

ADMINISTRATIVE POLICY AND PROCEDURE

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Subject: MODERATE AND DEEP PROCEDURAL SEDATION IN PATIENTS
WITHOUT CONTROLLED AIRWAY

Policy No.: B815

Supersedes: September 8, 2022

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Origin Date: October 1, 2009

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PURPOSE:

To provide standard guidelines and procedures for the safe provision of moderate and deep procedural sedation (MDPS) in patients without a controlled airway in designated locations outside the perioperative areas.

Moderate Sedation will be used to minimize patient's discomfort, anxiety and/or pain during diagnostic and therapeutic procedures. Moderate sedation will be used to reduce risks and complications that are associated with the use of general anesthesia.

POLICY:

All appropriately credentialed physicians or dentists (referred to as "attending"), shall provide (MDPS) for patients safely without a controlled airway according to the following procedures in any of the designated locations in the facility.

This policy does not apply to minimal sedation, anxiolysis, anesthesia medications used for the management of pain or seizures, or administration of pre-operative medications. Refer to Administrative Policy and Procedure B859 "Propofol Continuous Intravenous Infusion" for the use of Propofol.

DEFINITIONS:

Rancho Los Amigos National Rehabilitation Center has adopted the following "Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia" as approved and updated by American Society of Anesthesiologists, 2018 (Attachment A)

1. **Minimal Sedation (Anxiolysis)** is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.
2. **Moderate Sedation/Analgesia ("Conscious Sedation")** is a drug-induced depression of consciousness during which patients respond 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. Protective reflexes (coughing, gag, and/or corneal reflexes) are maintained. Cardiovascular function is usually maintained. *Reflex withdrawal from a painful stimulus is not considered a purposeful response.
3. **Deep Sedation/ Analgesia:** A drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The

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ability to independently maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

PROCEDURE:

A. Personnel

1. All MDPS must be administered under direct supervision of a physician or dentist who has the current privileges to perform MDPS.
 - i. To obtain privileges to perform MDPS, the medical staff member (physician, dentist, provider) must complete the following:
 1. Submit documentation of appropriate training or pass the exam
 2. ACLS/PALS training
 3. Perform five proctored cases at Rancho
 4. Review the current moderate/deep sedation policy
 - ii. To maintain current privileges to perform MDPS, the medical staff member must:
 1. Submit documentation of current ACLS/PALS
 2. Review the current moderate/deep sedation policy
2. At least two personnel are required to be present during the MDPS:
 - i. A responsible physician or dentist supervising/providing MDPS, and performing the procedure
 - ii. A qualified practitioner (registered nurse, physician, dentist) is responsible for monitoring the patient's vital signs and level of consciousness during the procedure and recovery period.
 - iii. The person responsible for monitoring the during MDPS may administer medications ordered by the responsible medical staff member, but cannot act as the assistant for the procedure.
3. Registered nurses responsible for monitoring or managing the care of a patient receiving MDPS must:
 - i. Demonstrate age-appropriate competency per Department of Nursing Policies and Procedures.
 - ii. Provide documentation of current ACLS/PALS
4. Anesthesiologists, certified registered nurse anesthetists, and board-certified critical care and pulmonary physicians need not request MDPS as a separate privilege as their training includes MDPS.

B. Locations and Equipment

1. MDPS may be provided in areas of the hospital that are appropriately equipped for monitoring, recovery, and emergency care and recovery. These areas include:
 - i. Intensive care unit
 - ii. Medical imaging and MRI
 - iii. Dental clinic
2. Each location at which MDPS is provided must have appropriate monitoring and emergency, resuscitation, and reversal equipment and supplies such as:
 - i. source and supplies to provide supplemental oxygen
 - ii. pulse-oximetry
 - iii. blood pressure cuff
 - iv. crash cart
 - v. suction
 - vi. ECG monitoring

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- vii. Continuous capnography (EtCO₂)
- viii. Appropriate selection of masks and airways
- ix. Resuscitative Equipment
 - o Bag - valve - mask device (“Ambu-bag”) with CO₂ detector
 - o Additional oxygen delivery devices (e.g. non-rebreather face mask)
 - o Airway devices (e.g. oral/nasal airway)
 - o Ancillary oxygen source
 - o Emergency Crash Cart with Defibrillator

C. MDPS Planning and Assessment

1. The physician or dentist responsible for the administration of MDPS shall determine and document the appropriate MDPS plan by completing the Pre-Sedation Note/Pre-Procedure Sedation Evaluation found in the electronic medical record.
2. The physician or dentist shall perform an appropriate patient assessment within 30 days prior to the administration of MDPS, of which this Pre-Sedation Note/Pre-Procedure Sedation Evaluation includes the following documentation:
 - i. history and physical exam performed and reviewed
 - ii. any changes to health noted in box
 - iii. ASA classification (Attachment B), which serves as the anesthesia risk assessment.
 - iv. Evaluation of airway: normal or abnormal/ high-risk airways: thick neck, short thyromental distance, etc
 - v. Documentation of the patient’s airway classification (Attachment C).
3. Informed consent for procedures must be obtained and include the administration of MDPS in accordance with existing policy and procedure. Informed consent must be within 30 days of the procedure.
4. Appropriate pre-sedation instructions must be given to the patient, including NPO requirement (Attachment D), the need to make transportation arrangements, and the need to be accompanied by a competent adult.

D. MDPS

1. Immediately prior to the administration of MDPS, the medical staff member providing the MDPS must re-evaluate the patient to ensure that he/she is still a suitable candidate for the proposed MDPS plan and the procedure. This re-evaluation shall include:
 - i. review of patient chart
 - ii. verification of NPO status (Attachment D)
 - iii. pain assessment
2. The qualified practitioner responsible for monitoring the patient shall perform a pre-MDPS Assessment and the Universal Protocol “time out” including all the following:
 - i. verify correct patient, procedure, and site
 - ii. baseline vital signs, including pain assessment
 - iii. verification and documentation of NPO status
 - iv. oxygen saturation
 - v. pre-MDPS Aldrete Scale assessment (Attachment E)
 - vi. availability of the correct equipment, supplies and other items
3. Intravenous access in patients receiving intravenous medications will be established by the appropriate person.
4. Supplemental oxygen must be available throughout the MDPS and recovery.

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5. Monitoring of the patient must be continuous throughout the procedure and must include documentation of the following parameters every 5 minutes or immediately if there is a significant change or event:
 - i. heart rate
 - ii. blood pressure
 - iii. respiratory rate
 - iv. oxygen saturation
 - v. level of consciousness
 - vi. EKG monitoring
 - vii. capnography (ETCO₂)

E. Post-MDPS Recovery and Discharge

1. Patients will be recovered at or near the site where the procedure was performed. Patients taken from the ICU for a procedure will be returned to the ICU as soon as he/she can be safely transported
2. Patients will be observed and monitored for a minimum of 30 minutes after the procedure. If a reversal agent is used, the patient must be monitored for an additional 90 minutes minimally. The following parameters must be documented every 15 minutes or more frequently until the patient meets discharge criteria:
 - i. heart rate
 - ii. blood pressure
 - iii. respiratory rate
 - iv. oxygen saturation
 - v. level of consciousness
3. Discharge criteria includes Aldrete Score 8 or higher or baseline. Patients who fail to meet the desired outcome status or have an Aldrete Score less than 8 will be evaluated by the attending physician to consider further monitoring and recovery.

F. MDPS Documentation

1. Documentation of MDPS may include:
 - i. date, start time and end time
 - ii. pre-MDPS assessment including vital signs, pain, and Aldrete score
 - iii. universal protocol
 - iv. procedure performed
 - v. name, dose and time administered of all sedative agents and medications used including amount/rate of supplemental oxygen
 - vi. time started, type, rate, amount of intravenous fluids infused and time discontinued
 - vii. records of continuous monitoring
 - viii. patient response to procedure/sedation
 - ix. patient status at the end of the procedure, including post-procedure and recovery monitoring
 - x. post-MDPS assessment including vital signs, pain, and Aldrete score
 - xi. post-procedure findings
 - xii. unusual events or interventions
 - xiii. discharge instructions
 - xiv. disposition of the patient
 - xv. person responsible for patient at discharge
 - xvi. personnel performing the procedure and monitoring the patient

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G. Outcomes

1. MDPS practices and outcomes shall be monitored and evaluated by the Department of Anesthesiology on a regular basis.
2. The Department of Anesthesia Chair will address any practice concerns in collaboration with Critical Care Committee, Pharmacy and Therapeutics, and/or Quality Risk Management Patient Safety committees as appropriate.

REFERENCES:

1. American Society of Anesthesiologists (ASA), Practice Guideline for Moderate Procedural Sedation and Analgesia, Anesthesiology 2018: 128:437-79.
2. Rancho Los Amigos Professional Staff Association, Bylaws, Rules and Regulations.

ATTACHMENTS

Attachment A: Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

Attachment B: ASA Risk Classification

Attachment C: Mallampati Classification

Attachment D: NPO Guidelines

Attachment E: Aldrete Scale

Attachment A: Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia
Responsiveness	Normal Response to Verbal Stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful response after repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained

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Attachment B: ASA Risk Classification

- Class 1: Normal, Healthy Patient
- Class 2: Patient with Mild Systemic Disease (e.g. slightly limiting organic heart disease, mild diabetes, essential hypertension, anemia, chronic bronchitis)
- Class 3: Patient with Severe Systemic Disease (e.g. insulin dependent Diabetes, immunosuppressed, moderate degree of pulmonary Insufficiency, stable CAD, asthma, extreme obesity)
- Class 4: Patient with Severe Systemic Disease that is a constant threat to life. (e.g. organic heart disease with marked signs of cardiac insufficiency, persistent angina, active myocarditis, advanced degrees of pulmonary hepatic, renal, or endocrine insufficiency).
- Class 5: Moribund Patient not expected to survive without the procedure.
- Emergency: An Emergency procedure

Attachment C: Mallampati Classification

- Class 1: Soft palate, tonsillar fauces, tonsillar pillars, and uvula visualized completely
- Class 2: Soft palate, tonsillar fauces, uvula visualized partially
- Class 3: Soft palate and base of uvula visualized
- Class 4: Soft palate not visible

Attachment D: NPO Guidelines

The following NPO guidelines apply for otherwise healthy patients. Deviations from these guidelines may be indicated in some patients because of their clinical presentation.

Patients greater than 2 years old, including adults may take clear liquids up to 4 hours before procedure and may take solids up to 8 hours before the procedure

Clear liquids are defined as water, fruit juices without pulp, carbonated beverages, clear tea and black coffee. The volume of liquid is less important than the type of liquid ingested.

The ASA suggest that patients may have a light meal up to 6 hours before a procedure, (a light meal is defined typically as toast and clear liquids)

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Attachment E: Aldrete Scale

ACTIVITY

Moves all extremities	2
Moves 2 extremities	1
Moves 0 extremities	0

RESPIRATION

Deep breathes/cough freely, O ₂ Sat >90	2
Dyspnea, shallow/limited breathing, O ₂ Sat <90	1
Apneic	0

CIRCULATION

SBP +/- 20 mm Hg of the pre-sedation level	2
SBP +/- 20 -50 mm Hg of the pre-sedation level	1
SBP +/- 50 mm Hg of the pre-sedation level	0

CONSCIOUSNESS

Fully awake, alert, oriented	2
Aroused/awakened with stimulation	1
Not responding	0

COLOR

Normal	2
Pale, dusky, blotchy, jaundiced, other	1
Cyanotic	0