Moderate Sedation/Analgesia

DEPARTMENT APPLIES TO

All clinical areas providing moderate sedation.

OVERVIEW

To provide continuity of quality of care and safety, including appropriate administration of medications which produce varying levels of sedation and monitoring of the patient undergoing a procedure with Moderate Sedation/Analgesia.

POLICY

A. This policy is designed to provide specific recommendations for the safe care of patients during delivery of medications for moderate sedation / analgesia by non-anesthesiologists during diagnostic, therapeutic, or surgical procedures. Examples of such procedures include:

1. Endoscopic examinations;
2. Vascular and cardiac catheterizations;
3. Diagnostic or interventional radiological procedures; and
4. Other in-hospital procedures that are performed in procedure rooms and clinics, on patient care units, or in the emergency department.

B. Moderate sedation / analgesia must be provided in areas where resuscitation capabilities are available;

1. In situations where it is anticipated that the required sedation will lead to loss of protective airway reflexes, such patients require a greater level of care than recommended by this policy;
2. In addition, certain patients will not be candidates for moderate sedation / analgesia and will receive either no moderate sedation or will be intubated with airway control prior to sedation (refer to exceptions below).

C. The Anesthesia Department, with input from the hospital medical staff, administration, pharmacy and the Department of Nursing is responsible and accountable for assuring the safe implementation of this policy and procedure.

D. Sedation for patients undergoing diagnostic, surgical or therapeutic procedures may only be ordered by a
credentialed Physician.

E. This policy pertains specifically to Moderate Sedation;
   1. It does not apply to Minimal Sedation and is not inclusive of Deep Sedation and/or General Anesthesia (see definitions).

F. Each department shall purchase and maintain its own clinical monitors;
   1. The medical director of each department administering Moderate Sedation/Analgesia will be responsible for ensuring that these policies and procedures are followed;
      a. The medical staff member performing the diagnostic therapeutic procedure and directing the Moderate Sedation/Analgesia shall be responsible for that individual patient's care;
      b. The Anesthesia Department will assist in ensuring there is an up-to-date Moderate Sedation/Analgesia policy.

G. Exceptions: This policy specifically excludes the following:
   1. Management of patients by a member of the Anesthesia department;
      a. Management of these patients is covered by policies within the Anesthesia Department;
      b. Deep sedation in the Emergency Department;
      c. Propofol, Ketamine and Brevital are usually used as anesthetic agents and therefore are infrequently used for the production of Moderate Sedation/Analgesia. Propofol, Ketamine and Brevital should only be used by physicians thoroughly familiar with the actions, contraindications and potential complications such as laryngospasm. The use of these agents is restricted to individuals who have been credentialed to perform deep sedation by the Department of Anesthesia; principally the Emergency Department, by Board Eligible/Board Certified Emergency Room Physicians;
         Appropriately credentialed physicians may use propofol for sedation where patients are mechanically ventilated and cared for in an intensive care setting;
   2. Patients who may require a greater level of care than recommended by these guidelines including but not limited to the following:
      a. Patients at specific risk for complications from sedation/analgesia;
      b. Pregnant patients not undergoing OB/GYN procedures;
      c. Infants with severe cardiac, pulmonary, airway, or neurologic problems; and
      d. Substance abusers;
      e. ASA 3 - ASA V category patients.

PROCEDURE –

A. Medical Staff:
   1. Providers responsible for the oversight of the patient receiving moderate sedation must meet the credentialing requirements for administration of moderate sedation, to include any education or competency assessments, as determined by the hospital's Medical Executive Committee (MEC);
      a. Privileges are granted for two years after which the medical staff member shall reapply for credentialing;
b. If twenty (20) moderate sedation cases are not performed within two (2) years; re-credentialing must be completed through the Medical Executive Committee (MEC) and include education or competency assessment.

2. Providers must sign a statement which evidences his/her agreement to abide by the St. John policy addressing the administration of Moderate Sedation/Analgesia by a non-anesthesiologist;

3. Providers must be aware of the hospital code blue policies so as to facilitate the summoning of additional personnel capable of advanced life support techniques in a timely manner;

4. Providers responsible for the oversight of the patient receiving moderate sedation must meet the following requirements:
   a. Current Certification in Advanced Cardiac Life Support (ACLS); or
   b. Advanced Trauma Life Support (ATLS); or
   c. Other advanced life support approved certification approved by the respective hospital's MEC;
   d. Exception: Board Certified/Eligible physician in Anesthesiology or Emergency Medicine.

B. Nursing Competency:

1. Registered Nurses (RN) authorized to administer medications for moderate sedation / analgesia, assess and monitor and/or provide immediate pre-procedure, procedure and post-procedure care to patients receiving moderate sedation /analgesia shall demonstrate and document:
   a. Skills and competency in the management of patients receiving moderate sedation/analgesia including the completion of an initial Moderate Sedation course and competency assessment;
   b. Annual competency assessment for moderate sedation;
   c. Completion of ACLS, and/or Pediatric Advanced Life Support (PALS), and/or Neonatal Advanced Life Support (NALS). Note: PALS and/or NALS are required in those areas where pediatric or neonatal sedation may occur; and
   d. Evidence of competency of arrhythmia recognition and treatment intervention;

2. Be aware of the hospital code blue policies so as to facilitate the summoning of additional personnel capable of advanced life support techniques in a timely manner.

C. Staffing:

1. Sufficient numbers of qualified personnel (in addition to the physician performing the procedure) shall be present during procedures using moderate sedation;

2. The RN will supervise perioperative nursing care;

3. The RN administering, managing and/or monitoring moderate sedation shall have no other responsibilities during the procedures that would leave the patient unattended or compromise continuous monitoring;

4. The registered nurse will monitor Moderate Sedation/Analgesia patients in the following, but not limited to, areas:
   a. Ambulatory Procedure Clinic;
   b. Critical Care;
   c. Emergency Department;
   d. Endoscopy;
e. Invasive and Non-Invasive CVI;

f. Radiology;

g. Surgery; and

h. Recovery – peri-anesthesia care unit (PACU).

D. Equipment and Monitoring:

1. Appropriate equipment for care and resuscitation is available for monitoring vital signs including heart and respiratory rates and oxygenation using pulse oximetry equipment;

2. Heart rate and oxygenation are continuously monitored by pulse oximetry;

3. Respiratory frequency and adequacy of pulmonary ventilation are monitored to include end tidal CO₂ monitors;

4. Blood pressure is measured at regular intervals (at a minimum; every 5 minutes during procedures);

5. EKG is monitored in all patients;

6. Reversible agents shall be readily available;

7. A Crash Cart shall be immediately available.

E. Patient Selection Criteria:

1. American Society of Anesthesiologist (ASA) guidelines for risk classification are utilized in the selection of patient to receive moderate sedation / analgesia:

   a. Class I: A normal healthy patient;

   b. Class II: A patient with mild systemic disease;

   c. Class III: A patient with severe systemic disease that limits but is not incapacitating;

   d. Class IV: A patient with severe systemic disease that is a constant threat to life;

   e. Class V: A morbid patient who is not expected to survive with or without the operation/ procedure;

   f. Class VI: A declared brain-dead patient whose organs are being removed for donor;

   g. E: If the case is an emergency (E), is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part;

2. All patients must be carefully evaluated by the credentialed Provider and stratified in the proper ASA classification:

   a. Patients who are an ASA III or IV, might not be candidates for sedation administered by a non-anesthesiologist;

   b. Consultation with anesthesia should be considered by the credentialed Provider for ASA III or ASA IV patients;

3. Discharged patients must have a responsible, designated adult to escort them home;

   a. This must be established prior to starting the procedure and the patient will not be discharged without an escort.

F. Consent:

1. The patient and/or authorized representative must be informed about the risks and alternatives of sedation as a component of the planned procedure;
a. The Provider shall discuss the proposed plan for sedation with the patient or legally authorized representative prior to the procedure, including:
   i. The relevant benefits, risks, complications or side effects of the procedure and recuperation period;
   ii. The potential for a favorable outcome and/or the likelihood of achieving goals;
   iii. Any reasonable alternatives, including no treatment, and the relevant risks, benefits, and side effects related to reasonable alternatives or no treatment;
   iv. An opportunity for the patient to ask questions; and
   v. If the consent is related to clinical trials or research, the consent will contain the name of the person who provides the related information and the date the form was signed;

2. The Provider shall make a record, in the History and Physical, Progress Note, Operative Note or other appropriate place in the medical chart, confirming that a discussion regarding the elements above was conducted with the patient or other legally authorized representative;

3. Signed consent should be documented utilizing St. John Health System (SJHS) form entitled Authorization and Consent for Surgery, Special Diagnostic or Therapeutic Procedures; and indicate the procedure to be performed under moderate sedation;
   a. Written consent forms will not be presented to the patient for signature until the physician's discussion with the patient about the proposed moderate sedation plan has occurred and an order has been written for the procedure;

G. Nothing by Mouth (NPO) Guidelines:
1. Patients undergoing moderate sedation / analgesia for elective procedures must not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying before their procedure (see guidelines below);
   a. The use of sedation must be preceded by an evaluation of food and fluid intake. Restriction of food and liquids should be as follows; applies to all ages;
   b. Recommendation: Ingested material
      i. Clear liquids 2-h minimum fasting* period
      ii. Breast milk 4-h minimum fasting* period
      iii. Infant formula 6-h minimum fasting* period
      iv. Nonhuman milk 6-h minimum fasting* period
      v. Light meal 6-h minimum fasting* period
      vi. Fried foods, fatty foods or meat 8-h or more may be needed
   c. These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the guidelines does not guarantee complete gastric emptying.
      *The fasting periods noted above apply to all ages. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee. Because nonhuman 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. Additional fasting time (e.g., 8 h or more) may be needed in these cases. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period;

2. **Gastric emptying** may be influenced by many factors including pain, abnormal autonomic function with decreased gastrointestinal motility (e.g., diabetes), pregnancy, morbid obesity and mechanical obstruction predisposing to gastro esophageal reflux;
   a. These patients should be treated in a more conservative regimen of 6 hours for clear liquids;

3. In urgent, emergent, other situations when gastric emptying is impaired the potential for pulmonary aspiration of gastric contents must be considered in determining the timing of the intervention and the degree of sedation/analgesia;

4. If the patient requires an emergency procedure and he or she has not been NPO, conscious sedation may be dangerous;
   a. In such situations moderate sedation/analgesia options must be considered by the Physician who will determine if it will be:
      i. Delayed;
      ii. Done judiciously to avoid unconsciousness and suppression of airway reflexes;
      iii. Not administered; or
      iv. Anesthesia consultation for Endotracheal intubation and general anesthesia.

H. **Patient Management and Monitoring:**

1. **Pre-Procedure:**
   a. Prior to the procedure, it shall be validated that the patient is an appropriate candidate for moderate sedation / analgesia by the physician utilizing the following criteria:
      i. The patient's state of consciousness and medical condition are appropriate for use of moderate sedation / analgesia;
      ii. The patient has an individual sedation plan, which indicates medication(s) to be used for moderate sedation / analgesia;
      iii. Appropriate history and physical are documented in the patient's chart prior to the procedure: and all procedural documentation recorded using the SJHS Moderate Sedation Record to include;
         1. Actual weight in kilograms;
         2. Allergies and previous allergic reactions;
         3. Concurrent medication(s);
         4. Time of last oral intake;
         5. Pertinent medical history including history of tobacco, alcohol, or substance abuse;
         6. History of sedation/anesthesia problems; and
         7. Baseline vital signs incl. blood pressure, heart rate, respiratory rate, and O2 Sat;
iv. Physical exam must include the following:
   1. General neurological status (e.g., mental status, presence or absence of stroke
deficits, etc.);
   2. Airway Assessment (e.g., range of neck motion, Short Chin, Protruding upper teeth);
   3. Pulmonary status;
   4. Cardiac status;

v. ASA Classification documented;

vi. Documented anticipated needs in order to plan for the post-procedural care;

vii. If medications will be administered intravenously, ensure the patient has a functioning IV
     line, saline lock, or intraosseous cannulation;

viii. All patients for moderate sedation should have Oxygen administered via nasal cannula or
     O2 mask.

ix. The patient has:
   1. Been instructed in the concepts of moderate sedation /analgesia and about the
      sedation planned for the procedure;
   2. Been instructed to report any problems associated with the procedure or moderate
      sedation (e.g., pain, tender site, itching, difficulty breathing) to the individual
      responsible for monitoring the patient; and
   3. Reviewed and received written post sedation/procedural instructions;

x. A “time out” must be conducted immediately before starting the procedure as described in
   the Universal Protocol;

xi. Confirmation of the immediate availability of the appropriate IV medications, monitors and
    rescue medications and equipment to include a crash cart and airway supplies;

b. Pre-operative laboratory testing should be guided by the patient's underlying medical condition
   and the likelihood that the results will affect the management of the Moderate Sedation/
   Analgesia;

c. If a history/physical has been completed within the last 30 days and a copy is available in the
   medical record, the Provider shall document significant changes in patient status or that the
   patient has been examined and there are no changes in the history/physical;

d. For hospitalized patients, the current hospital record may suffice for adequate documentation of
   pre-sedation health status;

e. If the clinical or emergency condition of the patient precludes acquiring complete information
   before sedation, this health evaluation should be obtained as soon as feasible;

f. During procedures where a verbal response is not possible (e.g., oral surgery, upper
   endoscopy), the ability to give a "thumbs up" or similar indication of consciousness in response
   to verbal or tactical (light tap) stimulation suggests that the patient will be able to control his
   airway and take deep breaths if necessary. Note that a response limited to reflex withdrawal
   from a painful stimulus represents a greater degree of sedation than that intended under the
   definition of Moderate Sedation/Analgesia;

g. Ventilatory function should be continually monitored by observation, pulse oximetry and ETCO2.
(capnography), (pulse oximetry and ETCO2 monitoring are mandatory for all sedations);

h. Temperature should be monitored and recorded prior to the procedure and at discharge;

i. Monitoring device alarms shall be continuously utilized and a set at appropriate levels;

j. Immediately prior to the initiation of moderate sedation, the patient shall be re-evaluated;

k. The re-evaluation shall be documented on the SJHS form entitled Moderate Sedation Procedure Record;

2. Intra-Procedure:

a. During the procedure, the skilled practitioner(s) whose responsibility it is to monitor the patient shall continuously monitor and document the following vital signs at least every 5 minutes, on the SJHS moderate sedation / analgesia record;

   i. Level of consciousness/responds to verbal commands;

   ii. O2 saturation/pulse oximetry and ETCO2;

   iii. Blood pressure;

   iv. Respiration; and

   v. Heart rate and rhythm;

b. Document all IV fluids, including blood products, and medications(s) administered including route, site, time, dosage, and initials of individual administering medication;

c. Record any oxygen therapy given in liters/minutes or FiO2 and means of oxygen therapy delivery (e.g., nasal prongs);

d. The individual who monitors the patient must inform the Physician of any changes in the patient's physiological status from his/her baseline assessment and record its occurrence, interventions and outcome;

3. Post Procedure and Recovery following Sedation:

a. Following sedation, the patient's vitals and physiological status should be immediately assessed and observed until they are no longer at increased risk for cardio-respiratory depression;

   i. Vital signs should be monitored at least in 5 minute intervals and respirations should be monitored continually until patients return to their pre-procedure level of consciousness;

b. The RN(s) whose responsibility it is to monitor the patient shall ascertain and record the patient's vital signs including:

   i. During recovery and at Discharge;

      1. Level of consciousness;

      2. O2 saturation/pulse oximetry;

      3. Blood pressure; and

      4. Heart rate/rhythm;

c. All patients receiving Moderate Sedation/Analgesia should be monitored until appropriate discharge criteria are satisfied;

   i. The duration of monitoring must be individualized depending upon the level of sedation achieved, the overall condition of the patient, and nature of the intervention for which
sedation was administered;
d. The recovery area should be equipped with appropriate monitoring and resuscitation equipment;
e. A RN should be in attendance whenever a patient is present;
f. Level of consciousness, pain intensity and vital signs (including frequency and depth of respiration in the absence of stimulation) should be recorded at regular intervals during recovery;
   i. The responsible Physician should be notified if vital signs fall outside of reasonable limits or those specifically established for each patient;

4. Guidelines for Discharge;
   a. Ensure the patient meets the following discharge criteria:
   b. The Modified Post Anesthesia Discharge Scoring System or the Modified Aldrete must be ≥9, or baseline score shall be used for those patients discharged home, along with individual evaluation. (See Attachment 3);
      i. Stable vital signs and oxygen saturation, including a finger stick blood sugar (FSBS) for all diabetics, should be evaluated and treated based on individual patient condition;
      ii. Returns to pre-sedation level of consciousness and/or until patient is completely arousable and responsive and/or responding appropriately for age;
      iii. Able to ambulate with minimal assistance if tolerated by physical status and procedure;
         1. The pediatric patient's activity/mobility level is appropriate for their age;
      iv. If discharge criteria are not met, the physician shall be notified;
         1. The physician must reassess the patient and determine appropriate action;
   c. If reversal agents have been given sufficient time (up to 2 hours) should have elapsed following the last administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become re-sedated after reversal effects have worn off;
   d. Patients should be discharged to the care of a responsible adult who will accompany them home and be able to report any post-procedure complications;
   e. Adults responsible for pediatric patients should be warned of the risk of airway obstruction should the head fall forward while the child is in a seated position;
   f. The Anesthesia Department, at its discretion may review any procedures with adverse events/unexpected complications. Procedures resulting in adverse events/unexpected complications shall be reviewed by the departmental Quality Assurance Committee to which the provider belongs, in addition to Peer Review to analyze and identify opportunities to improve patient care.

DEFINITIONS -

A. Deep Sedation/Analgesia: is 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.
B. **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.

C. **Minimal Sedation:** (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

D. **Moderate Sedation/Analgesia:** ("Conscious Sedation") is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, 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.

**REFERENCES -**

42 CFR §482.52;

Joint Commission PC.01.01-PC.03.01.07;

American Society of Anesthesiologist (Anesthesiology 2018; 128: 1-43);

Oklahoma Board of Nursing Policy/Guideline #P-06 Moderate (Conscious) Sedation Guidelines for Registered Nurse Managing and Monitoring Patients,

NIAHO Anesthesia Services Interpretive Guide

**Appendix :**

**Modified Aldrete Scoring System**

<table>
<thead>
<tr>
<th>Respiration:</th>
<th>O2 Saturation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 = able to deep breathe and cough freely</td>
<td>2 = Maintains SpO2 &gt; 92% on room air</td>
</tr>
<tr>
<td>1 = dyspnea</td>
<td>1 = Needs O2 inhalation to maintain O2 saturation &gt; 90%</td>
</tr>
<tr>
<td>0 = apnea</td>
<td>0 = O2 saturation &lt; 90% even with supplemental oxygen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activity (age appropriate, surgery):</th>
<th>Consciousness:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 = able to move 4 extremities voluntarily or on command</td>
<td>2 = Fully awake</td>
</tr>
<tr>
<td>1 = able to move 2 extremities voluntarily or on command</td>
<td>1 = Arousable on calling</td>
</tr>
<tr>
<td>0 = unable to move any extremities</td>
<td>0 = Non-responsive</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Circulation:</th>
<th>Adequate recovery is achieved if Modified Aldrete score is ≥ 9 or if patient has reached baseline post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 = BP± 20mm Hg preop</td>
<td></td>
</tr>
<tr>
<td>1 = BP ± 20-50mm Hg preop</td>
<td></td>
</tr>
<tr>
<td>0 = BP ± 50 Hg preop</td>
<td></td>
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</tbody>
</table>
Clinical and treatment related policies, procedures and protocols are intended as guidelines. It is recognized that situations can be unique and health care providers are expected to follow established practice and sound medical judgment in making decisions and practicing safety in their daily activities.

**Attachments:**

**Approval Signatures**

<table>
<thead>
<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>JEFFREY NOWLIN: President</td>
<td>05/2018</td>
</tr>
<tr>
<td>DAVID PHILLIPS: President</td>
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<td>Michael Christian: Hospital President SJS</td>
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<td>Mike Moore: President</td>
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<tr>
<td>ROSEMARY HOLDERMAN</td>
<td>02/2018</td>
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<tr>
<td>DON MACIVER</td>
<td>02/2018</td>
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</tbody>
</table>

**Applicability**

St. John Broken Arrow, St. John Medical Center, St. John Owasso, St. John Sapulpa