



NATIONWIDE
CHILDREN'S
HOSPITALSM

Patient/Family Care Policy

Nationwide Children's Hospital
Columbus, Ohio

Number: XI-30:50	Originated: 7/93
	Revised: 8/200, 3/2001; 6/02, 11/03, 2/05, 02/09, 4/10, 12/10
Subject:	SEDATION: USE AND MONITORING IN PATIENTS

PURPOSE:

This policy is designed to ensure the provision of one standard of anesthesia and procedural sedation services throughout the institution. It is also intended to provide a uniform approach for the preparation, monitoring, and recovery of patients requiring procedural sedation.

These guidelines are meant to aid in properly and safely managing patients undergoing sedation. The sedation provider will understand the necessity to assess the patient and the intended level of sedation before initiating the procedure. In addition the guidelines reinforce satisfactorily fulfilling the appropriate requirements for personnel, equipment, monitoring, documentation, and pain assessment prior to undertaking any sedation. Sedation is managed before, during and after a procedure, and until the patient is transferred to an inpatient unit or discharge to home.

This policy is written with the awareness that regardless of the level of sedation intended or route of administration, sedation represents a continuum from mild sedation through deep sedation and even into general anesthesia. The deepest level of sedation has a greater risk of the patient losing protective airway reflexes or central control of ventilation. A patient may move easily and quickly from a light level of sedation to obtundation with the loss of airway reflexes and/or apnea. The distinctions among the levels of sedation are made for the purpose of describing the anticipated physiologic responses during the different levels of sedation with the understanding that the medication used cannot be used as a guide as to which level of sedation will be achieved. As such, the guidelines for preparation, personnel, and monitoring of the patient should be strictly adhered as specifically outlined in Attachment 30:50A, regardless of the anticipated level of sedation.

POLICY STATEMENT:

These guidelines do not apply to the following circumstances:

1. The administration of sedative, analgesic or anesthetic medications by anesthesia providers (anesthesiologists or CRNA's) in the operating room.
2. The administration of sedative, analgesic or anesthetic medications by anesthesia providers (anesthesiologists or CRNA's) outside of the operating room.
3. The use of intravenous or non-parenteral (oral, rectal, transmucosal) medications for premedication by anesthesia providers. For example, the administration of oral midazolam for pre-medication prior to an operative procedure.
4. The administration of sedative or analgesic agents in the intensive care unit setting to critically ill patients during acute illnesses. For examples, the continuous or intermittent administration of midazolam or fentanyl to provide sedation and analgesia during mechanical ventilation or following major surgical procedures.

APPROVED: _____

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5. The administration in the intensive care units or pediatric ward of intravenous opioids by intermittent dosing or patient-controlled analgesia (PCA) to provide analgesia during acute illnesses or following surgical procedures.
6. Medical procedures performed using local anesthetic agents.
7. Therapeutic management of patients with seizure disorders.
8. Therapeutic management of patients with chronic pain conditions.
9. The use of sedative medications in appropriate doses to facilitate sleep or in the treatment of insomnia.

The patient's age, developmental level, biophysical/psychological functioning and pre-sedation or "normal" state of activity (baseline) and a need for pain management will be considered when selecting the desired level of sedation, administering the medication(s), monitoring and discharging the patient. Additionally, the goals of sedation (amnesia, immobility, analgesia) will vary based on the type of procedure. A post-sedation level of behavior shall be as close as possible to the normal level for an individual prior to transfer or discharge or the reason why this level has not been achieved should be documented in the record and the patient admitted to the hospital.

RELATED POLICIES:

Patient/Family Care Policy XI-30:30 – Pain Management Protocol

DEFINITIONS:

The definitions below illustrate the differences between the various types of anesthesia services. Not all of the definitions are considered "anesthesia." The definitions are generally based on American Society of Anesthesiologists definitions found in the practice guidelines in *Anesthesiology* 2002;96:1004-1017.

SEDATION LEVELS

Sedation levels are defined by the intended level of altered pain perception, voluntary and involuntary movement, autonomic function, and memory and/or consciousness required to perform a given procedure. Sedation levels are not based on a specific medication or route of administration, but rather the physiologic response of the patient. There are five levels of sedation on the sedation scale, ranging from 0 to 4. The following descriptions define each of the levels.

- **TOPICAL OR LOCAL ANESTHESIA (level 0):** The patient has blunted pain perception through the administration of local or topical anesthetic agents, but responds normally to verbal commands, and coordination is not affected.
- **MINIMAL SEDATION (level 1):** A drug-induced state during which the patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, respiratory and cardiovascular functions are unaffected. For example, a patient undergoing an MRI or CT scan may receive minimal sedation with an oral medication to decrease or eliminate anxiety, and to facilitate the patient's coping skills.
- **MODERATE SEDATION (PROCEDURAL SEDATION) (level 2):** A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or following light tactile stimulation. No interventions are required to maintain a patient's airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. For example, a patient undergoing the

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reduction of a dislocated large joint or fracture may require this form of sedation to tolerate the procedure.

- **MONITORED ANESTHESIA CARE (DEEP SEDATION)** (level 3): A drug-induced depression of consciousness during which patients cannot be easily aroused even to verbal stimulation, but respond purposefully following repeated or painful stimulation. The ability to independently maintain respiratory function or upper airway patency may be impaired. Patients may require assistance to maintain a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- **GENERAL ANESTHESIA** (level 4): A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory function is often impaired. Although spontaneous ventilation may be maintained, hypercarbia may be present. 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.

II. CANDIDATE CLASSIFICATION:

- A. The responsible practitioner must assess and record each patient's suitability for sedation using the American Society of Anesthesiologists (ASA) Class I, II, or III on the Sedation Form AM-69.
- B. **CLASSIFICATION MODIFIED FROM THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS CLASSIFICATION OF PATIENT STATUS:**
 - 1. **CLASS I:** There is no organic, physiologic, biochemical, or psychiatric disturbance. The pathologic process for which operation is to be performed is localized and is not a systemic disturbance.
 - 2. **CLASS II:** mild-to-moderate systemic disturbance caused either by the condition to be treated surgically or by other pathophysiological processes.
 - 3. **CLASS III:** Severe systemic disturbance or disease from whatever cause, even though it may not be possible to define the degree of disability with finality.
 - 4. **CLASS IV:** Indicative of the patient with severe systemic disorder already life threatening, not always correctable by the operative procedure. Requires additional monitoring, location, and staffing.
 - 5. **CLASS V:** The moribund patient who has little chance of survival without the operation so is submitted to operation in desperation. Requires additional monitoring, location, and staffing.
- 6. The procedure being performed is considered an emergency. This qualifier can be placed with any of the above ASA numbers. For examples, 2E.

III. PERSONNEL REQUIRED Refer to Attachment 30:50 A.

- 1. The practitioner responsible for the treatment of the patient and/or the administration of sedation drugs and airway management shall be appropriately trained and deemed competent in the use of such techniques (verified by their Section Chief).
- 2. It is recommended that personnel have specific assignments and current knowledge and competency in response to emergency resuscitation. The sedated patient will be attended by trained personnel at all times. Refer to Attachment 30:50-A.
- 3. The person providing or directing the sedation and monitoring the patient must not also be the one performing the procedure.

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IV. EQUIPMENT AND FACILITY REQUIREMENTS: Refer to Attachment 30:50-A

Sedation shall be performed only in areas of the hospital that can accommodate the necessary personnel, monitoring equipment, and for emergency intervention if needed. All geographic locations for procedural sedation must be similarly prepared and equipped to ensure optimal patient care and safety. Two general levels or types of equipment are specified: 1) standard equipment which is routinely prepared and employed during procedural sedation and 2) emergency equipment which is not routinely prepared prior to procedural sedation, but should be immediately available and fully functional within one minute. Similar standards must be maintained during the transport of patients (Refer to Attachment 30:50A). The equipment and monitoring guidelines follow the recommendations as outlined by the American Academy of Pediatrics (*Pediatrics* 2006;118:2587) and the American Society of Anesthesiologists (*Anesthesiology* 2002;96:1004).

The following equipment is required (Refer to Attachment 30:50 A):

1. A functioning source of oxygen capable of delivering oxygen for 60 minutes to a spontaneously breathing patient and a size-appropriate delivery device such as nasal cannula, simple facemask, CPAP bag, or blow by apparatus.
2. A CPAP device or self-inflating bag-valve-mask device with size-appropriate transparent anesthesia mask for the application of CPAP or assisted ventilation.
3. Advanced airway equipment including size appropriate oral and nasal airways, laryngeal mask airways, laryngoscope and blades, endotracheal tubes, and stylets.
4. A functioning suction apparatus with flexible and rigid (Yankaur) disposable suction catheters.
5. A functioning stethoscope.
6. A multi-channel electrophysiologic monitoring capable of continuous monitoring or electrocardiogram and pulse oximetry as well as intermittent, non-invasive monitoring of blood pressure and body temperature. Continuous monitoring of body temperature is recommended in patients at risk for hypothermia.
7. When nitrous oxide is in use, continuous monitoring of the inspired oxygen concentration, proportioning device to eliminate the possibility of delivering less than 30% oxygen, and a fail safe device to stop the flow of nitrous oxide in the event of an oxygen supply failure.
8. Although not mandated, given the risk of apnea, airway obstruction or hypoventilation during procedural sedation, monitoring of end-tidal carbon dioxide should be considered.
9. Standard pediatric crash cart with defibrillator, intravenous supplies and emergency medications including flumazenil and naloxone (as indicated).
10. As needed, devices to maintain normothermia.

1. MONITORING REQUIREMENTS FOR ALL LEVELS:

PRE-PROCEDURE Refer to Attachment 30:50A

An initial baseline oxygen saturation for non-oral sedation and those patients with potential for airway obstruction; blood pressure, heart rate, respiratory rate, pain assessment and sedation scale are recorded immediately prior to the sedation. For patients at risk of airway obstruction or who will be out of

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visual observation, end-tidal carbon dioxide monitoring is encouraged. These same parameters are recorded every 5 minutes during the procedure.

The practitioner should consider the risks vs the benefits in the timing of the procedure in relation to oral intake. Patients being scheduled for general anesthesia or procedural sedation fall under NPO guidelines for the Department of Anesthesia & Pain Medicine. In specific circumstances, non-adherence to these guidelines is acceptable in the Emergency Department as dictated by the patient's status and the urgency of the procedure.

- **NO** food is permitted 6 hours prior to the procedure.
- Patients may receive formula or breast milk up to 6 (six) hours prior to the procedure by mouth or feeding tube.
- Patients less than 12 months old may receive breast milk up to 4 (four) hours prior to the procedure.
- Patients may receive clear liquids up to 2 hours prior to surgery.
 - CLEAR LIQUIDS ARE DEFINED AS water, apple juice, 7-up or Pedialyte.
 - **THESE ARE NOT CLEAR LIQUIDS:** thickened feeds, milk, popsicles, broth, Jell-O, and orange juice – and these **MUST** be discontinued 6 (six) hours prior to the procedure.
- NOTE: If a child is found chewing gum, then the procedure will be delayed 2 hours from the time the gum is expectorated. If the patient swallows the gum, the procedure will be delayed 6 hours from the time it's swallowed.
- NOTE: If the sedating practitioner, in conjunction with the attending clinician, deems it necessary to proceed under urgent or emergent circumstances without a full NPO time period, then documentation of need should be reflected in the medical record.

DURING THE PROCEDURE Refer to Attachment 30:50 A

The oxygen saturation for those patients with potential for airway obstruction, heart rate, pain level and the sedation level as needed, based on response and level of intended sedation, see pain and sedation scales.

TRANSFER OR DISCHARGE Refer to Attachment I - 30:50 A

- If the patient is to be transferred or discharged, blood pressure, respiratory rate, heart rate, pain scale and sedation level are recorded immediately before transfer or discharge and vital signs must be stable.
- The post-sedation level or behavior shall be back to the patient's normal (baseline) level prior to transfer or discharge.

UPON ARRIVAL TO FLOOR/UNIT: Refer to Attachment 30:50 A

FOR ALL LEVELS:

Blood pressure, heart rate, pain assessment and respiratory rate are recorded according to practitioner order on the floor or unit. The responsibility for the sedated child rests with the sedating physician. Transfer of sedated patients from a procedure site to the inpatient floor requires close communication between the sedating physician and the floor accepting care. If

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the floor is not equipped to accept the patient, then the transferring physician retains responsibility for monitoring unless an alternate unit can be found to accept the patient (i.e. PACU, ED observation, etc.). Monitoring of the child and documentation of the child's status must be uninterrupted during transfer.\

DISCHARGE CRITERIA:

Cardiovascular stability is achieved: the blood pressure, heart rate, and respiratory rate have returned to pre-procedure baseline.

Airway/respiratory stability is achieved. As age and cognitive level appropriate, the patient can take a deep breath and cough. The respiratory rate and depth have returned and pre-procedure baseline.

The patient is in or has returned to the baseline interactive state. There is controlled movement of extremities. The patient can follow commands, is awake, alert, oriented for age or pre-sedation state.

- The post-procedure discharge criteria must be met by assessing the vital signs, pain scale and sedation scale.

ALL LEVELS:

- Practitioners must discharge patient from hospital by order or may be by criteria.
- When the treatment or procedure has been completed, the practitioner or designee, shall assess and discharge the patient when the post-procedure discharge criteria are met by the vital signs, pain scale and sedation scale.
- Patients are returned to the level of care provided prior to the procedure before transfer back to floor/unit. For both outpatients and inpatients, the same discharge criteria apply.

2. DOCUMENTATION - Refer to Attachment 30:50 B. (Sedation Form AM-69 or electronic medical record)

1. All required areas are to be completed by the practitioner or delegate. Documentation is required by practitioner or delegate on the Sedation Documentation Record Form AM-69 or electronic medical record.
2. PRE-SEDATION ASSESSMENT IS LABELED ON THE LEFT MARGIN AND INCLUDES THE UPPER HALF, refer to Form AM-69
 - a. A pre-sedation blood pressure, heart rate, pain assessment, respiratory rate, temperature and intended level of sedation are documented immediately prior to sedation on the form.
 - b. Procedure related benefits / risks, options and alternatives explained and accepted
 - c. A history and physical is complete, a diagnostic history is documented, the airway is assessed using the Mallampati Airway Assessment tool, and a risk assessment is completed with an ASA score assigned.
 - d. All menstruating females and any girls older than 12 years of age will receive a urine pregnancy test before undergoing sedation or anesthesia unless the testing is refused by the parent or legal guardian and the consent form (AM-20) is initialed.
 - e. A Time out is conducted immediately prior to procedure being performed. Patient, procedure and site are all verified utilizing "Time Out" Checklist Form OCC-759.

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3. SEDATION MEDICATION ORDERS:

A practitioner's order is required for medication used for sedation. Practitioner' orders will be carried out in accordance with existing standards, policies, procedures, bylaws of Nationwide Children's Hospital and state laws and regulations.

- a. Verify allergy, weight, right patient, right medication, right dose, right route, right site of administration, and time of administration will be documented and calculated in milligrams per kilogram or per square meter of body surface area. When prescriptions are used, a copy or a note describing the content of the prescription should be in the patient's chart along with a description of the instructions given to the parent.

4. DURING SEDATION: Refer to Attachment 30:50 A for monitoring requirements

5. POST-SEDATION DOCUMENTATION:

- Record time, blood pressure, heart rate, O₂ sat and patient response to pain, and level of sedation.
- The patient is in or has returned to the baseline interactive state.

VII TEACHING:

Teaching related to sedation and pain management will be provided to the patient and family and documented as needed.

VIII.THERAPEUTIC HOLDING

Devices should be age appropriate and used judiciously In general, if an appropriate depth of sedation is achieved, such devices are not needed. If used, they should be checked frequently to prevent chest or limb restriction. The child's head position should be checked frequently to ensure a patent airway.

IX. EDUCATION AND CREDENTIALING:

The purpose of this policy is to ensure one standard of care throughout the institution. Any sedation medication given by any chosen route can result in a state of clinical unconsciousness (i.e., level 4 general anesthesia). Therefore, practitioners and staff must be prepared through training for the possibility of unintentional deeper levels of sedation especially level 3. The following stipulations are made to safeguard against adverse or sentinel events.

1. Practitioners may use any sedative medication approved by the Pharmacy and Therapeutics Committee and dosages for which they have been trained and credentialed.

The process entails:

- Knowledge of the procedural sedation policy statement.
- Current PALS for procedural support staff (NRP/ACLS as age appropriate)
- Knowledge and mastery of the medications being used
- Passing score on credentialing examination (80%)
- Credentialing to be verified by the Chief of Anesthesiology or designee.
- Adherence to guidelines for pre-sedation preparation, NPO status, monitoring, documentation, and recovery of the patient.
- It may also entail taking the NCH procedural sedation course and/or the use of the simulation scenarios to demonstrate competency.

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2. The practitioner (attending) who is supervising sedation must be present on the unit or in the immediate vicinity during the time that the patient is sedated.
3. Adverse drug reactions, sentinel events, or near miss/medication errors will be reported as incident reports and reviewed by the Pharmacy and Therapeutics Committee in conjunction with Quality Improvement Services and Legal Services.

X. CREDENTIALING CRITERIA:

1. The Chairman of the Department of Anesthesiology & Pain Management or designee is responsible for verifying the capability of each member administering sedation.

For Attending Practitioners to administer or supervise sedation:

- Educational materials must be reviewed and mastered concerning the sedation policy as well as all available sedative medications. Sedation policy educational materials are prepared by the Sedation Committee.
- Current PALS verification. (NRP/ACLS as indicated)
- Procedural, sedation, and verification of airway management skills observed and verified by the Chairman of the Department of Anesthesiology & Pain Medicine or designee. These can be based on training and clinical experience in lieu of specific observation or demonstration.
- Achievement of a passing score (80%) on the procedural sedation examination.
- New applicants for sedation privileges must perform 5 sedations proctored by a credentialed practitioner approved by the Chief of Anesthesia or designee.
- Complications of sedation (adverse drug reactions, incident reports or sedation audits) is included as part of ongoing practitioner performance evaluation and reported to the medical staff at least every six months.
- Educational material for sedation shall be reviewed and updated at least every two years.