POLICY ■ PROCEDURE

SOUTHWEST
Washington Medical Center

Title: Procedural Sedation

Number: 8720.718
8610.P050

Originating Department: Clinical Practice Committee
Administration

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GENERAL POLICY STATEMENT:

Level I (Moderate Procedural) Sedation shall be provided to patients undergoing diagnostic, therapeutic, or surgical procedures following identified standards required for non-anesthesiologist physicians and qualified RN or RCT staff in all inpatient and ambulatory settings.

The Washington State Nursing Care Quality Assurance Commission affirms that it is within the role and scope of practice for the registered nurse (RN) to administer procedural sedation (known as Level I, Moderate Procedural Sedation at SWMC), upon order of a qualified licensed independent practitioner, and to manage patients who are receiving and recovering from procedural sedation.

Washington State Nursing Care Quality Assurance Commission Position Statement (2005). *Scope of Practice for the Registered Nurse in the Administration of Procedural Sedation and the Management of Patients Receiving Procedural Sedation*. Retrieved July 31, 2008 at: https://fortress.wa.gov/doh/hpqa1/hps6/Nursing/practice.htm

PURPOSE:

To establish standards for the safe and consistent care of patients receiving procedural sedation in all settings throughout the continuum of care.

DEFINITIONS:

The American Society of Anesthesiologists (2004) defines:
Level I (Moderate Sedation): a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands either alone or accompanied by light tactile stimulation. A patient receiving Level I (Moderate Sedation) ideally has a minimally depressed level of consciousness and retains the ability to continuously and independently maintain a patent airway and respond appropriately to physical stimulation and verbal commands. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.

Level II (Deep Sedation): a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following 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.
(Developed by the American Society of Anesthesiologists; approved by ASA House of Delegates October 27, 2004.)

KEYPOINT: * Reflex withdrawal from a painful stimulus is not considered a purposeful response.

KEYPOINT: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended.

- ❖ Individuals administering Level I (Moderate Procedural Sedation) should be able to rescue patients who enter a state of Deep Sedation.

Pediatric: For procedural or deep sedation, a pediatric patient is defined as age 15 or under and 100 lbs. or less.

Registered Cardiovascular Technologist (RCT): Includes Registered Cardiovascular Radiologic Technologists and Registered Cardiovascular Invasive Specialists who complete specialized training and are certified as Washington State Health Care Assistants Levels A,B,D,F, and maintain ACLS certification allowing them to participate in providing procedural sedation in the presence of a physician.

Qualified RN or RCT: All RN/RCT personnel assigned to assist with or monitor a patient during or after procedural sedation shall have successfully completed/demonstrated the specific competency requirements.

EXCLUSIONS:

1) Does not include oral pre-medication
2) Does not apply to administration of narcotics and sedatives for pain or anxiety
3) Excludes preoperative medication of patients prior to their transport to the Operating Room
4) Excludes patients receiving inhalation anesthetics
5) Excludes patients who receive continuous IV sedation per protocol to manage conditions requiring mechanical ventilation (e.g., traumatic injury, post-surgical intervention)
6) Excludes patients who are receiving sedation for the purpose of intubation

PROCEDURE:

A. Pre-Procedure

1. Clinicians administering sedation/analgesia shall be familiar with sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia, including
    - abnormalities of the major organ systems
    - previous adverse experience with sedation/analgesia as well as regional and general anesthesia
    - drug allergies, current medications, and potential drug interactions
    - time and nature of first oral intake; and
    - history of tobacco, alcohol, or substance use or abuse

a. Patients presenting for sedation/analgesia shall undergo a focused physical examination, including vital signs, auscultation of the heart and lungs, and evaluation of the airway (see Appendix A)

b. Pre-procedure laboratory testing shall be guided by the patient's underlying medical condition and the likelihood that the results will affect the management of sedation/analgesia
   1) These evaluations should be confirmed immediately before sedation is initiated

2. Practitioner Responsibilities for Pre-Procedure
   a. Providers administering procedural sedation must be privileged for Level I sedation and are responsible to know if the privilege is current
   b. The following shall be completed by the practitioner and documented in the medical record prior to procedure

KEYPOINT: Document assessment on Procedural Sedation Interdisciplinary Progress Record (refer to: Intranet; Forms database; # 2077) or department specific form.

1) Assessment:
   a) An appropriate history and physical assessment with other pertinent information
   b) An airway assessment immediately prior to the procedure including:
      i Mallampatti classification using the graphic assessment tool
      ii Mandible measurement (finger distance from the inner surface of mandible to hyoid bone during neck extension)
      iii Neck range of motion
      iv Condition of teeth
   c) Previous anesthesia history including poor or questionable outcomes
   d) Physical Status Classification (ASA Score):
      i <u>Class I:</u>
         a) Normally healthy individual with no systemic disease
         b) Patient not at extremes of age
      ii <u>Class II:</u>
         a) Individual with one system, well-controlled disease
         b) Mild obesity, alcoholism, and smoking may be incorporated here

      KEYPOINT: Class I and II are appropriate for procedural sedation

      iii <u>Class III:</u>
         a) Individual with multiple system disease or well controlled major system disease
         b) Disease status may limit daily activity
         c) No immediate danger of death from any individual disease
      iv <u>Class IV:</u>
         a) Individual with severe, incapacitating disease
         b) Disease state is poorly controlled or end-stage
         c) Danger of death due to organ failure is always present
      v <u>Class V:</u>
         a) Patient who is in imminent danger of death
         b) Patient not expected to live through the next 24 hours

      KEYPOINT*:* Class III, IV, and V require additional individual consideration and documentation of rationale for procedure; Class IV or V patients requiring procedural sedation shall be considered for anesthesia provider support.

2) Complete the informed consent process for sedation (refer to: Intranet; Forms & Printing; Form # 450 or department specific consent form)

KEYPOINT: Surgical consent form may be used, unless approved department specific consent is standard.

3) Complete procedural sedation plan and orders prior to initiating procedure

KEYPOINT: Implement Procedural Sedation Plan, Interdisciplinary Progress Record: (refer to: Intranet: Forms & Printing: Form #2077) and/or department specific Pre Printed Order: (ED implements Procedural Sedation Flow Record; see Intranet: Forms & Printing: Forms Database #2329)

3. RN or Registered Cardiovascular Technician Responsibilities

a. Verify physician or physician assistant privileges for planned procedure and procedural sedation levels (Level I or Level II privileged)

1) Physicians may be privileged for Level I or Level II Deep Sedation for Non-Anesthesia Practitioners

KEYPOINT: Refer to the physician credentialing website on the SWMC Intranet to identify level of physician sedation privileging. All physician or PA personnel ordering/performing procedural sedation must meet the specific competency requirements identified in the privileging process.

b. Verify completion of:

1) Informed Consent for sedation
2) History and Physical
3) Pre-Procedure Airway Assessment and Plan for Sedation
4) Pre-Procedure Checklist

c. Evaluate and document NPO/fasting status

Ingested Material	Minimum Fasting Period[2]
Clear liquids[3]	2 h
Breast milk	4 h
Infant formula	6 h
Non-human milk[4]	6 h
Light meal[5]	6 h
Regular meal	8 h

[1] These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee that complete gastric emptying has occurred. Causes of delayed gastric emptying include: diabetes, narcotic use, presence of ascites or other intra-abdominal processes which may make the stomach smaller than normal, significant uremia, chronic significant neurological disease, etc.

[2] The fasting periods noted above apply to all ages.

[3] Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

[4] Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.

[5] A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

KEY POINT: In emergent situations or when patients are at risk for pulmonary aspiration of gastric contents, appropriate pharmacologic treatment to reduce gastric volume and increase gastric pH may be of benefit prior to sedation and/or airway protection may be required**.** In emergency situations when pre-procedure fasting is not practical, the targeted level of sedation should be modified (i.e. less sedation should be administered). Consideration shall be given for consultation with an anesthesia credentialed practitioner.

d. Assessment: Registered Nurse (RN) or Registered Cardiovascular Technician responsibility
   1) Baseline pain assessment
   2) Baseline sedation score (See Addendum "OAS/S Sedation Scale")
   3) Baseline Vital Signs (BP, P, R, T, O_2 sat)
   4) Height and weight
   5) Allergies/sensitivities
   6) Verification of appropriate transportation home shall be obtained (i.e. the patient is not driving) when the patient is expected to be discharged following the procedure

e. Establish IV Access
   1) Vascular access must be established prior to administration of procedural sedation.

f. Personnel - Procedural Sedation (the Sedation Plan shall determine personnel requirements)
   1) Personnel – Level I Moderate Procedural Sedation
      a) The Physician or PA:
         i Be present during the initial administration of IV sedation
         ii Be <u>readily available</u> within the department until the patient meets the pre-procedure Aldrete Score
      b) Additional care providers
         i One RN or Registered Cardiovascular Technologist whose <u>primary</u> responsibility during the procedure is to monitor the patient, maintain the airway and be qualified and competent to identify and manage a compromised airway must be present
         KEYPOINT: The qualified RN or RCT responsible for monitoring the patient may not engage in tasks that would compromise continual assessment.
         ii Advanced Cardiac Life Support (ACLS) certified personnel immediately available (i.e. Code 199 team available by page)

KEYPOINT: A sufficient number of staff shall be in attendance to safely monitor and provide care to the patient based on patient health status and complexity of intended procedure, complying with all regulatory standards and published National Specialty Organization Standards.

g. Equipment/Supplies for Moderate Procedural Sedation
   1) Continuous oxygen saturation monitor
   2) Intravenous access supplies, fluids
   3) Supplemental oxygen including nasal cannulas, masks, regulator and equipment to perform positive pressure ventilation (i.e. Ambu bag)
   4) Blood pressure monitoring equipment
   5) Suction and suction catheters present
   6) Reversal agents to be at the bedside prior to the start of the procedure
   7) Cardiac monitoring
   8) Code 199 cart present

   KEYPOINT: All equipment and supplies must be suitable for the age and size of the patient being treated.

B. Intra-Procedural Care

1. Final Verification and Time Out
   a. The Licensed Independent Practitioner performing the procedure, as well as all personnel present, shall participate in completing the final check in the location where the procedure is to be performed, immediately prior to the beginning of the procedure (refer to policy # 8720.103, "Universal Protocol: Patient, Procedure and Site Verification")

2. Medication administration
   a. Level I Moderate Procedural Sedation
      1) Physician or PA must be present in the work area during IV sedation medication administration and readily available within the department until the patient meets the pre-procedure modified Aldrete Score
   b. Dosage and rate of administration must be individualized based on patient condition (drug manufacturer's recommendations, response to previous dose)
   c. Medication administration shall be performed incrementally
      1) Dosages and rates of administration must be individualized with adequate time between doses to assess full pharmacologic effects
   d. The administration of each dose shall be by the order of the physician performing the procedure

      KEYPOINT: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. The patient's age and pre-existing medical conditions may significantly alter the dosing requirements needed for sedation.
   e. Reversal agents shall be used at the discretion of the Physician or PA or as outlined in Procedural Sedation Reversal Policy #8720.717

3. Airway management
   a. Supplemental oxygen at 2 liter per nasal canula, given as indicated by patient condition (oxygen flow rate may vary according to individual patient assessment and medical condition)

      KEYPOINT: Do not use supplemental oxygen when procedure site is near nares and electrosurgical equipment is being utilized.

4. Patient monitoring shall include:
   a. Continuous visual monitoring with documentation upon initiation and every 10 minutes for the following:
      1) Patient's level of consciousness and responsiveness
      2) Heart rate
      3) Blood pressure
      4) Respiratory rate
      5) Continuous pulse oximetry
      6) ECG

C. Post Procedure Care
1. Monitoring
   a. Monitor and document vital signs and oxygen saturation every 10 minutes or more frequently as indicated by patient response until patient reaches a modified Aldrete Score of 8 (Attachment A)
   b. Report significant variations in physiologic parameters to the physician immediately including but not limited to:
      1) Variation of ≤ ± 20% of baseline
      2) Arrhythmia
      3) Oxygen saturation ≤ 90% or ≥ 5% below baseline
      4) Dyspnea, apnea, or hypoventilation
      5) Diaphoresis
      6) Inability to arouse patient
      7) Other untoward or unexpected patient response
   c. When the modified Aldrete score reaches 8 or above obtain vital signs every 15 minutes x 2
   d. Patient shall not be discharged prior to a minimum of 30 minutes since last dose of sedation medication
   e. Follow Standard of Care (refer to: Post Anesthetic and Post Procedural Care for Non Critical Care, (#2019), Outpatient Surgical or Invasive Procedure (#2033))

2. Documentation for Procedural Sedation
   a. Complete Procedural Sedation Flow Record (refer to: Intranet; Forms database; #2097)
   b. Physician performing procedure shall sign the Procedural Sedation Plan Interdisciplinary Progress Record (refer to: Intranet; Forms; Forms database; # 2077), or department specific form/order set

3. Patient Discharge for Procedural Sedation
   a. Maintain IV access until discharge criteria are met
   b. Discharge Criteria:
      1) Return to pre-procedural level of consciousness and activity level
      2) Vital Signs within ± 20% of pre-op/pre-procedural
      3) Absence of vomiting, minimal nausea after PO fluids (notify attending physician of vomiting)
      4) Able to ambulate with minimal dizziness, sit up unassisted as appropriate for age and/or return to pre-operative status

5) Dressing, if present, dry and intact
6) Responsible adult present to escort/drive patient home
7) When discharge criteria are not met, notify physician for further orders
KEYPOINT: Pediatric patients shall demonstrate pre-procedural developmental tasks such as sitting or talking and an adequate state of hydration prior to discharge.
8) When a reversal agent is administered, prolonged observation (minimum of two (2) hours from time of administration) is recommended
9) Document time and condition of patient at discharge
10) Provide patient with discharge instructions

D. Quality Improvement

1. Random chart audits shall be conducted for compliance with regulatory standards

2. Adverse events and/or patterns during Procedural Sedation shall be documented and submitted to the appropriate supervisor/manager/director within 24 hours of occurrence
   a. Adverse events include (not limited to):
      1) Adverse patient reaction
      2) Respiratory depression requiring ventilatory assistance
      3) Administration of a reversal agent
      4) Respiratory and cardiac depression requiring Code 199
      5) Patient expiration
   b. Manager/Supervisor/Director investigates the occurrence, completes the documentation and submits to Quality Care Resources for appropriate review (refer to: Intranet; Forms; Forms database; # 050)

E. Competency Requirements

1. Physician must maintain privileges and competency requirements as outlined in Medical Staff Bylaws for Level I Procedural Sedation

2. Procedural Sedation Competency must be completed to be deemed competent (refer to: Intranet: Manuals; Competency; Targeted; # 645 - Procedural Sedation)

3. Pediatric Procedural Sedation Competency must be completed to be deemed competent for pediatric procedural sedation.
KEY POINT: Supporting Procedural Sedation Competency Reference Manuals are available in designated departments and the Library; the Sedation Simulator is available in the Library, Emergency Department and at Memorial Campus in Pain Management.

APPENDIX A Airway Assessment Procedures for Sedation and Analgesia

ATTACHMENTS:

A. Modified ALDRETE Scoring System, OAS/S Sedation

REFERENCES:

Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists:
Anesthesiology, V 96, No 4, April 2002, pgs, 1004 – 1017

A Clinical Sign to Predict Difficult Tracheal Intubation, a Prospective Study:
Journal of Canadian Anesthesia Society, Vol 32, 1985, pg 429 – 434 (Mallampati SR, GATT, SP)

Continuum of Depth of Sedation Definition of General Anesthesia and Levels of Sedation/Analgesia:
Approved by ASA House of Delegates on October 13, 1999, and amended on October 27, 2004
Washington State Nursing Care Quality Assurance Commission Position Statement:
"Scope of Practice for the Registered Nurse in the Administration of Procedural Sedation and the Management of Patients Receiving Procedural Sedation"

RELATED POLICIES:

8720.717 Procedural Sedation Reversal
8720.103 Universal Protocol: Patient, Procedure and Site Verification

RELATED FORMS, STANDARDS OF CARE:

Diagnostic Imaging Admission/Intra Procedure Record	Form #2644
Emergency Department Procedural Sedation Checklist	Form #2328
Endoscopy Consent	Forms #2213, 2214, 2215, 2216, 2400
Endoscopy Services Procedure Record	Form #2126
Informed Consent for Cardiac Catheterization	Form #2623
Occurrence Report	Form #50
Outpatient Surgical or Invasive Procedure	Standard of Care #2033
Patient Informed Consent	Form #450
Post Anesthetic and Post Procedural Care for Non Critical Care	Standard of Care #2019
Procedural Sedation Chart Review	Form #2910
Procedural Sedation Flow Record	Form #2097
Procedural Sedation Flow Records Emergency Department	Form #2329
Procedural Sedation Interdisciplinary Progress Record	Form #2077

APPENDIX A

Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal intubation, may be necessary if respiratory compromise develops during sedation-analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

History:

- Previous problems with anesthesia or sedation
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (e.g., trisomy 21)

Physical Examination

- Habitus
  - Significant obesity (especially involving the neck and facial structures)
- Head and Neck
  - Short neck, limited neck extension, decreased hyoid-mental distance (< 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, dysmorphic facial features (e.g., Pierre-Robin syndrome)
- Mouth
  - Small opening (< 3 cm in an adult); edentulous; protruding incisors; loose or capped teeth; dental appliances; high, arched palate; macroglossia; tonsillar hypertrophy; nonvisible uvula
- Jaw
  - Micrognathia, retrognathia, trismus, significant malocclusion

Modified ALDRETE Scoring System:

Patients receiving procedural sedation shall be assessed according to the Modified Aldrete Scoring System prior to discharge from the procedure. A score of 8 or greater is required for discharge from the procedure except on written order from the attending physician.

RESPIRATIONS	**2 = Free deep breathing**	**1 = Dyspneic, hyperventilating, obstructed breathing**	**0 = Apneic ~~or~~**
CIRCULATION	**2 = Blood pressure within 20% of pre-op level**	**1 = Blood pressure within 50%-20% of pre-op level**	**0 = Blood pressure 50%, or less, of pre-op level**
LOC (Level of Consciousness)	**2 = Fully Awake**	**1 = Responds to name**	**0 = No response**
ACTIVITY ON COMMAND	**2 = Moves all extremities**	**1 = Moves two extremities**	**0 = No movement**
OXYGEN SATURATION	**2 = SpO_2 >92% on room air**	**1 = Supplemental O_2 required to maintain SpO_2 >92%**	**0 = SpO_2 >92% with O_2 supplementation**

OBSERVER'S ASSESSMENT OF ALERTNESS / SEDATION (OAA/S) SCALE

OAA/S SCALE: 5	OAA/S SCALE: 4	OAA/S SCALE: 3	OAA/S SCALE: 2	OAA/S SCALE: 1
• Responds readily to name spoken in normal tone • Normal speech • Normal facial expression • Eyes clear, no ptosis	• Lethargic response to name spoken in normal tone • Mild slowing or thickening of speech • Mild relaxation of facial expression • Eyes glazed or mild ptosis	• Responds only after name is called loudly and/or repeatedly • Slurring or prominent slowing of speech • Marked relaxation of jaw • Eyes glazed or marked ptosis	• Responds only after mild prodding or shaking • Few recognizable words	• Does not respond to mild prodding or shaking