PROCEDURE RELATED SEDATION

Outline

I Introduction

II Definitions: The 5 Levels of Sedation and Anesthesia

III Emergency Procedures, Critical Care Areas and Policy Exclusions

IV The Pre-Sedation Assessment

V NPO: The Timing of Eating and Drinking before Sedation

VI Review of Some Agents Used for Sedation

VII Orders for Procedure Related Sedation

VIII Environmental Requirements and Monitoring During Sedation

IX Post-Procedure Monitoring and the PAR Score

X Discharge Criteria and Concluding Post-Procedure Monitoring

PROCEDURE RELATED SEDATION

Lance Brown, MD, MPH

I. Introduction

The purpose of this tutorial is to familiarize the reader with the Loma Linda University Medical Center Policy M-86 for Procedure Related Sedation. Procedure related sedation is used to make necessary medical procedures as comfortable as possible for patients and to facilitate the performance of necessary medical procedures by health care providers (typically physicians). It is important for health care providers performing procedure related sedation to be familiar with the pharmacologic characteristics of the agents being used, to understand the risk factors for complications related to procedure related sedation, and to individually plan the sedation for each patient. Each health care practitioner privileged to provide procedure related sedation takes responsibility for both the **comfort and safety** of the patients in their care.

II. Definitions

At Loma Linda University Medical Center, we have defined five distinct levels of sedation and anesthesia. Familiarity with the definitions of these levels of sedation is important for safely providing procedure related sedation and for complying with the policy of the Medical Center. It must be recognized, however, that sedation occurs along a continuum and that individual patients may have different degrees of sedation for a given dose and route of medication. Although one level of sedation is planned, a patient may unexpectedly progress from lighter sedation to deeper sedation. Each health care practitioner involved in providing procedure related sedation must be prepared at all times during the sedation to promptly and safely manage a patient who has unexpectedly become sedated beyond the planned level of sedation. The definitions are as follows:

1. Minimal Sedation (Anxiolysis):
Minimal sedation has been achieved when a patient enters a drug-induced state during which he/she responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is planned using a single agent regardless of route. Midazolam, in particular, may be used for minimal sedation.

Although care should be individualized for each patient and circumstance, the following patients may be considered inappropriate candidates for minimal sedation:

- Known or suspected abnormal airway anatomy
- Suspected or known oral or neck mass that may impede necessary airway management
- Prior history of failing minimal sedation

NOTE: If a combination of drugs is used to facilitate a procedure, the patient is, by definition, undergoing moderate, dissociative, or deep sedation. In other words, if two or more drugs are being used to facilitate a procedure, the health care provided **cannot** claim to be providing minimal sedation.

2. Moderate Sedation/Analgesia:
Moderate sedation/analgesia has been achieved when a patient enters a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (reflex withdrawal from a painful stimulus is considered a purposeful response) either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

3. Deep Sedation/Anagesia:
Deep sedation/analgesia has been achieved when a patient enters a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after 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.

4. Dissociative Sedation:
Dissociative sedation is a trance-like cataleptic state induced by the dissociative agent ketamine (alone or in conjunction with small doses of a benzodiazepine) characterized by profound analgesia and amnesia with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability.

5. General Anesthesia
General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

III. Emergency Procedures, Critical Care Areas and Policy Exclusions

There are certain circumstances in which the Medical Center policy for procedure related sedation does not apply. These exclusions are defined in the Medical Center Policy on Procedure Related Sedation.

First, the use of sedatives for mechanically ventilated (e.g., intubated) patients undergoing procedures in the intensive care units or Emergency Department is excluded from the Medical Center Policy for Procedure Related Sedation. These patients are often critically ill, are already being carefully monitored, have a protected airway, are not eating, have no expectation of being discharged at the conclusion of their procedures, and

undergo frequent procedures as part of what could be considered their "routine" care in these critical care areas. However, if a mechanically ventilated patient leaves these critical care areas for a procedure that is not an emergency or life saving procedure (e.g., a magnetic resonance imaging study), then the Medical Center Policy **does** apply.

Second, the use of sedative drugs to facilitate emergency and life saving procedures is specifically excluded from the Medical Center Policy for Procedure Related Sedation. The urgency with which emergency and life saving procedures typically need to be performed may make it impossible to meet all of the criteria of the policy prior to starting the sedation and performing the procedure. The risks and benefits need to be weighed by the responsible health care provider in each individual circumstance.

Third, the use of anxiolytics (e.g., a medication to relieve anxiety) or analgesics (e.g., a medication to relieve pain) for purposes other than to facilitate a procedure is excluded from the Medical Center Policy for Procedure Related Sedation. Procedure-related sedation must, by definition, involve a procedure. For example, if a patient is given a pain medication for a headache, the administration of this pain medication is not covered under the Medical Center Policy for Procedure Related Sedation because an analgesic was administered to relieve pain, not to facilitate a procedure. However, if this same patient is given sufficient pain medication to make them drowsy (e.g., a drug-induced depression of consciousness during which the patient responds purposefully to verbal commands accompanied by light tactile stimulation) in order to facilitate getting a computed tomographic (CT) scan of the head, then the Medical Center Policy for Procedure Related Sedation **does** apply.

IV. The Pre-Sedation Assessment

Each patient who will be undergoing procedure related sedation must undergo a pre-sedation assessment **immediately** prior to the administration of the medication(s). If the patient has recently undergone an outpatient evaluation in preparation for a procedure, a re-assessment must be performed immediately prior to the administration of the medication(s). The components of a pre-sedation assessment or re-assessment **must include all of the following:**

a. History and physical examination (focusing on risk factors for complications of sedation
b. Procedural indication (why the procedure is being performed)
c. Assessment of the American Society of Anesthesiologists (ASA) physical status classification (see Table 1)
d. NPO status (see Section V of this tutorial: "NPO: The Time of Eating and Drinking Before Sedation")
e. History of allergies
f. History of prior adverse events during sedation, if any
g. Plan for sedation

h. Documentation that the risks, benefits, and alternatives to the planned sedation have been discussed with the patient, parent, or legal guardian of the patient, as appropriate
i. Acknowledgement of informed consent.

In addition, the patient, procedure, and site if laterality or digits involved shall be accurately identified immediately prior to the administration of sedation.

Table 1 ASA Physical Status Classification

ASA Physical Status Classification – a classification system designed by the American Society of Anesthesiologists (ASA) to provide a general description of a patient's physical status. It is used as a preassessment tool to determine a patient's suitability for sedation and/or analgesia. Each clinician should be able to assign an ASA class to each patient. If patients are a physical class 3 or above, consultation with an anesthesiologist should be considered.

Class	Description	Examples	Suitability for Sedation
1	A normal healthy patient		Excellent
2	A patient with mild systemic disease	Heart disease that slightly limits activity, essential hypertension, diabetes, anemia, obesity, chronic bronchitis	Generally good
3	A patient with severe systemic disease	Heart disease that limits activity, poorly controlled hypertension, diabetes with vascular complications, chronic pulmonary disease that limits activity, angina, history of myocardial infarction	Increased risk – consider benefits relative to risks
4	A patient with severe systemic disease that is a constant threat to life	Congestive heart failure, unstable angina, advanced pulmonary, renal, or hepatic disease	Poor – consider benefits relative to risks
5	A moribund patient who is not expected to survive	Ruptured abdominal aneurysm, cerebral trauma, massive pulmonary embolus	Extremely poor
E	Patient requires emergency procedure	Appendectomy, Dilatation and Curettage for uncontrolled bleeding	Not applicable

NOTE: Patients undergoing emergency procedures shall be designated class E in addition to a classification 1 through 5.

V. NPO: The Timing of Eating and Drinking Before Sedation

The decision of *nil per os* (NPO) status should be made by the responsible health care provider who has weighed the risks and benefits of procedural timing on a case by case basis. There are currently no evidence-based guidelines available. There have been, however, consensus-based guidelines published (Anesthesiology 1999; 90: 896-905) that give some guidance based on the nature of the food and drink ingested.

For elective cases performed on healthy individuals, the following guidelines are presented in the Medical Center Policy for Procedure Related Sedation:

a. 2 hours if clear liquids have been ingested
b. 4 hours if breast milk has been ingested
c. 6 hours if non-human milk or infant formula has been ingested
d. Longer time periods (at least 8 hours, for example) may be deemed appropriate if fatty or solid foods have been ingested.

For non-elective cases where the NPO period is deemed inadequate by the responsible health care provider, airway protection (e.g., endotracheal intubation) should be considered.

VI. Review of Some Agents Used for Sedation

See Table 2 for a list of some agents used for sedation.

VII. Orders for Procedure Related Sedation

Orders for procedure related sedation are to be written **exclusively** by individuals privileged to administer procedure related sedation.

Orders must specify the name of the medication, the dose, and the route of administration. If multiple doses are planned, the frequency of administration is to be indicated. Sedation medications are frequently titrated for effect. Orders may reflect this.

VIII. Environmental Requirements and Monitoring During Sedation

The location in which procedure related sedation occurs should be one in which the health care provider can work comfortably and in which the patient is comfortable and safe. The Medical Center Policy for Procedure Related Sedation provides a description of those features which all locations must have in order for procedure related sedation to be in compliance with the policy.

The location in which the procedure related sedation occurs must have the following:

a. Adequate lighting to observe the patient and the monitors

b. Adequate power outlets and clearly labeled outlets connected to the Medical Center's emergency power supply
c. Immediate access to emergency numbers including the appropriate Code Team (except in the Emergency Department and intensive care units)

The following equipment must be available before and throughout the sedation process:

a. Oxygen
b. Airway equipment
c. Appropriately sized bag-valve mask
d. Defibrillator
e. Suction equipment
f. Emergency drugs and reversal agents
g. Equipment to monitor the patient's physiologic status including heart rate, respiratory rate, and oxygenation

Although an intravenous line is not indicated for all cases of procedure related sedation, an individual with the skills to establish intravenous access must be immediately available during procedure related sedation.

Two personnel, as a minimum, must be present during the procedure. These two personnel are typically the practitioner privileged to perform the procedure and an assistant competent to monitor designated physiologic variables. One common example of the required personnel would be a physician who initially provides the sedation and then proceeds to perform a procedure while a nurse monitors the patient.

Monitoring requirements are based on the level of sedation that is planned. If a patient unexpectedly progresses to a deeper level of sedation than was planned, the monitoring should be modified to reflect this change. The monitoring requirements include the following:

Moderate sedation monitoring requirements:

a. Continuous pulse oximetry
b. Documentation of pulse oximetry, blood pressure, heart rate, respiratory rate, and level of consciousness before the administration of medication and **every 15 minutes** throughout the sedation and recovery phase.
c. Continuous cardiac monitoring is not mandatory for moderate sedation, but may be appropriate for patients with pre-existing medical conditions.
d. The assistant (usually a nurse) may assist with minor, interruptible tasks.

Deep sedation monitoring requirements:

a. Continuous pulse oximetry
b. Continuous cardiac monitoring

c. Documentation of pulse oximetry, blood pressure, heart rate, respiratory rate, and level of consciousness before the administration of medication and **every 15 minutes** throughout the sedation phase and **every 15 minutes** during the recovery phase.
d. The assistant (usually a nurse) may have no duties other than monitoring the patient.

Dissociative sedation monitoring requirements:

a. Continuous pulse oximetry
b. Continuous cardiac monitoring
c. Documentation of pulse oximetry, blood pressure, heart rate, respiratory rate, and level of consciousness before the administration of medication and **every 15 minutes** throughout the sedation and recovery phase.

Complications and the management of the complications must be documented in the medical record.

IX. Post-Procedure Monitoring and the PAR Score

Since one of the goals of procedure related sedation is to have a patient comfortable throughout an entire procedure, it is expected that the sedation will last longer than nearly all procedures. Because patients remain sedated beyond the time of the procedure, they are still at risk for complications from the sedation and, therefore, must be monitored beyond the time of the procedure.

The documentation for post-procedure monitoring must begin within 5 minutes after the completion of the procedure and include the following:

a. Pulse oximetry
b. Level of consciousness
c. Heart rate
d. Blood pressure
e. Respiratory rate
f. All medications, fluids, and blood products administered
g. Post-procedure complications and the management of those complications
h. Signature of the registered nurse or respiratory care practitioner who was supervising care.

Post-procedure assessments must be performed at least every 15 minutes and may be performed more often if the patient's condition warrants more frequent monitoring.

If the patient is to be transported following a procedure (e.g., returning from the Radiology Department after a CT scan), a person familiar with resuscitation and airway management **must** accompany the patient at all times until the post-procedure monitoring has concluded (see below).

A useful tool for assessing a patient's recovery from sedation is the post-anesthesia recovery (PAR) score (See Table 3). Unless a PAR score cannot be determined (e.g., in a paraplegic or quadriplegic), a score of **at least 8** is to be achieved before post-procedure monitoring may be discontinued. Given that different pharmacologic agents given by different routes have different durations of action for individual patients, there is not single number of minutes for which a patient must be observed. On a case-by-case basis, patients must be monitored for a time period adequate to assure a reasonable likelihood that the patient will not have a delayed medication effect following the completion of the procedure.

Table 3

Post Anesthesia Recovery (PAR) Score
The total scores from Activity, Respiration, Circulation, Neurologic Status, and Color are added to generate the PAR Score. Scores range from 0 to 10.

Activity Points	**Adult Responses**	**Pediatric Responses**
2	Can move 4 extremities	Moves purposefully
1	Can move 2 extremities	Moves to command or light touch
0	Can move 0 extremities	Not moving
Circulation		
2	Able to breathe deeply	Able to breathe deeply
1	Limited breathing	Limited breathing
0	Apnea	Apnea
Circulation		
2	BP $\pm$ 20 Base mmHg	BP $\pm$ 20% Base mmHg
1	BP $\pm$ 20 to 50 Base mmHg	BP $\pm$ 20% - 50% Base mmHg
0	BP $\pm$ 50 Base mmHg	BP $\pm$ 50% of more Base mmHg
Neurologic Status		
2	Fully awake	Fully awake
1	Arousable	Arousable
0	Not responding	Not responding
Color		
2	Normal	$Sa0_2$>95%
1	Pale/blotchy	$Sa0_2$ 90% - 95%
0	Cyanotic/dusky	$Sa0_2$<90%

X. Discharge Criteria and Concluding Post-Procedure Monitoring

Transferring a patient to an unmonitored Medical Center area or to home must be done at a time that is safe for the patient. Even though post-procedure monitoring may have concluded based on the above criteria (See Section IX. Post-Procedure Monitoring and the PAR Score), the patient may not be ready for discharge from the sedation area. For example, a patient who is repetitively vomiting may have recovered from the sedation and yet still not be ready for discharge home.

Once the post-procedure monitoring has concluded, a patient may be transferred to an unmonitored area of the Medical Center if all of the following area met:

a. The patient has been observed for a time period adequate to assure a reasonable likelihood that the patient will not have a delayed medication effect following completion of the procedure.
b. The patient has stable vital signs.
c. The patient has adequate respiratory function or has returned to the pre-procedure/pre-sedation state.
d. The patient's mental status is normal and has returned to the pre-procedure/pre-sedation state.
e. The patient has normal circulation or has returned to the pre-procedure/pre-sedation circulatory state.
f. The patient is free from undue discomfort caused by the procedure and has a reasonable likelihood of having no ongoing bleeding related to the procedure.

Patients who are to be discharged home will no longer be under direct medical care and so must be able to do more on their own. Once the post-procedure monitoring has concluded, a patient may be discharged to home if all of the following are met:

a. The patient has been observed for a time period adequate to assure a reasonable likelihood that the patient will not have a delayed medication effect following completion of the procedure.
b. The patient has stable vital signs.
c. The patient has adequate respiratory function or has returned to the pre-procedure/pre-sedation respiratory state.
d. The patient's mental status is normal or has returned to the pre-procedure/pre-sedation state.
e. The patient has normal circulation or has returned to the pre-procedure/pre-sedation circulatory state.
f. The patient is free of undue discomfort caused by the procedure and has a reasonable likelihood of having no ongoing bleeding related to the procedure.
g. The patient should be able to stand upright and ambulate as appropriate for age and condition.
h. The patient should be able to swallow and retain oral fluids, if appropriate.
i. The patient should be able to void when applicable.

j. The patient has demonstrated an appropriate post-anesthesia recovery score (PARS) (See reference M-86-C and section 7.5 of Medical Center Policy M-86).
k. Appropriate discharge instructions (based on the procedure performed, the medications administered, the patient's underlying medical conditions, the patient's age, and the outpatient follow-up plans) have been provided to the patient, parent or legal guardian of the patient as appropriate.
l. The patient shall be instructed not to operate a motor vehicle for 24 hours.
m. The patient will be discharged directly to the supervision of an adult sponsor who will accompany the patient to his/her home or place of lodging.

Hopefully, by following our Medical Center Policy for Procedure Related Sedation, we can provide the most comfortable and safe environment possible for our patients.