Objectives

- Identify competency requirements for physicians and non-physicians assisting with and providing medications for procedural sedation
- Verbalize the four levels of sedation & the risks associated with sedation administration
- Verbalize medical center policies regarding Sedation Procedures; consents, Universal Protocol (Time-Out, pre-procedure verification requirements, medication labeling)
- Verbalize patient assessment and documentation requirements for sedation procedures

Sedation for Procedures – MCP370.1

- “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”.
- Policy ensures all favorable conditions are met
- Provides guidelines for patient management for all personnel performing procedural sedation

Moderate Sedation Initial Competency For Physicians and Non-Physician Licensed Personnel

- **Prerequisite:**
  - Current Adult Resuscitation Training (ART) or Adult Cardiac Life Support (ACLS) certification
  - In neonatal care areas: Current AHA and AAP joint accredited Neonatal Resuscitation Provider (NRP) Program certification
  - Attend the Moderate (Procedural) Sedation Core Course and complete competency objectives

Q 2 Year Moderate Sedation Competency Verification

- By exam and observed procedure
- Self Assign Adult Moderate Sedation For Procedures Competency exam on LMS every 2 yrs.
- Demonstrate competence in assisting with moderate sedation by one of the following:
  - Staff observation during a moderate sedation procedure
  - Successful performance during mock moderate sedation check off
  - Chart audit of procedure when experienced RN was providing moderate sedation
Sedation Competency Exceptions

- Physicians who routinely practice all levels of sedation
- Area / Specialties:
  - Anesthesiology, ED, Trauma, Pulmonary Critical Care, Neurocritical Care, and Neonatal Intensive Care
  - Residents practicing in above areas while under direct supervision of attending physician within specialty
- Certified Registered Nurse Anesthetist (CRNA)
  - Credentialed for Moderate and Deep Sedation

Sedation Policy

- Policy does not apply to sedation used in ICU for intubated patients unless the patient is or may become deeply sedated when additional sedatives and/or analgesics are given to facilitate a procedure
- Example:
  - Bronchoscopy via endotracheal tube
- Manage patient assessments and documentation in same manner and frequency as procedural sedation

UCSD Medical Center Policy 370.1

Attending Physician Competence

- In addition to Moderate Sedation Initial Competency Requirements and Prerequisites:
  - Must have Medical Staff Attending Membership status
  - Must be granted the privilege to perform moderate sedation via the credentialing process
  - Apply for the privilege per the Departmental Delineation of Privileges form via the Credentialing process of the Medical Staff.

Fellow and Senior Resident Sedation Competence

- In addition to Moderate Sedation Initial Competency Requirements and Prerequisites:
  - Fellows and residents who are 3rd year or above in residency or fellowship with active CA Medical License may administer (if not participating in the procedure) or direct moderate sedation under the guidance of a physician
  - First 3 moderate sedations procedures must be proctored by an Attending Physician privileged in Moderate Sedation
  - Endorsed by Training Program Director & MSEC
  - Competency listed on the “Resident Procedure Competencies” or New Innovations website

UCSD Physician Privileges

- From Webref or Intranet Search
  - Clinical Tools or “Physician Privileges”
  - Intern/Resident/Fellows
  - Link to use “New Innovations” site
- If unable to locate physician competency in New Innovations, Call House Supervisor
Physician’s, Residents and Fellows Not Credentialed in Moderate Sedation

- May perform sedation for procedure only under direct observation of a supervising attending physician
- The supervising attending physician must be credentialed to perform moderate sedation
- The supervising attending physician must be present in the procedural area for the duration of the operation/procedure

Non-Physician Licensed Personnel (NP, PA-C, RN)

- American Association of Moderate Sedation Nurses (AAMSN) teaches the position that registered nurses trained and experienced in critical care, emergency and/or peri-anesthesia specialty areas may be given the responsibility of administration and maintenance of moderate or conscious sedation in the presence, and by the order, of a physician.

- The registered nurse has the knowledge and experience with medications used and skills to assess, interpret and intervene in the event of complications.

Other (Non-Physician) Licensed Personnel (NP, PA-C, RN)

- Competency Assessment:
  - Moderate sedation competence is required for all other licensed personnel who perform moderate sedation
  - Must be able to manage sedation one level deeper than the level intended
  - Includes:
    - Current ACLS or UCSD Adult Resuscitative Training (ART).
    - In neonatal areas, providers will have NRP (AHA and AAP accredited program)

Non-physician Licensed Personnel Training On Deep Sedation

Propofol, thiopental, methohexital, ketamine, etomidate, dexmedetomidine (Precedex™) or any other "general anesthetic" are more likely to produce deep sedation

- Non-physician licensed personnel using these medications must meet the competency requirements for deep sedation and may administer under the direct supervision of a physician privileged to perform deep sedation
- Deep sedation may occur in the emergency department, critical care areas

Levels of Sedation

- Light Sedation / Anxiolysis
- Moderate Sedation
- Deep Sedation
- Anesthesia

Sedation Procedure Goals

- Accomplish the procedure
- Behavior control or immobility for procedure
- Patient safety
- Minimal physical discomfort and pain
- Minimal psychological response to procedure
- Rapid return to baseline state of consciousness according to Aldrete Score
**Light Sedation / Anxiolysis**
- A drug induced state during which patients respond normally to **verbal** commands
- Cognitive function and coordination may be impaired
- Ventilation and cardiovascular functions are unaffected
- **RASS -2**

**Moderate Sedation**
- A drug induced depression of consciousness to facilitate a procedure during which:
  - Patients respond purposefully to **verbal** commands
    - "Hold up two fingers"
  - Reflex withdrawal from painful stimulus is not considered purposeful response
  - Patient is able to maintain patent airway and spontaneous ventilation
  - Cardiovascular function is maintained
  - **RASS -3**

**Deep Sedation**
- A drug induced depression of consciousness during which
  - Patients cannot be easily aroused, but may respond purposefully with **repeated or painful** stimulation
  - May have **impaired ventilation** and require assistance in maintaining patent airway
  - Cardiovascular function is usually maintained
  - Sometimes sedation level used for continuous mechanical ventilation in ICU
  - **RASS -4**

**Anesthesia**
- Used in operating room
- Consists of:
  - Drug induced loss of consciousness
  - Patient is **not arousable with verbal or tactile stimulation**
  - Requires assistance to maintain airway and ventilation
  - Cardiovascular function may be impaired
  - **RASS - 5**

**Implications For Sedation Practice**
- Moderate sedation can rapidly become deep sedation or anesthesia
- Practitioner must prepare for one level deeper that what is intended by
  - Maintaining a high level of vigilance
  - Assure area is fully equipped with monitoring equipment and appropriate personnel

**Level of Consciousness = Level of Sedation**
- Assess Level of Sedation using RASS Scale
- Level of sedation
  - May not be as distinct as the definition
  - May change with time
  - May vary with patient response
Moderate or Deep Sedation May Not Be Appropriate

- Patients presenting with any of the following:
  - History of adverse events associated with sedation and analgesia
  - Airway problems: i.e. obstructive sleep apnea, difficult intubation, or syndromes involving airway abnormalities
  - Delayed gastric emptying or increased risk of aspiration;
  - Pregnant or breast feeding females.

- NOTE: Clinician judgment of risk should always be evident in the decision making process when administering sedation to any of these patients.

American Society of Anesthesiologists (ASA) Physical Status Classification

- Standardized description of patient’s physical status to determine patient’s appropriate for moderate sedation and / or at risk for complication
  - ASA 1 = normal healthy patient
  - ASA 2 = mild systemic disease
  - ASA 3 = severe systemic disease
  - ASA 4 = severe systemic disease that is a constant threat to life
  - ASA 5 = moribund, not expected to survive without procedure

Pre-Procedure Fasting Guidelines

- Adults
  - Solid food 6-8 hours
  - Liquids 2-3 hours
- Factors that decrease gastric emptying
  - Anxiety
  - Opioids
  - Trauma
  - Pregnancy
  - Intestinal obstruction

Rescue

For all levels of sedation, the practitioner must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

- RESCUE
  - Minimal = Rescue from Moderate Sedation
  - Moderate = Rescue from Deep Sedation
  - Deep = Rescue from General Anesthesia

Designated area for Moderate Sedation at UCSD Hillcrest Campus

- Main Operating Room, PACU
- Same Day Surgery Suites
- GI Endoscopy Suite
- Cardiac Catheterization Lab
- Electrophysiology Lab
- Pulmonary Special Procedures Unit
- Radiology: MRI (in-house), CT, IR
- ICU SICU, CCU, MICU, BURN, IMU/PCU, NICU
- ER

Designated areas for Moderate Sedation UCSD La Jolla Campus

- Operating Room
- PACU and PTU
- Same Day Surgery
- Intensive Care Unit and IMU/PCU
- Special Procedure Suite
- Emergency Department
- Radiology: MRI, CT, IR
- Moores Cancer Center: Procedural suites, MRI, Radiation Oncology
- Shiley Surgical Suite: 3rd floor
Room Set up, Monitoring and Support Equipment

- Adequate lighting
- Adequate space
- Adequate power outlets
- Reliable two way means of communication
- Ability to provide immediate changes in patient position including Trendelenburg

Procedures Requiring Patient Consent

- Transfusion of blood products
- General anesthesia, moderate sedation or regional blocks
- Are performed in the OR
- Involve placement of implantable devices
- Involves tissue biopsy
Examples of procedures that require consents:

- Bronchoscopy
- Central Line Placement
- Chest tube insertion
- Intracranial Pressure (ICP) devices

Informed Consent Requirements

- Physician member of treatment team, or licensed practitioner, who is credentialed to perform the procedures
- Complete & document informed consent discussion
- Obtain patient or surrogate decision maker’s consent on consent form

Who May Sign a Consent Form

<table>
<thead>
<tr>
<th>Decisional Capacity</th>
<th>Lack Decisional Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can understand his/her condition, the risks and benefits of the recommended treatment and available alternatives (including no treatment)</td>
<td>Unable to understand their medical condition and the risks and benefits of recommended treatment and available alternatives</td>
</tr>
<tr>
<td>Can express a choice.</td>
<td>Cannot express a choice</td>
</tr>
<tr>
<td>Adults are presumed to have decisional capacity.</td>
<td></td>
</tr>
</tbody>
</table>

Who May Sign a Consent Form?

- Patients lacking decisional capacity may have the following person(s) give consent, in the order of their availability:
  - Agent designated in the Durable Power of Attorney for Healthcare.
  - Conservator or guardian of patient.
  - Closest available relative (refer to list below).
  - Court appointed surrogate decision-maker (Probate Code §3400).

Closest Available Relative (in order)

- Spouse, **including** same-sex spouses and registered domestic partners
  - NOTE: California **does not** recognize "common law" marriages
- Son or Daughter
- Mother or Father
- Brother or Sister
- Grandmother or Grandfather
- Aunt or Uncle
- Nephew or Niece

Surrogate Decision-Maker

- An individual making health care decisions in substituted judgment on behalf of a decisionally incapacitated patient in conformance with the patient’s desires.
- If the patient’s desires are unknown or unclear, the surrogate shall act in the patient’s best interest.
- A surrogate decision-maker can be a parent on behalf of a child, a legal representative appointed by the patient or the court, and/or the patient’s next of kin.
**Surrogate Decision Maker not Present?**

- Telephone consent with surrogate, Responsible physician and witness listening in on the conversation (with the surrogate decision-maker’s permission).
- The consent form may be completed by either the Responsible Physician or the witness.
- Consent Form will have
  - The surrogate’s name
  - Date consent was obtained
  - Witness signature and indicates the consent was obtained via telephone
  - Responsible physician signature

**Witness Definition MCP 339.1:** A professional employee, preferably a nurse who verifies with the patient:

- Patient, or individual giving consent, can state, in their own words, the procedure that will be performed
- All of their questions were answered to their satisfaction
- DNAR or blood transfusion issues have been addressed
- Validate it is the patient’s, or individual giving consent, signature on the form

The witness is not required to be present for the informed consent conversation between the physician and the patient, or individual giving consent

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**Interpreter Services**

- UC San Diego Policy requires the use of facility approved interpreters
- Interpreting Services Office employs certified on-site medical interpreters qualified to provide Spanish interpretations during business hours only

**Interpreter Services**

- UC San Diego and vendor interpreters, that are present, must sign the consent
- Use of interpreters must be referenced by using the interpreters name or ID number
  - **Note:** live interpreters do not have an ID number

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**Universal Protocol**

The standardized methodology that our physicians, nurses and other health care providers, in cooperation with our patients, employ to effectively eliminate wrong site surgery/ procedure by initiating a pre-operative / pre-procedural verification, site marking and timeout process
Universal Protocol / Time Out!

- Time-Out initiated just before the procedure by responsible attending MD or provider in location where the procedure will be done.
- Entire team participates to confirm and agree on:
  - Right Patient using name band & 2 distinct identifiers (MR # & name)
  - Right Procedure, Right Side & Right Site
- When part of the team, RN is to document Time-Out in EPIC or program specific to area.

Time Out documentation location according to work area:

- **ED**: EPIC ASAP Sedation Narrator
- **OR**: EPIC Optime Intra Procedure Record
- **PACU**: PACU Navigator, PACU procedure section
- **Inpatient (ICU, PCU)**: Doc Flowsheets Procedure Flowsheet OR Procedures Tab Intra Procedure record
- **Cath Lab**: Pre-procedure verification in CCL charts; Time out in MacLab
- **GI Endoscopy Procedural Units**: EPIC Optime Intra-Procedure Record
- **IR**: EPIC Optime Intra-Procedure Record
- **Moores Procedural Suite**: Epic MCC Procedural Record
- **Radiation Oncology**: Sedation Flowsheet (paper)
- **Moores Multi-Specialty Clinic**: Physician progress note
- **Clinic Setting**: Progress note using smart phrase

Documentation Requirements

- **Pre-Procedure Verification of**: Time-Out documentation
- Informed consent for the RIGHT procedure completed and signed by the physician and witnessed
- Verify if patient has any special equipment such as implants or devices.
- Verify documentation is complete including:
  - History and Physical > 24 hours but < 30 days needs Interval Assessment / > 30 days, must complete new H&P
  - Pre-Anesthesia assessment done
  - Pre Procedure note completed
  - All needed labs, preps and diagnostic test results have been completed
  - Pre-Procedural assessment, VS, cardiac rhythm strip and post in chart

Pre-Procedural Mental Checklist

- Patient VS, Wt (kg.), allergies documented
- Consent and procedure verified
- History
- Nasal airway
- NPO status verified
- Oral airway
- ID band
- Code cart
- Patent IV
- Phone available
- Patient on monitor
- Overhead lights on
- Oxygen on
- Position of comfort and covered for privacy
- Suction hooked up

MCP 320.4 Prepared Medication

- Medications prepared on the sterile or non-sterile, field in the operating room OR other procedural area, for use during a single patient case, should be labeled with the following & discarded at the end of the case:
  - Medication name
  - Strength or concentration and diluent (for IV admixtures)
  - Amount of volume if not apparent from the container

Administering Medications for Sedation
The Joint Commission

- Verify all medications or solution labels both verbally and visually
- Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it
- Label each medication or solution as soon as it is prepared, unless it is immediately administered
- Discard any medication or solution found unlabeled
- Do NOT pre-label medication containers including syringes, medicine cups, and basins

Sedative Administration and Monitoring

- The minimal number of available personnel should be two.
  - The physician (performs procedure)
  - Non-physician licensed personnel will continuously monitor the patient from the time of first drug administration until recovery to baseline or Aldrete Score > 15 has been achieved
- Medications are given during the procedure according to verbal physician order after verbal order read back verification
- Reversal agents available if needed

Intra-Procedure Medication Administration

- Start low then increase dose to achieve desired effect
- Verbal order read back includes drug name, dose
- Communicate with physician and anticipate procedural needs
- Have reversal agents readily available
- Monitor patient safety and comfort

Complete Pre-Procedure Checklist

- EPIC DOCUMENTATION FLOWSHEET FOR PROCEDURES AT THE BEDSIDE
Intra-Procedure and Recovery Vital Signs

- Maintain continuous cardiac monitoring
- Obtain vital signs every 5 minutes:
  - HR
  - RR
  - BP
  - Sp02
- Assess LOC every 15 minutes using RASS scoring
- If patient goes into deep sedation, increase VS documentation to every 3 minutes!

Adverse Event Documentation

- Note in medical record, and create iReport if any of the following occurs:
  - Use of reversal agent or unintended interruption of procedure due to medication use
  - Unplanned intubation
  - Unplanned admission or transfer to higher level of care
  - Chest pain during procedure
  - Drop in oxygen saturation - <92 for >5 minutes
  - Hypotension and use of a vasopressor
  - Aspiration
  - RRT/Code Blue
  - Death

Patient Monitoring Post-Procedure

- Continue monitoring patient with same frequency VS / LOC/RASS score in sedation area until:
  - Modified Aldrete Score of 15 or greater AND 30 min since last dose IV or 90 min since last dose IM or transmucosal medication
    - If reversal agents used, monitor for 90 minutes after last dose to assure resedation does not occur
    - Once criteria is met, physician will discharge
    - If Modified Aldrete Score is less than 15, continue to monitor and reassess until DC criteria is met

Recovery

- Patients sedated in the ICU or ED may be recovered in their respective areas
- If pt does not meet recovery criteria, must be transported to PACU
Recovery & Discharge

- Patients will be assessed for stability prior to transport
- Inpatient level of care will be maintained during transport
- Patients discharging to home may be released to responsible adult
- Provide and review discharge education

Potential Complications

- Airway Obstruction
- Laryngospasm
- Bronchospasm
- Noncardiogenic Pulmonary Edema
- Aspiration
- Cardiovascular complications

Post Procedure Patient Education Handouts

Conscious Sedation Video

- New England Journal of Medicine Conscious Sedation

Care Plan and Patient Education
References

- UCSD Medical Center MCP 370.1
- UCSD Medical Center MCP 339.1
- UCSD Medical Center MCP 301.9
- New England Journal of Medicine