Protocol/Procedure XX

Title: Procedural Sedation/Moderate Sedation

A. DEFINITION

Procedural Moderate Sedation/Analgesia is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light or tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. The following guidelines describe the minimum requirements for the delivery of procedural sedation (SFGH policy number 19.08 titled, "Procedural Sedation: Moderate and Deep") by the Nurse Practitioner/Certified Nurse Midwife/Physician Assistant during procedures within the Women's Options Center. The nurse practitioner (NP)/certified nurse-midwife (CNM)/physician assistant (PA) practices under the supervision of the Medical Director or designee. Practitioners producing a level of sedation are to be trained to rescue patients whose sedation becomes deeper than initially intended as evidenced by partial or complete loss of protective reflexes and the inability to maintain a patent airway. Respiratory and cardiovascular monitoring, provisions for managing airway and cardiovascular emergencies must be in place. Procedures may only be performed in the designated areas for procedural sedation within the Women's Options Center, as adequately equipped and staffed, according to departmental and hospital policy.

Materials necessary for procedural sedation and rescue include:

a. Appropriate monitoring equipment.
b. Emergency medications and equipment for care and resuscitation, including a cardiac defibrillator, must be immediately available. Medications include, but are not limited to, reversal agents (naloxone and flumazenil) and vasoactive medications (phenylephrine and dopamine).
c. Supplemental oxygen and positive pressure ventilation equipment.
d. Suction equipment/supplies.
e. Intravenous access.

Indications:

Procedural sedation may be indicated for first-trimester abortion and other minor gynecologic procedures, such as difficult intrauterine device placement or endometrial biopsy.

Contraindications:

a. Regarding the patient's American Society of Anesthesiologists (ASA) class, the Anesthesia Service should be consulted for patients who

have an ASA score of 3 or greater. A procedure requiring sedation would not be performed on a patient with an ASA score above a three (3) without anesthesia assistance.

b. Anticipated difficult intubation.

Precautions:

a. Inability to obtain informed patient consent.

B. DATA BASE

1. Subjective Data
    a. Obtain a history 24 hours of the procedure and sedation, or if earlier, an interim history must be completed.
    b. History and review of symptoms relevant to the presenting complaint or procedure to be performed.
    c. Pertinent past medical history, surgical history, hospitalizations, habits, anesthetic, allergy and drug history.

2. Objective Data
    a. Physical exam within 24 hours of procedure and sedation, or if earlier, an interim physical must be completed. The exam is to include an airway evaluation (mouth opening and neck flexibility and extension, loose teeth, and weight)
    b. Diagnostic data, as appropriate.
    c. All Point of Care Testing (POCT) will be performed according to SFGH POCT policy and procedure 16.20.
    d. Laboratory and imaging results, as indicated, relevant to the history and physical exam.

C. DIAGNOSIS/ASSESSMENT

1. A judgment as to the appropriateness of the procedure and safety of sedation for the particular patient that includes consideration of the patient's age, medical condition, and the procedure and sedation side effects and risks.
2. Assignment of an ASA physical status. Patients with a Physical ASA class of IV or V will not undergo moderate sedation by the NP/CNM/PA in the Women's Options Center (WOC).
3. Assignment of the pre-procedure Modified Aldrete Score.
4. Evidence of verification of compliance with the NPO status (adult: minimum 8 hours (solids) and 2 hours (clear liquids) before procedure to decrease risk of aspiration).
5. Assess and document the benefits of sedation against the risk of possible aspiration.
6. A responsible adult is available to take the patient home after the procedure.

D. PLAN

1. Therapeutic Treatment Plan shall follow SFGH policy number 19.08 titled “Procedural Sedation: Moderate and Deep”
    a. Informed consent for the procedure and sedation must be obtained and documented by the NP/CNM/PA prior to the delivery of sedation. Consent forms must be completed for the procedure to be performed as well as for the planned sedation.
    b. Pre-procedure patient education shall be given and documented, to include, but not be limited to:
        1. Informed consent for the procedure and sedation and answering the patient's questions to their satisfaction; orientation to the procedures and equipment.
        2. Risks, benefits, and alternatives.
        3. Review of the pain scale and the patient's responsibility to inform staff of their pain status and any unexpected changes they might experience.
        4. Date/time of procedure.
        5. Necessity of an adult escort for discharge to home in an appropriate mode of transportation.
    c. Re-assessment prior to the procedure to include:
        1. Indication for procedure.
        2. Two patient identifiers.
        3. A “time out” documented.
        4. Immediate pre-procedure vital signs (blood pressure, cardiac rhythm, heart rate, oxygen saturation and end-tidal carbon dioxide, or ETCO2).
        5. An assessment of level of movement and consciousness, and responsiveness.
    d. The Procedure:
        1. Verify pre-procedure assessment and monitoring guidelines.
        2. Administer appropriate medications as indicated.
        3. Continuously assess the patient’s response (level of consciousness, blood pressure, heart rate, respirations, oxygen saturation, ETCO2, rhythm, and pain level).
        5. Reversal agents, if indicated.
    e. Post-procedure
        1. Monitor level of consciousness, respiratory (RR, SaO2) and cardiovascular parameters, and pain level.
    f. Termination of Treatment
        1. If the patient does not tolerate the procedure, has significant unanticipated compromise, or otherwise indicated.
2. Patient conditions requiring Attending consultation:
    a. ASA status 3 or greater.
    b. Aspiration.
    c. Acute decompensation of patient.
    d. Unexplained historical, physical or laboratory findings.
    e. Upon request of patient, NP, CNM, PA, or physician.

f. Problem requiring hospital admission or potential hospital admission.

3. Education
   Patient will be instructed on signs and symptoms of complications. A 24-hour emergency advice number will be given to the patient for any post-procedural problems.

4. Follow-up
   A. If the patient is transferred to the recovery unit:
      1. The patient must be accompanied by trained and/or licensed personnel.
      2. The clinical unit performing the procedure must give a verbal report to the Recovery Room nurse caring for the patient. Items to report include, but are not limited to:
         a. The procedure performed.
         b. The condition of the patient; including pain score.
         c. The sedation agents administered, the total dosage and the last dose and time of sedation agent given.
         d. Any significant clinical events occurring during and post-procedure.
         e. Any additional orders relating to the post-procedural/moderate sedation care.
   B. Any patient receiving a reversal agent (naloxone or flumazenil) must be monitored for at least two (2) hours after administration of the agent to detect potential re- sedation. In addition an Unusual Occurrence Report must be completed.
   C. The outpatient is discharged “to home”:
      1. By a specific discharge order from a physician or NP/CNM/PA; or by a registered nurse who has been approved to discharge the patient according to an approved standardized procedure.
      2. Written post-procedural instruction along with a 24-hour emergency telephone number will be given to the patient for assistance with post-procedural problems.
      3. Outpatients who are discharged to home must be accompanied by a responsible adult.

E. RECORD KEEPING
   Patient visit, consent forms, and other procedure-specific documents will be recorded in the medical record and LCR as appropriate. The patient status and compliance with discharge criteria must be documented in the patient’s medical record by the physician, NP/CNM/PA or registered nurse discharging the patient. Document all

findings in the computerized procedure database, usually the PACS system.

F. Summary of prerequisites, proctoring & reappointment of competency

Prerequisites

A. Specialty Training

The NP/CNM/PA will be able to demonstrate knowledge of the following:

1. Indications for procedures.
2. Risks and benefits of procedures.
3. Related anatomy and physiology.
5. Informed consent process.
6. Use of required equipment.
7. Steps in performing procedures.
8. Ability to interpret results and formulate follow-up plans.
9. Documentation.
10. Ability to recognize a complication.
11. The ability to take a medical history, perform a physical examination, order appropriate laboratory and imaging studies and initiate an appropriate treatment program based on the data obtained utilizing applicable protocols.

B. Training Program

1. Completion of the SFGH Procedural Sedation Test with a passing score of 80%.
2. Completion of Basic Life Support (BLS) training.
3. Completion of the Registered Nursing Moderate Sedation Education Module.
4. Furnishing License and DEA number.

Proctoring

A. Direct observation by WOC attending staff credentialed in moderate sedation for a minimum of 30 procedures under moderate sedation. An experienced practitioner who previously had moderate sedation privileges at another institution requires a minimum of 10 successful observed demonstrations.

B. Review by WOC attendings of 30 procedure notes.

Reappointment

A. Ongoing competency will be demonstrated by observation by the Medical Director of three procedures every 2 years.
B. Maintenance of BLS Certification.
C. Passing of Procedural Sedation test with a passing score of 80%.