

GUIDELINES FOR PROCEDURAL SEDATION/ ANALGESIA

CLEVELAND CLINIC FOUNDATION

I. **Definition and Scope:**

Procedural sedation/ analgesia is the proper administration of drugs to obtund, dull, or reduce the intensity of pain or awareness where the administration of those drugs by any route carries the risk of loss of protective reflexes. These guidelines have been designed to be applicable to procedures performed in a variety of settings by practitioners who are not specialists in anesthesiology, to insure uniform care across the entire Foundation.

A. **Definition of Levels of Procedural Sedation/ Analgesia:**

Levels 1 and 4 are not covered by these guidelines.

1. Anxiolysis: Normal response to verbal stimulation. Airway, ventilation, and cardiovascular function unaffected.
2. Moderate Sedation/ Analgesia: (Formerly termed “conscious sedation”) Purposeful response to verbal or light tactile stimulation. No airway intervention is required. Adequate spontaneous ventilation. Cardiovascular function is usually maintained.
3. Deep Sedation/ Analgesia: Purposeful response following repeated or painful stimulation. Airway intervention may be required. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
4. General Anesthesia: Unarousable even with painful stimulus. Airway intervention often required. Spontaneous ventilation is inadequate. Cardiovascular function may be impaired.

Note: Reflex withdrawal from painful stimuli is NOT considered purposeful.

B. **Exclusions:** (These guidelines specifically exclude the following)

1. Patients not undergoing a diagnostic or therapeutic procedure (e.g. anxiolysis, postoperative analgesia, sedation for treatment of insomnia).
2. Single dose drugs used as anxiolytics (where the patient retains a normal response to verbal stimulation and airway/ ventilation is unaffected) to perform such minimal procedures as lumbar puncture, dressing change, or bone marrow aspiration.
3. Otherwise healthy patients receiving peripheral nerve blocks, local or topical anesthesia, and/or no more than 50% nitrous oxide with oxygen and no other sedative or analgesic agents administered by any route.
4. Those patients mechanically ventilated in a critical care environment.
5. Those patients requiring emergency tracheal intubation.
6. Perioperative management of patients undergoing general anesthesia or major conduction anesthesia. It does not apply to procedural sedation analgesia in any location where a member of the Division of Anesthesiology and Critical Care Medicine is present and documentation occurs on approved anesthesia forms.

II. Patient Assessment and Selection:

A. Relevant History and Physical:

1. Patient age.
2. History of abnormalities of major organ systems, including heart, lungs, and kidneys, or airway (e.g. sleep apnea, snoring, stridor).
3. Pregnancy test only in women who are unable to insure (based on history) that they are not pregnant.
4. Current medications.
5. History of any adverse or allergic drug reactions with anesthesia or sedation/ analgesia.
6. History of prior sedation/ analgesia including the adequacy of pain control for those procedures.
7. History of tobacco, alcohol, or substance use or abuse.
8. Vital signs (weight, heart rate, blood pressure, respiratory rate).
9. Cardiopulmonary examination.
10. Airway examination.
11. The choice of laboratory evaluation should be based on the patient's medical condition and the effect the results of such evaluation will have on the plan for procedural sedation/ analgesia.

B. Patient Selection:

The attending physician will determine whether the patient is appropriate for procedural sedation. This determination is to be based on the intended procedure, the patient's medical status (as defined by the history and physical), and the level of sedation/ analgesia required to complete the procedure. Consultation from a member of the Division of Anesthesiology and Critical Care Medicine will be based upon any factor which the attending physician determines will enhance patient care and safety through the presence of an anesthesiologist. Examples include:

1. Those patients with severe systemic disease (e.g. severe obstructive pulmonary disease, coronary artery disease, congestive heart failure) in which the sedation/analgesia and/or the complexity of the procedure would reduce the patients reserve resulting in a threat to life.
2. Those patients with significant oxygenation, or anatomic airway/ ventilation abnormalities as noted by history or physical exam.
3. Those patients for which the expected procedure will require that sedation be taken to levels greater than that covered in these guidelines.

C. Pre-sedation Assessment: (on the day of the procedure).

1. Documentation of any changes in the history and physical.
2. Time and nature of last oral intake. (See appendix A for CCF guidelines on oral intake for non-emergent procedures)
3. Vital signs, including heart rate, blood pressure, respiratory rate, temperature.
4. Baseline ambulation status.
5. Patient or legal guardian must be informed about the risks, benefits, and alternatives of the proposed procedural sedation/ analgesia.

D. Pre-induction Assessment:

Vital signs, including heart rate, blood pressure, respiratory rate, oxygen saturation, sedation score.

III. Intra-procedural Phase:

Only a physician is qualified to prescribe, order, or select the medications to be used to achieve procedural sedation/ analgesia.

A. Documentation for procedural monitoring:

The "Procedural Sedation Record" will be used to document procedural sedation/ analgesia activity. For procedures performed on un-intubated patients in an ICU, documentation requirements contained in this guideline will be recorded either on the procedural sedation record or in the standard ICU patient chart.

B. Individuals dedicated to patient monitoring:

One person will have the primary responsibility of patient monitoring for any procedure requiring administration of procedural sedation/ analgesia. For deep sedation, the person responsible for monitoring the patient cannot have any other duties or responsibilities for assistance in the procedure room and must remain at the head of the patient at all times, unless the particular procedure renders this impractical.

C. Hemodynamics:

The patient's vital signs should be recorded at a frequency that depends upon the type and amount of medication administered, the length of the procedure, and the general condition of the patient. At a minimum, this should be: (1) before the beginning of sedation/ analgesia, (2) following administration of each additional dose of sedative/ analgesic agents, (3) at regular intervals during the procedure, (4) during initial recovery, and (5) just before discharge. For moderate sedation this will be no less frequent than every 15 minutes. For deep sedation it will be every 5 minutes.

D. Automated monitoring devices:

Pulse oximetry will be performed in patients receiving procedural sedation/ analgesia. EKG monitoring is indicated for patients with significant dysrhythmias or if they are anticipated either based on the patient's history of coexisting cardiovascular disease or the expected induction of dysrhythmias secondary to the scheduled procedure. Both pulse oximetry and EKG monitoring are required in all deep sedation cases, unless the particular procedure renders this impractical. Capnography and/or a pretracheal stethoscope are suggested adjuncts to assessing ventilation in deep sedation cases.

E. Sedation Scoring System:

1. Modified Ramsay Score (1 = Anxious; 2 = Awake, tranquil; 3 = Drowsy, responds easily to verbal commands; 4 = Asleep, brisk response to tactile or loud auditory stimulus; 5 = Asleep, minimal response to tactile or loud auditory stimulus; 6 = Asleep, no response).
2. It is expected that for moderate sedation cases that patients will not remain below level 4 for longer than 15 minutes, and will not be at levels 5 or 6.
3. For deep sedation it is expected that patients will not remain at level 6 for longer than 15 minutes.

F. Other factors for patient's safety:

1. The administration of supplemental oxygen decreases the incidence of hypoxemia. Oxygen must be available in each procedure area and should be administered when relative hypoxemia occurs for more than a transient period.
2. Reversal agents must be available in each procedure room.
3. If any intravenous sedation/ analgesia drugs are used, the intravenous access should be maintained throughout the procedure and recovery phases, in the event that reversal agents, fluids, etc. are required.
4. Emergency equipment in the unlikely event of respiratory or cardiac arrest must be immediately available either in or within close proximity to the procedure room, along with the expertise necessary to perform advanced life support measures. Emergency equipment includes suction, code cart, airway support with positive pressure ventilation, pharmacologic antagonists, defibrillator, and individuals trained in advanced resuscitative techniques (e.g. ACLS, PALS, etc.).

IV. Recovery Phase:

Basic principles for the establishment of discharge criteria for each procedural area Include:

- A.** The recovery area must be equipped with appropriate monitoring and resuscitation equipment.
- B.** The recovery area must be staffed by an individual capable of monitoring patients and able to recognize complications of procedural sedation/ analgesia. An individual able to establish a patent airway and deliver positive pressure ventilation should be immediately available. The physician performing the procedure or his physician designee should be available for consultation until the patient is discharged.
- C.** At time of discharge from the procedural area, the patient should:
 1. Be alert and oriented or at their baseline mental status.
 2. Have vital signs and pulse oximetry within acceptable limits and stable.
 3. Return to baseline ambulation status.
 4. For inpatients return to baseline status prior to transfer back to

their nursing unit.

5. For outpatients be discharged in the company of a responsible adult or have made other suitable arrangements for transportation home. Patients should not drive until after a nights sleep. Appropriate homegoing instructions and a phone number to call in case of questions or emergency will be provided.

- D. Any patient who has received a reversal agent should be observed for at least two hours after the agent has been administered.

V. Training and Education:

Only personnel with appropriate licensure and training may administer drugs for sedation/ analgesia. Monitoring of procedural sedation/analgesia will be performed by a qualified physician or physician supervised assistant trained in monitoring patients receiving procedural sedation/analgesia. For either moderate or deep sedation, there must be at least one person in the procedure room with training in advanced resuscitative techniques (e.g. ACLS, PALS, etc.).

The skill sets of individuals caring for the patient while under procedural sedation is defined by the planned level of sedation. The patient under sedation must be able to be rescued from an unavoidable and unintentional slip into a deeper-than-desired level of sedation/ analgesia. Specifically, this will include the following:

- Practitioners who have appropriate credentials and are permitted to administer moderate sedation are qualified to rescue patients from deep sedation and are competent to manage a compromised airway and to provide adequate oxygenation and ventilation.
- Practitioners who have appropriate credentials and are permitted to administer deep sedation are qualified to rescue patients from general anesthesia and are competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation.

A. Physician Privileging

Per standard CCF privileging practices, the Department who grants primary privileges for any procedure requiring sedation/ analgesia, will also specifically grant the privilege of “procedural sedation/ analgesia (moderate)” and/ or “procedural sedation/ analgesia (deep)” based on the physicians training and experience in compliance with standard CCF privileging policy. Assessment of physician performance will be the responsibility of the Departmental Chairman with advice from the Departmental Quality Review Officer. If the physician’s primary privileges involve airway management (e.g. Emergency Department physician, Intensivist), then airway competency is covered in the granting of those privileges.

Other physicians will demonstrate competency through education, training, and experience in basic resuscitative techniques (e.g. BCLS) and successful completion of an online sedation/ analgesia interactive training module administered through the CCF Office of Professional Staff Affairs (OPSA).

Those physicians granted the privilege of “procedural sedation/analgesia (deep)” will assure competency through education, training, and experience in advanced resuscitative techniques (e.g. ACLS, PALS, etc.), unless the physicians primary privileges additionally involve the management of unstable cardiovascular systems (e.g. Emergency Department physician, Intensivist, Cardiologist).

B. Assistants

Individuals administering or monitoring procedural sedation/ analgesia are required to be familiar with proper dosages, administration, adverse reactions, and interventions for adverse reactions and overdoses. They should know how to recognize an airway obstruction and demonstrate skills in basic life support, and be able to assess total patient care requirements or parameters, including but not limited to respiratory rate, oxygen saturation, blood pressure, cardiac rate, and level of consciousness. These individuals should have the knowledge and skills to intervene in the event of complications.

VI. Process and Outcome Measurement:

- A.** Each procedural area will identify an individual responsible for adverse event reporting and follow-up.
- B.** Each procedural area will determine a system for assuring compliance with the documentation requirements as outlined in these guidelines.
- C.** Monthly summary reports will be made to the CCF Office of Quality Management. Among these specific events to be reported include:
 - 1. Total number of sedation cases per month per physician and whether the cases were moderate or deep sedation.
 - 2. Potential process improvement markers:
 - a. Reversal agents when used to reverse unresponsiveness in patients due to oversedation.
 - b. Recovery phase greater than 3 hours.
 - c. Admissions to hospital as a direct result of procedural sedation.
 - d. Emergency resuscitation of any type (drugs, airway, or cardiopulmonary support) initiated due to procedural sedation.
 - e. Procedure cancellation due to adverse events related to sedation/ analgesia.
 - f. For moderate sedation cases, any prolonged airway intervention.
 - g. For moderate sedation cases any need to rescue the patient from slipping into deep sedation and for deep sedation cases any need to rescue the patient from slipping into general anesthesia.
- D.** These monthly reports will be reviewed by the Office of Quality Management and the Quality Review Officer of the Department or Division from which the report originated.

Approved: Procedural Sedation Task Force, 6/00; MEC, 7/00
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Appendix A

Fasting Recommendations to Reduce the Risk of Pulmonary Aspiration

- 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 below 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.

<u>Ingested Material</u>	<u>Minimum Fasting Period²</u>
Clear liquids ³	2h
Breast milk	4h
Infant formula	6h
Non-human milk ⁴	6h
Light meal ⁵	6h
Regular meal	8h