KEY WORDS:  Moderate Sedation, Procedural Sedation

PURPOSE:

To define the methodology of providing and monitoring patients receiving moderate/procedural sedation. This policy addresses moderate/procedural sedation for adult and pediatric populations.

DEFINITIONS:

**Minimal sedation:**
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.

**Moderate/procedural 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.

**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.

**General Anesthesia:**
A drug-induced loss of consciousness during which patients are not arousable and may have an impaired cardiorespiratory function requiring varying degrees of support. The patient is profoundly compromised and does not exhibit movement or autonomic responses to a standard surgical stimulus.
POLICY:

1. Moderate/procedural sedation can be utilized for patients undergoing therapeutic, diagnostic and/or surgical procedures. The physician will use moderate/procedural sedation to produce sedation only to the degree defined. Deep sedation is restricted to use by anesthesiologists and anesthetists, pediatric emergency physicians and emergency physicians. This policy is not meant for use in care such as pain control, patients using PCA therapy, benzodiazepines administered for anti-convulsant therapy or anxiolytic therapy. This policy does not apply to patients being intubated for the purpose of placement on a ventilator, or to maintain sedation of patients on ventilators.
   a. The licensed independent practitioner administering moderate/procedural sedation must have the appropriate privileges and be qualified to rescue patients from deep sedation, and must be competent to manage a compromised airway and to provide adequate oxygenation and ventilation.

2. A separate informed consent will be obtained for the administration of moderate/procedural sedation.

3. The patient and family will receive education regarding the appropriate types of moderate/procedural sedation. It is important to reduce patient anxiety prior to the procedure. The more relaxed the patient is, the less sedation he/she is likely to need.

4. The administration of moderate/procedural sedation can be done on the following units:
   a. Critical Care Units
   b. Intermediate Care Units (IMC)
   c. Emergency Departments
   d. Cardiac Cath Lab
   e. Imaging Departments
   f. Operating Rooms and Post Anesthesia Care Units
   g. UCMC Pre-op unit
   h. Pediatrics

5. Patient Selection
   a. Candidates for moderate/procedural sedation are those patients who must undergo painful or difficult procedures where cooperation and/or comfort will be difficult or impossible without pharmacologic support. Patients must be screened for potential risk
factors for any pharmacologic agents selected. This decision on which agent to use must be based on the goals of sedation, type of procedure and condition and age of the patient.

b. Patients will be screened by the ordering licensed independent practitioner for risk factors utilizing the ASA Physical Status Classification. Patients considered appropriate for moderate sedation are ASA Class I and Class II.

c. Patients who meet ASA Class III or Class IV criteria present special problems which may necessitate a consultation by a member of the Anesthesia Department. If the nurse disagrees with the classification, Anesthesia personnel will be consulted and agreement among the RN, Anesthesia personnel and LIP on appropriate monitoring and who should be responsible will be determined and agreed upon by those involved.

d. ASA (American Society of Anesthesiology) PHYSICAL STATUS CLASSIFICATION:

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Fit &amp; healthy, no organic, physiologic, or psychiatric disturbance.</td>
</tr>
<tr>
<td>Class II</td>
<td>Mild/moderate systemic disease, extremes of age, moderately severe obesity, or chronic bronchitis.</td>
</tr>
<tr>
<td>Class III</td>
<td>Multiple system disease, or well controlled systemic disease.</td>
</tr>
<tr>
<td>Class IV</td>
<td>Severe incapacitating systemic disease, poorly controlled or life threatening.</td>
</tr>
<tr>
<td>Class V</td>
<td>Moribund patient who has little chance of survival but submitted to operation in desperation.</td>
</tr>
</tbody>
</table>

Class E Emergency (Numerical classification must also be designated)

6. This policy does not apply to the following clinical circumstances:
   a. Patients who are mechanically ventilated via tracheotomy or endotracheal tube and fully monitored (SpO2, ECG, BP).
   b. Patients who require sedation to tolerate mechanical ventilation.
   c. Patients who require sedation secondary to an acute psychiatric disturbance, which may result in potentially harmful behavior.
   d. Patients who receive a single dose of an oral anxiolytic or analgesics administered in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain without the intent to provide moderate sedation.
      i. If it is suspected that the administration of anxiolytics or analgesics may cause the patient to enter a state of moderate sedation- all sections of this policy apply.
ii. Pediatric patients may receive a single dose of anxiolytic rectally or nasally, if necessary.

e. Analgesic therapies used alone, without concomitant administration of drugs with sedative properties, for ongoing (non-procedural) pain control.

f. The administration of deep sedation.

6. The registered nurse administering and monitoring moderate/procedural sedation must have completed designated validation skills, as provided by the Education and Resource Development Department.

7. All providers administering Moderate/Procedural Sedation must possess current privileges for Moderate/Procedural Sedation.

8. The Moderate/Procedural Sedation Record will be used to document this procedure.

9. Medications
   a. Medications in areas other than Emergency Department
      i. Medications will be administered according to established practice as defined in drug references, (Nursing Drug Reference, and/or Color Coded Pediatric Emergency Tape). Moderate sedation medication(s) will be administered by the physician or an R.N. under the direct supervision of a physician.
      ii. Moderate sedation may be achieved using the following medications:
          i. Dexmedetomidine (Precedex) – Critical Care Units only
          ii. Diazepam (Valium)
          iii. Ketamine
          iv. Lorazepam (Ativan)
          v. Midazolam (Versed)
          vi. Morphine sulfate
          vii. Nitrous Oxide
          viii. Sublimaze (Fentanyl)
      b. Medications in the Emergency Department
         i. Moderate/procedural sedation may be achieved using the medications listed above in 8.a.ii AND Etomidate and Propofol.
         ii. Etomidate and Propofol will ONLY be administered in Peri-operative Services and the Emergency Department and will only be administered by an anesthesiologist/anesthetist or Emergency Department physician.
            i. Physician monitors the airway; moderate/procedural sedation credentialed practitioner will perform the procedure.
iii. Two physicians or one physician and one NP/PA are required to be in attendance in the Emergency Department. One practitioner will administer the medication and monitor the patient and one will perform the procedure. One practitioner will remain with the patient until they are fully recovered.

c. If the physician requests a drug other than those listed, a pharmacist must be consulted.

1. Pediatric Considerations:
   a. All children requiring moderate/procedural sedation will be assessed appropriately for age and development, and monitored as per established protocol.
   b. Weights must be obtained and orders are to be written in mg/kg.
   c. Use of local anesthetics and sedation is more likely to result in amnesia and less likely to cause adverse drug reactions. Narcotics and sedatives used together to decrease pain may predispose young child to apnea.
   d. Pulse Oximetry should be continuously monitored throughout procedure and post-procedure period. B/P should be recorded intermittently based on assessment of the patient's condition, as this procedure may disturb the child and defeat the purpose of sedation. Cardiac rhythm is monitored continuously in children age 12 years and older. Cardiac monitoring is used at the discretion of the physician and/or RN for children less than 12 years of age.

2. Geriatric Considerations:
   a. Physiologic changes and alterations result in increased sensitivity to medications including prolonged medication half-life, cumulative pharmacologic effect and decreased plasma clearance.
   b. Awareness of the effects of the aging process using close monitoring is imperative to prevent the development of deep sedative states and prolonged recovery periods.
   c. Administer moderate/procedural sedation medications incrementally in small divided doses with adequate time to establish pharmacologic effect.
   d. Respiratory depression, confusion and disorientation and/or agitation may result from moderate/procedural sedation and may be indicators that sedation is too deep; no further sedation should be administered.

**PRE-PROCEDURAL PHASE:**

1. Immediately prior to the procedure, the patient receiving moderate/procedural sedation will be assessed. Assessment and documentation will include the following:
   a. **Physician Responsibility:**
      i. Informed Consents signed for both the procedure and moderate sedation.
ii. NPO status- LIP administering drugs reaffirms NPO status. See Summary of Fasting Guidelines below.

iii. History and Physical including pregnancy status if applicable. The same criteria used to determine the need for an EKG prior to the OR will be used for moderate/procedural sedation.

   1. Males >40 years / Females > 50 years with NO CARDIAC HISTORY or risk factors and no recent illness or symptoms will have an interpreted EKG within 6 months.

   2. Males > 40 years / Females > 50 years WITH A CARDIAC HISTORY or risk factors will have an interpreted EKG within 60 days.

iv. Pre-sedation assessment including pre-procedure airway assessment is to be completed and signed using the Moderate/Procedural Sedation Form PRIOR to the procedure.

2. A TIME-OUT is performed and documented on the Moderate/Procedural Sedation Form.

   a. Nursing Responsibility:

      i. Immediate Pre-Sedation Vital signs including temperature, BP, heart rate, respiratory rate, oxygen saturation, End Tidal CO2 (ETCO2), level of consciousness, pain level using 0-10 scale are to be obtained and recorded on the Moderate/Procedural Sedation Record.

         1. Level of consciousness score:

            a. 1 = Awake and Alert

            b. 2 = Slightly drowsy, easily aroused

            c. 3 = Frequently drowsy, arousable, drifts off to sleep during conversation

            d. 4 = Somnolent, minimal or no response to physical stimulation (For LOC rating of 3 or 4, no pain rating is necessary.)

         2. A Pre-Sedation Cardiac Strip is to be attached to Moderate/Procedural Sedation Record. Pediatric Patient: EKG monitoring in patients less than 12 years of age is left to the discretion of the physician/LIP and/or the nurse monitoring the patient.

         3. Oxygen will be placed on all patients.

         4. Universal Protocol Standardized List

         5. Verification of responsible adult to accompany the patient if being discharged from the hospital.

   b. Prior to administration, IV access will be secured for adult patients. IV access for children may be obtained after oral or rectal moderate/procedural sedation medication(s) is administered unless the patient's vital signs are unstable.
c. Procedural and Post-Procedural care areas will have the following equipment available and in working order:
   i. Equipment required for procedure
   ii. Pulse Oximetry
   iii. ETCO2 Monitor
   iv. Blood Pressure Monitoring Equipment
   v. Cardiac Monitor
   vi. Oxygen Source and Equipment
   vii. Oral Pharyngeal Airways
   viii. Ambu Bag and Facemask
   ix. Suction

d. Assure immediate accessibility of the following emergency equipment and personnel on the unit or in the area:
   i. Defibrillator with recorder capability
   ii. Adult or Pediatric Code Cart
   iii. Emergency Drug Box
   iv. ACLS Provider/PALS Provider

e. It is recommended that the patient be NPO according to the following guidelines.
Summary of Fasting Guidelines to Reduce the Risk of Pulmonary Aspiration

<table>
<thead>
<tr>
<th>Ingested Material</th>
<th>Minimum Fasting Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear liquids</td>
<td>Peds-3 hours/Adults- 2 hours</td>
</tr>
<tr>
<td>Breast Milk</td>
<td>4 hours</td>
</tr>
<tr>
<td>Infant formula</td>
<td>6 hours</td>
</tr>
<tr>
<td>Non-human milk</td>
<td>6 hours</td>
</tr>
<tr>
<td>Light meal</td>
<td>6 hours</td>
</tr>
<tr>
<td>Regular meal</td>
<td>8 hours</td>
</tr>
</tbody>
</table>

- These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following these guidelines does not guarantee complete gastric emptying.
- The fasting periods apply to all ages.
- Examples of clear liquids include water, fruit juice without pulp, carbonated beverages, clear tea and black coffee, Pedialyte, ice popsicles, clear broth.
- Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
- A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.

f. A “Time Out” will be performed immediately prior to the start of the procedure.
   i. Time Out will consist of verifying:
      1. Correct patient
      2. Correct procedure
      3. Correct site
      4. Correct patient position
      5. Special equipment and implants available
      6. Necessary documentation in the medical record: i.e., lab work, x-rays, consent
   ii. The “time out” will be performed in cooperation with the surgical/procedure team. Refer to Universal Protocol Policy in Nursing Clinical Division Policy and
Procedure Manual. As noted above, the time-out will be documented on the Moderate/Procedural Sedation Record.

**INTRAPROCEDURAL PHASE:**

1. The physician (or two physicians in the ED) must be immediately available in the room during the procedure.

2. The R.N. may administer the medication, except as noted in 8.c., and will monitor the patient.

3. The RN will not leave the patient unattended during the procedure compromising continuous monitoring as defined in this policy. In the event that the physician requires any assistance to perform the procedure, then additional personnel must be available.

4. The patient's vital signs, B/P, oxygen saturation, ETCO2, LOC, pain level and cardiac rhythm will be monitored and documented at five (5) minute intervals or less.

5. There must be a written/verbal order countersigned by the physician for all drugs administered.

**POST PROCEDURAL PHASE**

1. The post-procedure status of the patient is monitored, evaluated and documented.
   a. Vital signs, B/P, oxygen saturation, ETCO2, and cardiac rhythm are monitored every 15 minutes or less until the patient meets discharge criteria.
   b. Oxygen Saturation is monitored until it is maintained by patient at pre-procedure level for a minimum of 15 minutes without supplemental oxygen.
      i. Inpatients may be monitored and maintained at level with supplemental oxygen as ordered by physician.
   c. The Aldrete Score is monitored and recorded every 15 minutes or less. See Aldrete Score Guidelines below.
   d. Medications and IVs administered will be documented.
   e. Unusual events or post-procedure complications, and the management of those events will be documented. In the event that the patient's condition deteriorates, anesthesia or the appropriate code will be called STAT.

2. Pediatric Considerations:
   a. The following discharge criteria will be met for Infants and Children unless different prior to procedure.
i. Infant will be able to sit upright or crawl as appropriate for age/developmental stage.

ii. Infant and child will:
   1. Have pre-procedural vital signs
   2. Be able to follow commands and verbalize appropriately
   3. Demonstrate baseline motor function appropriate for age
   4. Be able to take popsicle or liquids
   5. Recognize, interact with, or is consolable by parent or caregiver
   6. Have responsible parent or guardian present

b. A child will be discharged at pre-procedural levels.

3. Procedures performed on patients outside of the Operating Room for whom the level of post-procedural care cannot be maintained will be transferred to the Post Anesthesia Care Unit depending upon patient admission status.

4. Sufficient time, or a minimum of 1.5 hours, should have elapsed following the administration of reversal agents to ensure that patients do not become re-sedated after reversal agent effects have abated.

5. Patients may be discharged when the following medical staff approved criteria are met:

a. Adult patient demonstrates an Aldrete Score of 7 or greater or their pre-procedural level.
b. Pediatric patient demonstrates an Aldrete Score of 7 or greater or their pre-procedural level.

Heart Rate, Blood Pressure and Respiration will be within 20% of pre-procedural level within the age appropriate ranges as listed below:

<table>
<thead>
<tr>
<th>Age</th>
<th>HR/min.</th>
<th>Systolic/Diastolic BP</th>
<th>Resp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mo. - 1 yr.</td>
<td>100-180</td>
<td>60-90 / 20-26</td>
<td>30-60</td>
</tr>
<tr>
<td>1 - 3 yrs.</td>
<td>80-110</td>
<td>87-105 / 53-66</td>
<td>24-40</td>
</tr>
<tr>
<td>3 - 6 yrs.</td>
<td>70-110</td>
<td>95-105 / 53-66</td>
<td>22-34</td>
</tr>
<tr>
<td>6 - 12 yrs.</td>
<td>65-110</td>
<td>97-112 / 57-71</td>
<td>18-30</td>
</tr>
<tr>
<td>12 - 19 yrs.</td>
<td>60-90</td>
<td>112-128 / 66-80</td>
<td>16-24</td>
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</tbody>
</table>

Aldrete Score Guidelines for Moderate Sedation:

**Activity**: Muscle activity is assessed by observing the ability of the patient to move his/her extremities spontaneously or on command.
(Pediatric activity/mobility level is appropriate for age and pre-sedation physical condition)
Able to move four extremities voluntarily on command = 2
Able to move two extremities voluntarily on command = 1
Unable to move = 0

Respiration: Respiratory efficiency evaluated in a manner that permits accurate and objective assessment without complicated physical tests.

Able to deep breath and cough freely = 2
Spontaneously maintains airway, with or without dyspnea = 1
Airway requires maintenance or patient is apneic = 0

Circulation: Uses changes of arterial blood pressure from pre-sedation level.

BP & HR +/- 20% of pre-sedation level (Riva-Rocci method) = 2
BP & HR +/- 20 - 50% of pre-sedation level = 1
BP & HR +/- 50% of pre-sedation level = 0

Consciousness:
Determination of the patient’s level of consciousness.
Physical stimulation should not be considered reliable as even a decerebrated patient might react to it.
Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Fully awake; Able to answer questions appropriate to age = 2
Fully awake and developmentally delayed as noted prior to medication administration/procedure = 2
Arousable with stimulation and with the presence of protective reflexes = 1
Not responding/absence of protective reflexes = 0
**Oxygenation:**

- Able to maintain O2 saturation > 92% on room air = 2
- Needs O2 inhalation to maintain saturation > 90% = 1
- O2 saturation < 90% even with O2 supplemented = 0

6. The physician will be notified if the patient does not meet discharge criteria within 1 hour post procedure.

7. If the patient has an Aldrete Score of 3-5; a nurse will be readily accessible by call bell with frequent assessment of patient. If the patient has an Aldrete Score of 0-2; the nurse will be at the bedside.

8. The physician may discharge the patient prior to meeting the discharge criteria only by written order. She/he must examine the patient and write a progress note specifying the rationale for early discharge.

9. Post-procedure patients may be transported using pulse oximetry and oxygen based on assessment and physician orders.

10. Outpatients and/or responsible adult (family or significant other) will receive written discharge instructions pertinent to the procedure performed. Written discharge instructions regarding sedation will be provided.
    a. Any additional verbal instructions given will be documented.

11. A responsible adult must be present to accompany the patient if discharged home. In the event that a responsible adult is not present or no longer present, physician clearance must be obtained and documented prior to discharging the patient.
PRIVILEGE CRITERIA FOR MODERATE SEDATION

Initial Education:
- MD, DO, DDS, DMD, CRNA

Minimum Formal Training:
Must have successfully completed one of the following:

1. ACGME or AOS approved residency training program in anesthesiology, emergency medicine or pulmonary/critical care medicine. Moderate sedation is considered a core privilege in these specialties; therefore testing and demonstration of airway management competency is not necessary.

2. ADA-accredited advanced or postgraduate training program in dental anesthesiology or oral and maxillofacial surgery.

3. Non-anesthesiologist licensed independent practitioners (LIPs) requesting the privilege of providing moderate sedation for adult patients must complete the UCH moderate sedation information packet, a subsequent test (with a score of at least 90%) to demonstrate competency, and have either current ACLS certification or complete an airway management competency provided by UCH Education Department.

4. Non-anesthesiologist licensed independent practitioners (LIPs) requesting the privilege of providing moderate sedation for pediatric patients must complete the UCH moderate sedation information packet, a subsequent test (with a score of at least 90%) to demonstrate competency, and have either current PALS certification or complete a pediatric airway management competency provided by UCH Education Department.

Required Previous Experience:
- Documentation of performance of six (6) moderate sedation cases in the previous 12 months.
- Reappointment of Privileges (not required for 1, or 2):
  Documentation of performance of 12 moderate sedation cases in the previous 24 months; and
- Current ACLS (or PALS for pediatricians) or completion of an airway management competency provided by UCH at the time of reappointment; and
- Completion of the UCH moderate sedation information packet, a subsequent test (with
a score of at least 90%) at the time of reappointment.

REFERENCES:


The Joint Commission Hospital Accreditation Standards, 2016.


“Guidelines for Care of the Patient Receiving Moderate Sedation/Analgesia”, Guidelines for Perioperative Practice; AORN 2016 Edition

Sacchetti et al; ProSCED Registry; Academic Emergency Medicine 2007

STAKEHOLDERS:

<table>
<thead>
<tr>
<th>Reviewed by</th>
<th>Date</th>
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<tr>
<td>Chair, Anesthesia Department</td>
<td>12/16, 3/19</td>
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<tr>
<td>Policy Oversight Committee</td>
<td>12/16, 3/19</td>
</tr>
<tr>
<td>MEC</td>
<td>1/17, 3/19</td>
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APPROVED BY: Title Date
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<th>POLICY/PROCEDURE/SOP TITLE:</th>
<th>FUNCTION/OWNER:</th>
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<tbody>
<tr>
<td>Moderate/Procedural Sedation Policy</td>
<td>Chairperson, Policy Oversight Committee</td>
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<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Joyce Fox</td>
<td>VP Patient Services</td>
<td>7/2017, 3/19</td>
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<tr>
<td>Lyle Sheldon</td>
<td>President/CEO</td>
<td>7/2017, 3/19</td>
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