UNIVERSITY of CALIFORNIA, SAN DIEGO
MEDICAL CENTER

Date

Dear UCSD Health Care Provider:

The use of moderate sedation has increased considerably over recent years. As a result, medical centers are under obligation by regulatory requirements, JCAHO, and state law to assure that procedures are done securely, hospital policy is followed and that a consistent level of education is provided to all practitioners using moderate sedation for procedures. An educational module has been developed to assist in fulfilling these requirements.

If you are a UCSD Health Care Provider and wish to perform moderate sedation at any UCSD licensed facility, then you must become familiar with UCSD's Moderate Sedation Policy and Procedure and successfully complete the educational module.

Attached you will find the Credentialing Packet for Moderate Sedation developed for use by UCSD physicians and other health care providers. The Credentials Committee and the Medical Staff Executive Committee have approved this packet. The purpose of this packet is to:

1) Provide a consistent level of familiarity with UCSD Medical Center's Moderate Sedation Policy and Procedure, and formally adopted standards across the medical center sites in compliance with JCAHO and Title 22.

The packet includes the following:

1) Educational document titled "A Clinical Approach to Moderate Sedation"
2) UCSD Medical Center Moderate Sedation Policy and Procedure (MCP 370.1D)
3) UCSD Moderate Sedation Credentialing Examination
4) Statement of Completion - Sedation Training/Competency Checklist

Please review the packet and return the Moderate Sedation Credentialing Examination and the Statement of Completion to the Medical Staff Administration office at 200 W. Arbor Drive, Mailcode 8821, San Diego CA 92103.

The pass rate is 85% or greater. The Medical Director will send a letter of confirmation of successful performance on your test for your medical staff file, and an additional copy will be sent to you. The Medical Director, Chair of Credentials Committee and/or an Anesthesiologist designee will notify you if your score is < 85%.

MODERATE SEDATION COMPETENCY OBJECTIVES
University of California, San Medical Center

- The practitioner and other health care provider will be able to perform an appropriate patient evaluation prior to initiation of sedation.

- The practitioner and other health care provider will be able to safely administer the pharmacological agents to achieve moderate sedation as defined by the American Society of Anesthesiologists and the Medical Center's Policy and Procedure.

- The practitioner and other health care provider will be able to provide continuous monitoring of the patient's vital signs, including the level of consciousness, at the desire level of sedation.

- The practitioner and other health care provider will be able to perform necessary rescue techniques for patients who unavoidably progress into deep sedation/anesthesia.

- The practitioner and other health care provider will be able to perform airway management or provide adequate oxygenation/ventilation and management to an unstable cardiovascular system as required.

- The practitioner and other health care provider will be able to evaluate the patient's appropriateness for discharge to a responsible party.

Credentialing Packet for Moderate Sedation
University of California, San Diego Medical Center

Welcome to the Moderate Sedation credentialing process for UCSD. This credentialing packet consists of:

1) An education document titled "A Clinical Approach to Moderate Sedation"
2) The UCSD policy for Moderate Sedation, MCP 370.1D
3) A written multiple choice examination
4) A statement of Completion-Sedation Training/Competency Checklist

We suggest you read through the educational document and the UCSD Moderate Sedation policy prior to attempting the examination. The examination is based on the material in both the educational packet and UCSD Moderate Sedation policy. You may refer to the educational packet and the UCSD Moderate Sedation policy while taking the examination.

There is a significant amount of material here to be learned (or reviewed). We think mastering of this information, however, is a necessary prerequisite for providing safe moderate sedation. It is expected that those intending to provide moderate sedation not only pass this written examination but also have clinical experience and expertise in this area.

This credentialing process applies only to the administration of moderate sedation. Providing deep sedation requires a separate, additional credentialing process here at UCSDMC. **Administration of propofol for sedation requires credentialing for administration of deep sedation**, and is thus not covered under the credentialing process for moderate sedation.

I. CLINICAL APPROACH TO MODERATE SEDATION

A Clinical Approach to Moderate Sedation

Providing moderate sedation to facilitate the performance of medical procedures can be a useful, albeit dangerous undertaking. It can greatly improve patient comfort and satisfaction, as well as providing temporary immobility in patients otherwise unable to cooperate (e.g. pediatrics). Sedatives and narcotics, on the other hand, can be profound respiratory and cardiovascular depressants. To assist non anesthesiologists in the administration of moderate and deep sedation, the American Society of Anesthesiologists has devised useful clinical guidelines. A synopsis of those guidelines, as well as a pharmacology review of commonly used sedatives and reversal agents is presented. Finally, a review of basic emergency airway management is offered.

I. Definitions

"Moderate sedation", formerly known as "conscious sedation" refers to a pharmacologically induced state of depressed consciousness in which the patient responds appropriately (although sometimes slowly) to verbal or tactile stimulation.

Table 1: Continuum of Depth of Sedation
Definition of General Anesthesia and Levels of Sedation/Analgesia
(Developed by the American Society of Anesthesiologists)
(Approved by ASA House of Delegates on October 13, 1999)

	Minimal Sedation ("Anxiolysis")	Moderate Sedation / Analgesia ("Conscious Sedation")	Deep Sedation / Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposefulresponse to verbal or tactile stimulation	Purposeful response following repealed or painful stimulation	Un-arousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Patients can quickly and unexpectedly undergo a progression in sedation status, and there is wide inter-patient variability in sensitivity to sedatives. Thus, practitioners providing moderate sedation should be well equipped to resuscitate patients who have progressed deep sedation, and those providing deep sedation should be fully qualified to care for those under general anesthesia. If the level of sedation required is expected to be "deep" or "general anesthesia", consultation with an anesthesiologist is suggested.

PRE-PROCEDURE EVALUATION: HISTORY, PHYSICAL EXAMINATION, NPO STATUS, AND APPROPRIATE LABORATORY RESULTS.

The history should focus on previous airway problems, drug reactions, chronic use of CNS altering agents, hepatic and renal disease, cardiac, and pulmonary disease. A history of sleep apnea may indicate a tendency toward airway obstruction upon loss of consciousness. The physical examination should center on examination of the airway (patency, anticipated ability to ventilate and intubate, table 2), heart and lungs.

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

Table 2. Airway assessment

Laboratory assessment should be appropriate for the procedure and the patient's medical condition.

PRE-PROCEDURE PREPARATION

The risks and benefits of sedation should be discussed with the patient, parent, or guardian. In non-emergent situations, sufficient time without oral intake should be allowed for gastric emptying. In general, six hours for solid foods, and two hours for clear liquids should be sufficient. These times may be shorter in pediatric patients. If unsure, the ASA guidelines for fasting should be consulted. If the procedure is emergent, or gastric emptying is likely delayed by a pathologic process, lighter levels of sedation should be provided.

MONITORING

There must be a qualified healthcare practitioner other than the person performing the procedure designated to monitor the patient. This person should have very few other responsibilities in the case of moderate sedation, and no other responsibilities if deep sedation is provided. They should monitor level of consciousness, ventilation, oxygen saturation with pulse oximeter, heart rate, and blood pressure. Ventilation can be monitored with observation, auscultation, and/or capnography. Vital signs should be determined prior to the procedure and at least every fifteen minutes once a steady level of sedation is achieved. EKG monitoring may be useful for patients at particular risk for cardiovascular complications. It should be monitored for all moderate sedations. Vital signs and other monitored parameters should be recorded contemporaneously, either manually or automatically. Administration of sedatives, supplemental oxygen, and other significant events should also be recorded.

TRAINING OF PERSONNEL

The practitioner responsible for administration of sedatives should be experienced and knowledgeable with regard to the pharmacology of the sedatives, particularly respiratory and cardiovascular depression. The practitioner responsible for monitoring should at least be trained in BCLS, and someone trained in ACLS should be immediately available (1-5 min away).

EMERGENCY EQUIPMENT

1. Intravenous equipment

Appropriately sized equipment for the establishment of intravenous access should be readily available.

2. Basic airway equipment

Appropriately sized equipment for establishing an airway, suctioning, and providing oxygen and positive pressure ventilation should be readily available. This equipment includes oxygen source, tongue blades, oropharyngeal airway, nasopharyngeal airway, suction catheters, and bag-valve-mask sets.

3. Advanced airway equipment

Appropriately sized laryngoscopes, endotracheal tubes, laryngeal mask airways should be available and in good working order.

4. Pharmacologic antagonists

Naloxone should be available for the reversal of narcotic-induced respiratory depression, and **flumazenil** should be available for reversal of the effects of benzodiazepines.

5. Emergency medications such as epinephrine, lidocaine, atropine, diphenhydramine, hydrocortisone, and dextrose should be available.

6. Defibrillator should be available for all procedures involving deep sedation, and for moderate sedation of patients with cardiovascular disease.

SUPPLEMENTAL OXYGEN

Supplemental oxygen should be readily available. It should be considered in patients receiving moderate sedation, and, if not contraindicated, given to those receiving deep sedation.

INTRAVENOUS ACCESS

The intravenous route is preferred for administration of sedatives and analgesics, because it allows predictability in the onset and duration of the drug actions, and ease of titration. Intravenous access should be maintained throughout the administration of sedatives and analgesics. Intravenous access should be maintained until the effects of the drugs, including cardiovascular and respiratory, have worn off. If sedation has been provided by means other than the intravenous route, practitioners should decide about intravenous access on a case-by-case basis.

PHARMACOLOGY OF SEDATIVE AND ANALGESIC MEDICATIONS

In adults, sedation is often provided with administration of benzodiazepines (e.g. midazolam) and opioids (e.g. fentanyl). Other drugs used for sedation have included barbiturates (e.g. methohexital), propofol, and ketamine. In general, the latter three can be a bit tricky, causing sudden onset of deep sedation or general anesthesia, and other unpredictable patient responses (e.g. laryngospasm with ketamine). Further, in contrast to midazolam and fentanyl, methohexital, propofol, and ketamine have no clinically available reversal agents. These drugs should be used with great caution, and practitioners administering them should be fully capable of rescuing patients from the general anesthetic state.

Midazolam

Midazolam (Versed) is a very commonly administered benzodiazepine for moderate sedation. It has replaced diazepam (valium) for this purpose, because it does not cause much pain on injection, has a shorter elimination half life (90 minutes), is more predicatably eliminated, and has a shorter duration of action (15-30 minutes). It is particulary effective in providing anxiolysis and amnesia, and has a rapid onset of action. Elimination is primarily hepatic, so caution should be exercised in patients with hepatic insufficiency. Being **about three times as potent as diazepam**, it's typical dose range for adults is 0.5-1.0 mg IV given incrementally. There is wide inter-patient variability in response, because of genetic and social factors. Significant cross-tolerance with alcohol has been noted, and chronic use of benzodiazepines is strongly associated with tolerance.

Occasionally a paradoxical excitement reaction can occur. Although "disinhibition" is often mentioned as a mechanism, the phenomenon is poorly understood. A useful reversal agent of benzodiazepines is **flumazenil** (Mazicon), which can be given 0.2 mg incrementally to reverse benzodiazepine effects. **Flumazenil should be given only with extreme caution to patients chronically taking benzodiazepines because acute withdrawal symptoms, including seizures, may occur**. Sedation regimens that call for routine reversal of sedatives and/or opioids are discouraged.

Fentanyl

Fentanyl is a highly potent synthetic opioid (about 100 times as potent as morphine) commonly used as an adjunct to moderate sedation. It is very useful as an analgesic, usually without causing significant euphoria. It has replaced morphine for moderate sedation because it is associated with less nausea and vomiting, less histamine release, superior hemodynamic stability, faster onset, and shorter duration of action. Typical dosage in adults is 25-50 ug IV incrementally, but the dose should be reduced in elderly patients, debilitated patients, and patients with significant lung disease. It is associated with a dose-dependent respiratory depression, usually (but not always) manifesting as a decrease in respiratory rate. Some patients suffer a decrease in arterial oxygen saturation prior to a drop in respiratory rate. Evaluation of pupil size (miosis) may be an unreliable indicator of the state of narcosis. Synthetic narcotics, when given in higher doses, have been associated with coughing and glottic closure. This may be associated with rigidity of the chest wall. Emergency airway equipment, of course, should be available. Since it undergoes both hepatic and renal elimination, fentanyl should be given with caution in patients with renal and hepatic disease. The effects of fentanyl can be reversed with naloxone (narcan). If respiratory depression is moderate, naloxone can be given in divided doses (.04-0.1 mg) until the desired result is achieved. If respiratory depression is severe, a full reversal dose can be given (0.4 mg). **Naloxone may cause acute pain, agitation, tachycardia, hypertension, and pulmonary edema. It should be used with particular caution in patients chronically taking opioids. In these patients acute withdrawal symptoms may result, occasionally culminating in death**. Sedation regimens that call for routine reversal of sedatives and/or opioids are discouraged.

Combinations of sedatives and analgesics

Combinations of sedatives (e.g. midazolam) and analgesics (e.g. fentanyl) can be very effective in providing patient comfort. Such combinations, however, may be synergistic in causing depression of consciousness, respiratory depression, airway obstruction, and cardiovascular depression. Thus, the drugs should be given individually, and administered so as to achieve their respective effects. For example, midazolam should be given to achieve anxiolysis and sedation, whereas fentanyl should be given primarily to provide pain relief. **The sedatives and analgesics should be given in small, incremental doses, titrated to the clinical situation and patient requirements**. Sufficient time should be allowed between doses to allow them to take effect. Drugs given by other routes other than intravenous, such as oral or rectal, should be allowed time to reach their effects.

RECOVERY CARE

The effects of sedatives and analgesics can prolonged. For example, patients who have received intramuscular meperidine / promethazine / chlorpromazine mixtures, or rectal chloral hydrate may exhibit unpredictable recovery profiles. Patients should be observed in a fully equipped area until the sedative, respiratory, and cardiovascular effects of the medications have dissipated. Particular attention should be paid to those requiring reversal agents-sufficient time (up to 2 hours) should have elapsed since the last reversal dose prior to discharge.

PEDIATRIC SEDATION

Sedation of pediatric patients is associated with unique problems and situations. It is suggested that practitioners sedating pediatric patients have appropriate qualifications and experience in this area. Properly sized monitoring and resuscitation equipment, appropriate drug dosages, and airway equipment must be readily available.

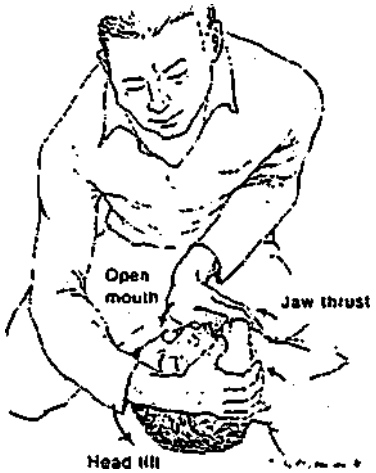
The most commonly used agents for sedation in children are chloral hydrate (25-75 mg/kg PO or rectal, depending on desired level of sedation) and pentobarbital (3-8 mg/kg IV). The action of chloral hydrate, itself being pharmacologically inactive, is dependent on the hepatic enzyme alcohol dehydrogenase. Alcohol dehydrogenase converts chloral hydrate to trichloroethanol, which causes sedation. Trichloroethanol, like other sedatives such as benzodiazepines and barbiturates, increases central nervous system gamma aminobutyric acid (GABA) activity. Chloral hydrate and pentobarbital in clinical doses are associated with 95% success rates in providing adequate sedation. Like other sedatives, however, they are occasionally associated with respiratory and/or cardiovascular depression and prolonged duration of action.

EMERGENCY AIRWAY MANAGEMENT

Practitioners providing moderate sedation should be skilled in basic airway management. The two most common causes of hypoventilation during sedation are central hypoventilation and airway obstruction. The central hypoventilation results directly from drug effects on the respiratory centers of the brain. Airway obstruction is an indirect drug effect, usually from the tongue falling back into the posterior pharynx. Occasionally, airway obstruction can result from glottic closure (laryngospasm). The following maneuvers may be useful in the treatment of hypoventilation. While these maneuvers are performed, the administration of reversal agents should be considered.

Jaw Thrust

The jaw thrust is usually the first maneuver performed in the treatment of sedative-induced hypoventilation. The practitioner places two fingers (or knuckles) behind the mandible, and pulls the mandible anteriorly. This has the effect of opening up the airway, as well as stimulating the patient (it's painful!). The combination of jaw thrust and positive pressure ventilation is often effective.



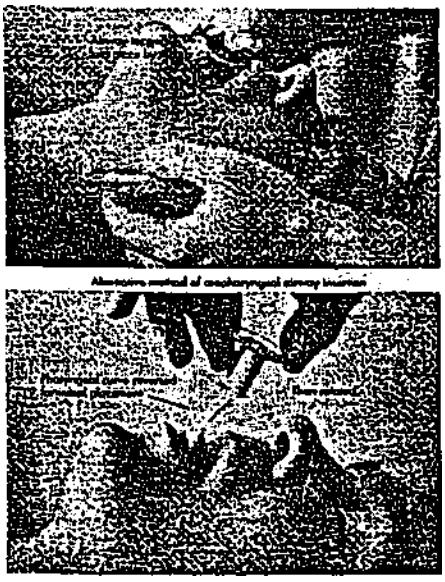
Positive Pressure Ventilation

The bag-valve-mask mechanism, connected to an oxygen supply, should be readily available. It should be considered early in the course of sedation-induced hypoventilation. The mask is held firmly on the patients face, with the mandible pulled anteriorly be the practitioners fifth finger. Extending the neck, if not contraindicated, facilitates this maneuver:

If mask ventilation is difficult, the two-handed technique shown below can be used. This is a combination of anterior jaw thrust and mask application. A second practitioner squeezes the bag:

Oropharyngeal Airway

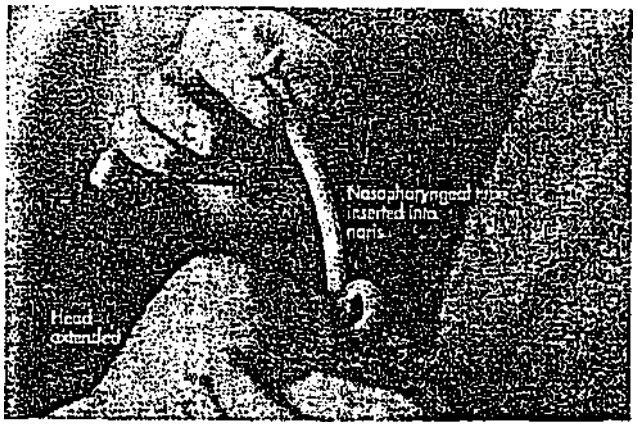
The oropharngeal airway, when properly placed, has the effect of opening the airway by moving the tongue anteriorly. It should be placed with the use of a tongue blade, so as to avoid pushing the tongue back further into the airway. If a tongue blade is unavailable, the oral airway can be placed with the approach upside down or sideways, to be adjusted to its proper position after it is in the pharynx. An oropharyngeal airway should be placed only if the jaw thrust with positive pressure ventilation is unsuccessful, because it can precipitate laryngospasm and/or traumatize the airway.



Nasopharyngeal Airway

This flexible rubber tube, placed in the nare, passes posterior to the tongue, allowing for an open airway. It should be performed only if the above measures fail, since it may be associated with

1. epistaxis and other airway trauma
2. bacterial seeding of the circulation
3. advance of tonsils, foreign bodies into the airway



Suction

Refractory cases of airway obstruction may be the result of a foreign body. Suction and/or laryngoscopy may be necessary for the removal of blood, teeth, or foreign bodies from the airway.

Advanced Airway Management

Laryngoscopes, endotracheal tubes, and laryngeal mask airways should be available. These devices should be used only by practitioners specifically trained and experienced with them. *The time you start reaching for a laryngoscope is usually well past the time you should have called for backup.*

SUGGESTED READING

The administration of sedation and the management of its potential problems is a very broad, deep topic. It is expected that those wishing to provide monitored sedation have gained specific training and experience in doing so.

For basic guidelines, the American Society of Anesthesiologists website, www.asahq.org is a good place to start. The guidelines summarized here are found at that website, and also in an article entitled "Practice guidelines for sedation and analgesia by non-anesthesiologists". This article is found in the journal *Anesthesiology,* volume 96, pages 1004-17,2002. For information about sedating pediatric patients, see American Academy of Pediatrics, Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatric 1992;* 89 :1110-1115.

More detailed information about the logistics of providing sedation and the pharmacology of sedatives is found in a relatively small book called Sedation and Analgesia for Diagnostic and Therapeutic Procedures, edited by Malviya S, Naughton N, and Tremper K. It is published by Humana Press, Totowa, N.J. Information about airway management can be found in any basic anesthesiology or emergency medicine text, as well as in the ACLS guidelines book.

II. UCSD POLICY FOR MODERATE SEDATION, MCP 370.1

UCSD Healthcare
UCSD Medical Center Policy & Procedures
MCP 370.1, Sedation Policy
Effective/January 15th, 2009

ABSTRACT:

The safe sedation of patients requires a combination of skilled personnel, appropriate selection of patients and drugs, appropriate physical facilities, minimum standards of monitoring and proper recovery of patients. This policy is designed to assist the clinician in ensuring that all of these favorable conditions are met when sedating patients for diagnostic or therapeutic procedures. This policy provides guidelines for patient management of all procedures requiring the use of moderate sedation throughout the facility.

RELATED POLICIES:

UCSDMC MCP 561.2**,** "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery"
UCSDMC MCP 327.2, "Medication Reconciliation"
UCSDMC Medical Staff Bylaws, Rules and Regulations

REGULATORY REFERENCE:

-- California Code of Regulations, Title 22, Licensing and Certification of Health Facilities and Referral Agencies, Sections 70223, 70233, 70235, 70237 and 70527;
-- The Joint Commission (TJC) Accreditation Manual for Hospitals: Care of Patients, and Management of Information Standards

I. DEFINITIONS

A. Vital Signs:

a. Heart Rate [HR]
b. Blood Pressure [BP]
c. Respiratory Rate [RR]
d. Pulse Oximetry

B. Sedation:

Note that solely the level of consciousness determines the level of sedation, not by the drug or the route of drug administration used to achieve this level of consciousness. While four distinct levels of sedation are defined, one should realize that, in actual clinical practice, these distinctions may be obscure. .Since the level of sedation may change with time and patients may exhibit considerable variability in their response to sedatives, it is expected that all practitioners be prepared at all times to manage a patient who becomes sedated beyond expectations.

1. Minimal sedation (anxiolysis): A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

2. Moderate sedation (formerly 'conscious sedation'): A drug-induced depression of consciousness during which patients respond purposefully to verbal commands (reflex withdrawal from a painful stimulus is not 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: 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.

4. Anesthesia: Consists of general anesthesia and spinal or major regional anesthesia. It does *not* include local 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.

5. American Society of Anesthesiology (ASA) Classification of Physical Status: A standardized description of the patient's physical status. It is based on the presence of systemic disease and its extent. The classification includes five categories of a patient's physical status:

ASA1: A normal healthy patient.
ASA2: A patient with mild systemic disease.
ASA3: A patient with a severe systemic disease.
ASA4: A patient with severe systemic disease that is a constant threat to life.
ASA5: A moribund patient not expected to survive without the procedure.

II. POLICY

A. General Considerations:

This policy is designed to cover settings for the patient who receives moderate and deep sedation.

B. All Serious Adverse Outcomes resulting from sedation will be discussed at departmental/divisional quality improvement meetings and morbidity/mortality conferences and documented in meeting minutes.

III. PROCEDURES AND RESPONSIBILITIES

A. Facilities. Moderate and deep sedation requires the following (see *Attachment A*, "UCSDMC Designated Operative and Invasive Procedure Areas"):

1. Adequate lighting to monitor the patient, and a source of back-up lighting in case of power failure.

2. Sufficient space for all personnel, monitoring equipment (to include cardiac monitor, pulse oximeter, BP monitor), and emergency equipment.

3. Adequate power outlets and clearly labeled outlets connected to the hospital emergency power supply.

4. A reliable means of two-way communication to summon help.

5. The ability to provide immediate changes in patient position, including the Trendelenburg position.

6. Resuscitation equipment, a standard hospital code blue cart and defibrillator, both in close proximity.

7. A source of oxygen adequate to provide a patient with at least 10 LPM flow of oxygen for a minimum of one hour and the devices needed for the appropriate delivery of the oxygen (i.e., regulators, nasal cannula, pulse oximetry) and a full back-up source (i.e. E-type cylinder) with regulator.

8. A functional self-inflating bag and mask system.

9. A functional system to suction the patient meeting institutional standards for operating room suction.

10. Functional cardiac monitoring equipment.

B. Personnel; Certification and Credentialing

1. Non-physicians:

A nurse practitioner, physician assistant, or registered nurse, certified in moderate sedation may administer sedation under the direction of an attending physician who is present and is privileged to perform moderate sedation.

a. Certification of Non-physicians for Moderate Sedation:

(1) A Nurse Practitioner, Physician Assistant or Registered Nurse

(2) Completion of the Sedation Self-Examination – repeated annually

(3) Completion of an American Heart Association accredited Advanced Cardiac Life Support Course (ACLS) or completion of the UCSD Advanced Resuscitation Training (ART) course which provides ACLS equivalent education.

(4) CRNAs are privileged for moderate and deep sedation under the direction of an Anesthesiologist.

2. Physicians:

a. Attendings:

(1) Must have Medical Staff Attending Membership status.

(2) Must be granted the privilege to perform moderate sedation via the credentialing process.

(3) Credentialing Process for Moderate Sedation:

(a) Apply for the privilege per the Departmental Delineation of Privileges form via the Credentialing process of the Medical Staff.

(b) Successful Completion of the Moderate Sedation Self-Examination.

(c) Approval by the Credential Committee and the Medical Staff Executive Committee (MSEC).

(d) Anesthesiologists, ED Physicians, Trauma Physicians and Pulmonary Critical Care Physicians are credentialed for moderate and deep sedation.

b. Fellows and Senior Residents:

(1) Must be enrolled as a trainee in a fellowship program or a PGY 3 year or above resident in residency training program with an active California Medical License.

(2) Must acquire the competency to perform moderate sedation per this Medical Center Policy. The trainee's Training Program Director and the MSEC must endorse the individual trainee as competent in moderate sedation and identify the acquired competency on the Intranet UCSD Healthcare "Resident Procedure Competencies" for trainees.

(3) Process to acquire competency in Moderate Sedation:

a) Be a PGY 3 or above resident in a residency program, or in a fellowship training program with an active California medical license.

b) Successfully complete the Moderate Sedation Self-Examination.

c) Approval by the Training Program Director and the Medical Staff Executive Committee (MSEC).

d) Physicians with acquired competency in moderate sedation will be identified on the UCSDMC Intranet "Resident Procedure competencies" for trainees.

e) Proctoring of trainees:

1) The first three procedures will be proctored by an Attending privileged in moderate sedation.

2) Feedback of these proctored cases to the Training Program Director is required.

3) The attending of record for the procedure requiring moderate sedation will be a physician privileged in moderate sedation.

(c) Supervision of Trainees: Trainees not credentialed to perform moderate sedation must do so under direct attending supervision. The supervising attendings must be present in the OR or Procedural Area for the entire duration of the operation/procedure, and must be credentialed to perform moderate sedation themselves.

(d) Trainees administering deep sedation must be under the direct supervision of Attendings with deep sedation privileges.

C. Documentation

1. Pre-Procedure:

a. Patient identification and consent documented by:

(1) Signed consent form *for the procedure*.

(2) Informed consent for the procedure documented by a physician. (Refer to MCP 339. 1, Consent for Anesthesia, Surgery, Special Diagnostic, or Therapeutic Procedures for more detailed information about informed consent.

(3) An identification armband and matching addressograph card.

b. A History and Physical Assessment is required for any procedure requiring monitored sedation, anesthesia or post-procedure observation of the patient elsewhere in the hospital. (Refer to Medical Staff Rules and Regulations for details on H&P requirements).

c. **Please Note:** If the History and Physical Assessment was performed and dictated more than 24 hours but less than 30 days prior to the procedure, a Interval Assessment must be completed in the medical record addressing whether or not there are any changes in the patient's history or physical exam findings, and if so, what changes are noted. If the History and Physical Assessment is more than 30 days, a complete new History and Physical Assessment must be performed and documented in the chart.

The History and Physical Assessment must include:

(1) vital signs, including pain assessment.

(2) allergies.

(3) pertinent system review

(4) pertinent medical history specific to patient's medical condition(s).

(5) focused physical assessment including airway assessment.

(6) Completion of the Medication Reconciliation Form (151-013). See MCP 327.2, Medication Reconciliation" for more detail.

A same day, pre-procedure assessment of the patient's medical status, documented by a physician signing the Pre-Procedure Assessment. (*Form # D-1582*).

d. Immediately preceding moderate sedation, vital signs are taken by the Registered Nurse with abnormalities of the patient's observed condition noted and this status communicated to the physician.

(1) Time Out Verification – The site of the procedure and the patient are accurately and clearly communicated using active communication techniques during a final verification process. A Time Out will be conducted in the location where the procedure will be performed involving the entire team (see MCP 561.2, "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery"). For example, prior to the start of any invasive or non-invasive procedure, a time out will be conducted prior to the procedure.

(2) This time out will be documented in the Procedure Record.

2. Intra-Procedure:

a. All Pre-Procedure documents must remain with the patient and will be part of the medical record.

b. A physician's order for all sedative drugs and dosage documented in the Sedation Procedure Record will be demonstrated by a signature of the physician prescribing these medications. This signed form will serve as the physician order for medication and treatment received. A separate physician order sheet is not necessary.

c. Verbal Order Read/Repeat Back: All verbal orders will be documented and verified by "read back/repeat" prior to drug administration except in emergent situations.

d. Sedative drug name, dose, administering personnel, and time given documented on the Sedation Procedure Record.

e. Patient monitoring during the procedure as documented by a physician signing the Sedation Procedure Record.

3. Post-Procedure:

   a. All Pre-Procedure and Intra-Procedure documents must remain with the patient as part of the Medical Record.

   b. Post operative physician orders.

   c. Post-procedural instructions.

   d. A brief, handwritten procedure note.

4. For patients in Intensive Care Units or in the Emergency Departments, the standard ICU or ED medical records can be used to document the above.

D. Sedative Administration:

1. A physician and the monitoring personnel will be available to direct patient care if an untoward event occurs.

2. Personnel who meet the requirements listed in Personnel and Certification (IV B) may actually administer the sedative drug under the direction of the credentialed physician in moderate sedation.

3. ASA-5 patients undergoing scheduled procedures should under most circumstances have the sedation managed by an Anesthesiologist.

4. Medications used for moderate sedation should be those easily titrated for this purpose (e.g. midazolam, fentanyl). Medications with specific pharmacologic reversal agents are strongly preferred. These include benzodiazepines (flumazenil reversal) and opiates (naloxone reversal). The reversal agents flumazenil and naloxone must be readily available whenever moderate sedation is provided. Rapid onset anesthetics that do not have effective pharmacologic reversal agents (e.g. propofol, etomidate, ketamine, and thiopental) are NOT appropriate for moderate sedation and MUST NOT BE USED for this purpose.

E. Monitoring Requirements

1. A physician, Nurse Practitioner, Physician Assistant or Registered Nurse, who is not performing the procedure and is credentialed/competent in moderate sedation per this policy, will continuously monitor the patient.

   This person will be available to the patient from the time of drug administration until recovery is judged adequate or the care of the patient is transferred to personnel in the recovery area or an ICU.

2. All patients undergoing moderate sedation should have the following parameters monitored: pulse oximetry. ECG monitoring respiratory rate, blood pressure, and level of consciousness.
For moderate sedation, vital sign parameters will be monitored and documented before each administration of medication and at least every 5 minutes, level of consciousness every 15 minutes thereafter and throughout the recovery period.

3. Documentation of baseline oxygen saturation prior to the administration of additional oxygen may provide a baseline for comparison at the end of the procedure.

F. Recovery

A licensed physician approves the patient's discharge.

Patients can be discharged directly from invasive procedure areas if the standard recovery criteria is met and it has been thirty (30) minutes since the last dose intravenous medication or ninety (90), minutes after the last transmucosal or intramuscular drug administration, including reversal agents.

a. If the patient does not meet the standard criteria as stated above, they must be transported to the PACU or other recovery area.

b. Patients who require transport will be assessed for stability prior to transport. This assessment includes, but is not limited to, spontaneous breathing, protected airway, controlled heart rate and rhythm, controlled bleeding, stable vital signs, adequate oxygen saturation with or without oxygen, and a patent airway.

c. Supplemental oxygen must be used during transport if oxygen saturation is less than 90% on room air.

d. Patients will be accompanied by licensed clinical personnel during transport

Documentation will be required if an adverse outcome has occurred during the procedure. For example:

a. Administration of a reversal agent.

b. Unplanned intubation.

c. Unplanned admission or transfer to higher level.

d. Chest pain during procedure.

e. Drop in Oxygen saturation -- less than 92 for greater than 5 minutes.

f. Nausea and emesis

An Electronic Quality Variance Report (eQVR) must be entered by the staff.

Recovery Criteria:

a. Recovery after the procedure and sedation is determined by a scoring criterion, based on the Modified Aldrete system.

(1) The patient must attain a score of at least 15, and

(2) It has been 30 minutes since the last intravenous dose of sedative or 90 minutes after the last transmucosal or intramuscular drug administration.

b. If the total score is less than 15, or there is a score of 0 in any category, then the patient must be assessed for potential discharge and released by a physician.

c. Other criteria related to the procedure (rather than sedation) may also be applied. These include: nausea and vomiting minimal, operative/procedure site without active bleeding and/or hematoma, voided/urinary bladder not distended.

d. Patients sedated in the ICU or ED may be recovered in the respective area.

e. Patients who have received sedation or anesthesia in the outpatient setting that are discharged may not drive themselves home.

G. Anxiolysis

1. Anxiolysis in the ambulatory care setting requires the following:

    a. A Physician's order
    b. History and Physical
    c. Patient monitoring as required per this MCP

IV. ATTACHMENTS

Attachment A: UCSD Medical Center Designated Operative and Invasive Procedure Areas

Attachment B: PHYSICIAN'S Pre-PROCEDURE RECORD FOR MODERATE SEDATION (Form D-1582)

V. APPROVALS

This policy and procedure was approved by the following committee(s):

Committee Name:	Date Approved:
Medical Staff Executive Committee	January 15th, 2009

AND

Richard J. Liekweg
Chief Executive Officer,
UCSD Medical Center

III. UCSD MODERATE SEDATION CREDENTIALING EXAMINATION

UCSD MODERATE SEDATION CREDENTIALING EXAMINATION

Choose the BEST answer:

1. All of the following are true about a patient who becomes agitated during procedure-related sedation EXCEPT:
   a) the agitation may be caused by hypoxia
   b) the agitation may be caused by hypercarbia
   c) the agitation may be caused by an unrelated CNS event
   d) the agitation can reliably be reversed with naloxone
   e) the agitation can be a paradoxical excitement response to a sedative

2. All of the following are predictors of difficult airway management EXCEPT:
   a) history of difficult intubation
   b) history of sleep apnea
   c) prominent mandible
   d) short neck
   e) large tongue

3. All of the following are predictors of difficult airway management EXCEPT:
   a) trisomy 21
   b) Pierre-Robin syndrome
   c) advanced rheumatoid arthritis
   d) presence of full set of teeth
   e) retrognathia

4. Propofol is a hypnotic drug. Its properties include all of the following EXCEPT:
   a) it causes pain on intravenous injection
   b) it can cause unpredictable levels of sedation
   c) it has a small therapeutic index
   d) its effects can be reliably reversed with flumazenil
   e) it can cause hypotension and tachycardia

5. Relative to morphine, fentanyl is
   a) equipotent
   b) twice as potent
   c) 5 times as potent
   d) 10 times as potent
   e) 100 times as potent

6. All of the following about the actions of fentanyl are true, except:
   a) decreased respiratory rate is always the first sign of respiratory depression
   b) miosis may be an unreliable sign of narcosis
   c) it causes a depressed response to carbon dioxide
   d) it may result in hypotension in hypovolemic patients
   e) hypoxia may be the first presenting sign of hypoventilation

7. A 47 year old woman undergoing cardiac catheterization has received 14 mg of intravenous midazolam and 50 jig of intravenous fentanyl during the past hour. She is sleeping during the procedure, but awakens and responds coherently when her name is spoken. Which of the following BEST describes this patient's level of consciousness?

a) analgesic but not sedated
b) moderately sedated
c) deeply sedated
d) anesthetized
e) deeply anesthetized

8. A 69 year old man is undergoing colonoscopy. After receiving 3 mg of intravenous midazolam and 50 ug intravenous fentanyl, he becomes completely unresponsive to verbal questioning and painful stimuli. His tongue obstructs his airway, and his oxygen saturation drops from 96% to 78%. Which one of the following BEST describes his level of consciousness?

a) analgesic but not sedated
b) moderately sedated
c) deeply sedated
d) anesthetized
e) twilight sleep

9. All of the following are required in hospital locations where moderate sedation is provided EXCEPT:

a) adequate lighting
b) sufficient space for all personnel and equipment
c) emergency power supply outlets
d) a means of 2-way communication
e) transcutaneous pacemaker

10. All of the following are required in hospital locations where moderate sedation is provided EXCEPT:

a) ability to provide immediate changes in patient position
b) a standard code blue cart with defibrillator nearby
c) oxygen source
d) suction source
e) transducers and catheters for invasive hemodynamic monitoring

11. A patient with past medical history remarkable only for type II diabetes mellitus, hypertension, and peripheral vascular disease presents for peripheral vascular stenting. His diabetes and hypertension are well controlled on medications. He has no history of cardiac or pulmonary disease. His ASA physical classification is

a)l
b)2
c)3
d)4
e)5

12. A patient receiving midazolam and fentanyl for sedation becomes unresponsive to verbal or painful stimuli. He is making strong ventilatory efforts (rate 18/min) but his airway appears to be obstructed. Your first maneuver, while assuring the delivery of supplemental oxygen, should be

a) suction the pharynx
b) insert an oropharyngeal airway
c) insert a nasopharyngeal airway
d) perform a jaw thrust
e) intubate his trachea

13. Which of the following causes respiratory depression, hypoxia, and hypotension?

a) chloral hydrate P.O.
b) pentobarbital P.O.
c) fentanyl I.V.
d) midazolam I.V.
e) all of the above

14. All of the following about chloral hydrate are true EXCEPT:

a) it can be given rectally or P.O.
b) in clinical doses it reliably produces sedation
c) it's action results from it's metabolism to an active metabolite
d) it is popular because it does not produce respiratory depression
e) it is commonly used in the sedation of children

15. Compared to I.V. diazepam, I.V. midazolam

a) is three times as potent
b) bums on injection
c) is longer acting
d) has a longer elimination half-life
e) causes less amnesia

16. Quantification of a patients readiness for discharge after moderate sedation is often accomplished with the

a) Glascow score
b) visual analogue pain score
c) percentage correct on the UCSD sedation credentialing exam
d) Aldrete score
e) ICU acuity score

17. A patient was moderately sedated until an additional 50 ug of fentanyl was given intravenously. The patient is now deeply sedated, with a patent airway and a respiratory rate of 12. All of the following are true EXCEPT:

a) the patient must have vital signs monitored at least every five minutes

b) preparations must be made to care for the patient should she become anesthetized

c) changes in level of sedation are common during procedure-related sedation

d) changes in level of sedation can occur despite small doses of sedatives being given

e) blood pressure and pulse are unlikely to change when a patient becomes deeply sedated or anesthetized

For questions 18-25:
Choose a if only 1,2, and 3 are correct
Choose b if only 1 and 3 are correct
Choose c if only 2 and 4 are correct
Choose d if only 4 is correct
e if all are correct

18. Combinations of opioids with benzodiazepines

1) exhibit additive respiratory depression
2) may be very effective in providing patient comfort
3) should be given with the entire dose at the beginning of the procedure, thus maximizing pharmacologic effect
4) should be given with the actions of each agent targeted at a therapeutic goal

19. Concerning monitoring for moderate sedation

1) The person performing the procedure should not be responsible for monitoring the patient
2) Vital signs should be obtained and recorded every 5 minutes
3) EKG should be monitored in all patients
4) if sedation progresses to deep sedation, vital signs determination more frequently than every 5 minutes may be necessary

20. Concerning flumazenil

1) it reliably reverses the effects of midazolam
2) high doses of midazolam can be used because one can simply plan to reverse it with flumazenil at the conclusion of the procedure
3) it should not be given to patients on chronic benzodiazepine therapy
4) its use in high dose often precipitates acute pain

21. The ASA physical status classification is used to determine, among other things, a patient's suitability for sedation. Which of the following is/are true?

1) anesthesiology consultation is suggested for status 3 and 4 patients requiring deep sedation
2) all ASA 5 patients should have their sedation managed by an anesthesiologist
3) ASA 3 patients who are moderately sedated may not need to have an anesthesiologist present
4) only ASA 2, 3, 4, and 5 patients are at risk for cardiovascular depression from moderate sedation

22. Concerning naloxone

1) it has been associated with rapid onset of pulmonary edema
2) it may precipitate myocardial ischemia in patients with coronary artery disease
3) it should be given in divided doses when possible
4) it reliably reverses the respiratory depression caused by midazolam

23. Concerning recovery from moderate sedation

1) administration of reversal agents facilitates early discharge
2) patients should stay in a fully equipped area for monitoring until the sedation and associated cardiorespiratory effects have worn off
3) Vital sign documentation is no longer necessary once the procedure is completed
4) patients having received oral and rectal sedatives exhibit unpredictable recovery profiles

24. Which of the following are associated with glottic closure and/or laryngospasm?

1) fentanyl
2) midazolam
3) ketamine
4) diazepam

25. Sedation-related hypoventilation may be caused by

1) decreased brainstem response to carbon dioxide
2) soft tissue airway obstruction
3) foreign body
4) laryngospasm

STATEMENT OF COMPLETION
SEDATION TRAINING/COMPTENCY CHECKLIST
University of California, San Diego Medical Center

Printed Name: _____ MD/RN

- Reviewed the education packet titled "A Clinical Approach to Moderate Sedation"
- Reviewed the UCSD Medical Center Sedation Policy and Procedure (MCP 370. ID)
- Sedation post-test score $\geq$ 85%

_____
Practitioner/Health Care Provider Signature Date

_____
UCSD Medical Director or designee Signature Date

ORIGINAL TO EMPLOYEE FILE