA) Physical Status Classification (Addenda D) . All patients must have an ASA physical status designation performed prior to receiving sedation. Patients who are ASA class 1, 2, or 3 are considered appropriate candidates for sedation. Patients in ASA class

4 or 5 present special problems – Consider consultation with the Department of Anesthesiology for ASA 4 or 5 patients.

2. Operative and Invasive procedure verification is required for patients undergoing operative and invasive procedures. This includes completion of a Checklist to verify: Patient Identification, presence of a History and Physical Exam (H &P), presence of Informed Consent, and Site Marking (if indicated).

3. An assessment is required before administration of Moderate or Deep Sedation and consists of two components: a patient evaluation (e.g. H & P), and an immediate pre- sedation assessment. Documentation for Moderate or Deep Sedation by non- anesthesiologists will be done utilizing the pre-procedural assessment form and procedural record or the Emergency Department record.

PRE-SEDATION ASSESSMENT

1. An immediate (i.e., at the time of the proposed procedure but prior to the administration of sedation) presedation assessment must be performed. This assessment includes but is not limited to:

    a. Baseline physiologic status including vital signs
    b. Mental status assessment regarding orientation to person, place and time.
2. A pre-sedation physical assessment will be conducted that addresses the following:
    a. Confirms a stable condition of the patient since the completion of the general "History and Physical Examination".
    b. Assesses areas pertinent to the procedure being performed.
    c. Auscultation of the heart and lungs with documentation.
    d. Consider NPO status.
    e. A specific plan for sedation.
    f. Patient's legal representative has been informed of the risks, hazards, limitations and benefits, as well as alternative treatment possibilities of the Moderate or Deep Sedation and the proposed procedure(s).
    g. Immediate pre-sedation vital signs, including oxygen saturation, will be documented on an approved sedation record prior to the administration of any sedation medication.
    h. The above should be incorporated to the time out prior to the sedation. See Universal Protocol/ Invasive Procedure Verification and Time Out Process policy as needed.
3. Presence of the appropriate equipment: Equipment must be available that is appropriate for the age and size of the patient being sedated. Minimum equipment must include:

    a. Sedation record.
    b. A positive pressure oxygen delivery system capable of administering greater than 90% oxygen at a 15 L/minute flow for at least 60 minutes.
    c. Masks and oral airways, Oxygen source, cannula and masks.
    d. Medications, including reversal agents as appropriate.
    e. Suction apparatus, with catheters and Yankauer tips.
    f. Warming devices as deemed appropriate.

4. Monitors:
    a. Cardiac Monitor
    b. Blood pressure monitor.
    c. Pulse oximetry.
    d. Temperature. Every patient receiving sedation shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.
    e. ETCO2 monitoring.
5. Equipment to institute intravenous access. If an IV is not established prior to sedation (and the plan is to administer sedation by a non-intravenous route), there must be a person immediately available during the period of sedation who is skilled in establishing vascular access in that aged patient.
6. Approved Hospital Resuscitation Cart with Defibrillator (may be located in an approved location in the procedure area).
7. Telephone or other device for summoning help in an emergency.

DOCUMENTATION OF THE PATIENT STATUS DURING MODERATE OR DEEP SEDATION

1. The following data must be continuously monitored and contemporaneously documented in the patient's sedation record at 5 minute intervals (more frequently if indicated):

    a. Heart rate.
    b. Baseline heart rhythm will be documented at the start of the procedure, and then any change in rhythm will be noted.
    c. Respiratory rate.
    d. Pulse oximeter (Sp02) numerical reading.
    e. Blood pressure.
    f. Level of consciousness (the ability to follow verbal commands and respond to tactile stimuli) or another similar sedation scale.
    g. Pain assessment utilizing the appropriate pain scale for patient. The "0 – 10" scoring system is preferred.
    h. Temperature - every patient receiving sedation shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.
    i. ETCO2 or other capnography to aid in monitoring adequacy of ventilation for deep sedation.

2. Time into and time out of the procedure room.
3. Start and stop times of the procedure.
4. The type of procedure performed and an event summary.
5. Medications administered with dose, time, route and effect.
6. IV fluid type and volume administered.
7. Estimated blood loss (when applicable).
8. Status of patient at the conclusion of the procedure.
9. The following must be documented on the record with time of occurrence:
    a. Airway obstruction and maneuvers used to remedy it,
    b. Emesis,
    c. Allergic reactions,
    d. Paradoxical reactions to medications such as agitation or dysphoria

e. ECG changes.

Post-Sedation Recovery

1. Recovery is performed in an area where the following equipment is immediately available:

    a. Suction apparatus, with catheters and Yankauer tips
    b. Positive-pressure oxygen delivery system
    c. Masks appropriate for the patient's size
    d. Airway management equipment
    e. Blood pressure, ECG, and pulse oximetry monitoring equipment
    f. Medicines used for reversal of sedation
    g. Resuscitation equipment equivalent to that used in the sedation area.

    2. Appropriate staff skilled in managing patients recovering from sedation will be in attendance to monitor and document at least every 10 minutes for at least 30 minutes after the last administration of sedation medication.:

    a. Heart rate
    b. Blood pressure
    c. Respiratory rate
    d. Continuous ECG
    e. Continuous pulse oximetry
    f. Pain score
    g. For patients recovering from Deep Sedation, the recovery facility should be staffed with an individual trained in recovery procedures whose only responsibility is to observe the patient during the recovery period.

Transfer/Discharge Criteria

Recovery is considered complete and the patient's care can be transferred to the primary care team when the following criteria are met over a period of at least two consecutive 5-minute intervals:

1. The patient is awake and aware or returns to pre-sedation level of consciousness.
2. Patient age specific activities return to pre-sedation levels.
3. Stable cardiopulmonary system to pre-procedure status:
    a. Stable blood pressure within 30% of the pre-procedure value and not to exceed 30% of age specific values.
    b. Heart rate and rhythm within normal range for age and history and within 30% of initial admission values.
    c. Respirations unlabored between 12-20 breaths per minutes, or as pre- procedure status.
    d. Breath sounds audible and clear or as pre-procedure status.
    e. Oxygen saturation at least 94% on Room Air or greater than or equal to the pre-procedure level.
    f. The patient can speak and/or neurologic status is at baseline.
    g. Minimal nausea, vomiting.
    h. Dressing checked (no excessive bleeding or drainage present if applicable).
    i. Swallow, gag, cough reflex present as appropriate.

j. For those incapable of the usual expected responses, the pre-sedation level of responsiveness or a level as close as possible to the normal level for the patient should be achieved.
k. Pain control is adequate.

4. All patients receiving pharmacological reversal agents will remain under post-sedation recovery for a ninety (90) minute period following administration of such agents.
5. If a Richmond Agitation Sedation Scale (RASS) scoring system is used, the patient must score at their pre-sedation RASS.
6. In the absence of meeting the above criteria, a member of the Medical Staff will reassess the recovering patient and provide written documentation in the patient's medical record for the ability of the patient to be transferred to the location of or to the care of the primary care team. If the patient is being discharged to home, the following criteria must also be met, as is appropriate for age or pre-procedure condition:
    a. Able to maintain pre-sedation mobility with minimal assistance.
    b. Able to tolerate oral fluids (unless contraindicated by procedure).
    c. A responsible adult is present to escort the patient home.
7. The patient and a responsible adult are given and acknowledge understanding of written discharge instructions that include but are not limited to:

    a. Information about acceptable activities following sedation.
    b. Instructions for eating.
    c. List of prescribed medications.
    d. Warning signs and complications.
    e. Physician and emergency telephone numbers.
    f. For infants or toddlers in car seats, a parent or responsible adult should be available to watch the child continuously on the way home from the hospital. It is not recommended that the driver be the sole observer of the child. If a parent is the sole observer, delay discharge until the patient is fully awake.

8. **INFANTS LESS THAN 2.5 MONTHS OF AGE AND FORMER PRETERM INFANTS LESS THAN 50 WEEKS POST CONCEPTUAL AGE REQUIRE AN EXTENDED PERIOD OF OBSERVATION AFTER RECOVERY** *For infants in these age categories, admission and observation for a minimum of 12 hours is mandatory after sedation. For this period of time monitoring will at a minimum include continuous pulse oximetry and apnea monitoring.*

9. NICU patients who remain intubated post procedure may be transported to the NICU with a team that includes a Neonatal Provider.

Transfer/Discharge

If a patient requires transport to another Unit, please refer to transport guidelines for appropriate monitoring requirements. Transferring a Patient between Care Units Policy and Telemetry Monitoring for Non-ICU Adult Patients Policy & Telemetry Monitoring for Non-ICU Adult Patients

ADDENDUM: **(these will be activated when posting policy)**

Addenda A Procedure for Care of Patients Requiring Procedural Sedation Administered by Non-Anesthesia Providers
Addenda B Requirements for Initial and Reappointment for Moderate Sedation
Addenda C Requirements for Initial and Reappointment for Deep Sedation
Addenda D Physical Classification American Society of Anesthesiologist (ASA)
Addenda E NPO & Fasting Guidelines
Addenda F Reference Adult Medications
Addenda G Reference Pediatric Medications
Addenda H Mallampati Classifications

POLICIES:

Universal Protocol/ Invasive Procedure Verification and Time Out Process policy

Transferring a Patient between Care Units Policy and Telemetry Monitoring for Non-ICU Adult Patients Policy

Telemetry Monitoring for Non-ICU Adult Patients

REFERENCES

Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department

Association for Radiologic & Imaging Nursing Clinical Practice Guideline Moderate Sedation and Analgesia

Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018: A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology

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.