



Society for Pediatric Sedation Policy Template January 2016

Purpose

The purpose of this document is to outline policy and procedure for the delivery of high-quality care for children receiving sedation to facilitate diagnostic or therapeutic procedures. The goals of high-quality procedural sedation include: 1) to ensure patient safety while minimizing physical discomfort, pain, and negative psychological responses associated with the procedure; 2) to effectively control patient behavior and/or movement to facilitate procedural success; and 3) to return the patient to a state from which safe discharge from medical supervision is possible. Ideally, these patient-specific goals should be met within a system that strives for timely provision of care along with efficient and equitable use of resources.

Goals and Objective

The goal of this policy is to review the care and management of the pediatric patient receiving sedation for diagnostic, therapeutic or minor surgical procedures.

Scope

This policy applies to all pediatric patients receiving minimal, moderate or deep sedation outside the Operating Room or Intensive Care Unit. This policy does not pertain to the administration of General Anesthesia.

Definitions

Procedural Sedation- technique of administering sedatives or dissociative agents with or without analgesics to produce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function

Analgesia- use of a technique or medication to alleviate pain; when systemic analgesic medications are used to alleviate procedural pain with the intent of also controlling the patient's behavior and/or level of consciousness during the procedure, procedural sedation guidelines and policies should be enforced

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 Sedation- a drug-induced depression of consciousness during which patients can respond purposefully to verbal commands, alone or accompanied by light touch; no interventions are required to maintain a patent airway, and cardiovascular function is usually maintained

Dissociative Sedation- a drug-induced trance-like cataleptic state characterized by profound analgesia and amnesia, but not necessarily complete unconsciousness; protective airway reflexes, spontaneous ventilation and cardiovascular stability are usually maintained

Deep Sedation- a drug-induced depression or loss of consciousness during which patients cannot be easily aroused but can respond purposefully to repeated or painful stimulation; the ability to independently maintain airway patency and adequate spontaneous ventilation may be impaired, though cardiovascular function is usually maintained

General Anesthesia- a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation; assistance in maintaining a patent airway is often required; positive-pressure ventilation may be required due to depressed spontaneous ventilation or depression of neuromuscular function, and cardiovascular function may be impaired

Sedation Provider- a physician, dentist, podiatrist, advanced practice nurse or physician's assistant who is credentialed by the Medical Staff to deliver procedural sedation. Credentialing requirements may differ by level of sedation and may vary among institutions; however, recognizing that sedation is a continuum and patient responses to sedation may be unpredictable, the sedation provider should possess adequate knowledge and skills to prevent, recognize and/or treat patient compromise during a sedation event

Sedation Scale- a calibrated descriptive system designed to quantitatively rank patient response during procedural sedation; typically four to seven levels ranging from agitation to obtundation; may include general level of consciousness and/or response to prescribed maneuvers, such as verbal command or glabellar tap. Examples include the Ramsay scale, Children's Hospital of Wisconsin Sedation Scale, and the University of Michigan Sedation Scale (UMSS) (see Appendices C1-3).

Recovery Scale- a calibrated descriptive score designed to quantitatively rank patient return to baseline level of function following a procedural sedation event; typically incorporates both level of consciousness as well as physiologic measures. Examples include Pediatric Post-Anesthesia Discharge Score (PADSS), the Vancouver Sedation Recovery Scale (VSRS), and Modified Aldrete Score (see Appendices C1-7). Sedation providers should consider using a more conservative patient recovery scale if administering long acting sedatives (ie, the Modified Maintenance of Wakefulness Test, see Appendix C7).

Procedure

A. General Guidelines

a. Patient selection and Preparation

1. **Pre-Sedation Evaluation:** A focused history and physical examination must be performed and documented in the medical record by a sedation provider within 30 days of the procedure with review and updates documented (medical history, patient interview and exam) with 48 hours of the procedure (per JC/CMS).

a. The minimum necessary content of pre-sedation assessment includes:

1. Sedation/anesthesia history, including relevant family history
2. Review of systems including
 - a. Major organ system/medical abnormalities
 - b. History of anatomical features causing actual or potential airway compromise
3. Drug/food allergies
4. Current medications and potential drug interactions
5. Current vital signs
6. Physical exam of heart, lungs, airway structures, habitus
7. Pre-procedure labs as needed
8. Pregnancy status for menstruating females should be established per institutional policy

9. Documentation of most recent solid and fluid intake. (See Appendix A for recommended NPO Guidelines for elective procedures.)
 - a. For urgent or emergent procedures, the benefits of the procedural sedation must be weighed against the risk of vomiting and aspiration associated with shorter fasting periods.
 10. ASA status (see Appendix B) and sedation plan should be documented.
 - b. The pre-sedation evaluation is reviewed along with pre-procedural vital signs immediately prior to sedation, and any changes in the patient's condition are documented.
 - c. For deep sedation, the pre-procedure evaluation must be performed by a practitioner qualified to administer deep sedation (per CMS).
 - d. The sedation provider should reevaluate the patient immediately before administering moderate or deep sedation (per JC).
 2. Consent: Informed Consent for the use of sedation will be discussed with the patient/legal guardian prior to the procedure, including the risks, benefits, and alternatives to sedation. Informed consent is not required for minimal sedation.
 3. Vascular Access: Patients who are reasonably expected to be deeply sedated should have IV access in place for the sedation. Those with anticipated minimal or moderate sedation levels may have an IV in place or have a person skilled in establishing vascular access immediately available.
 4. Consultation/Referral: Consider consultation with Anesthesiology or Critical Care for patients with ASA Status of ≥ 3 or those with significantly increased risk of complications during the sedation.
 5. The sedation provider should offer preprocedural education to the patient and family regarding the sedation plan of care.
- b. Personnel
- i. Licensed Independent Practitioner (LIP)
 1. Competency/Credentialing Requirements: LIP and support personnel must be qualified and credentialed (per hospital policy and state law) to administer the planned sedation, monitor appropriately, and safely detect and manage complications of the sedation.
 - a. At least basic life support skills training are required for those monitoring patients with moderate sedation. Current advanced life support skills training and completion of the appropriate institution sedation exam/certification are required for deep sedation practitioners.
 - b. Practitioners should be qualified to rescue patients from at least one sedation level deeper than anticipated.
 - c. Per CMS, MAC/deep sedation may only be administered by the following types of practitioners who conform to generally accepted standards of anesthesia care:
 1. a qualified anesthesiologist
 2. a non-anesthesiologist MD or DO
 3. A dentist, oral surgeon, or podiatrist who is qualified to administer deep sedation under state law
 4. A CRNA or anesthesiologist's assistant supervised by an anesthesiologist

d. Patients receiving propofol should receive care consistent with at least deep sedation via appropriately credentialed practitioners.

2. Responsibilities:

a. At least one individual who is not performing the procedure should monitor the patient throughout the sedation/analgesia.

1. Moderate sedations require a sedation provider to consistently monitor and record the patient's vital signs and sedation level.

This individual may also assist with interruptible, short, procedure-related tasks.

2. Deep sedations require the sedation provider's exclusive attention to the patient's monitoring without other procedure-related duties.

c. Equipment and Supplies

i. An emergency cart containing equipment and drugs suitable for children of all ages and sizes being treated, including appropriate reversal agents.

1. Defibrillator should be immediately available for moderate sedation of children with cardiovascular disease and for all deep sedation patients.

ii. Functioning suction apparatus with appropriate suction catheters.

iii. Positive pressure oxygen delivery system, capable of administering >90% oxygen

1. Supplemental oxygen (ex. nasal cannula) should be considered for moderate sedation and is recommended during deep sedation

iv. Blood pressure monitoring device

v. Continuous pulse oximetry for monitoring oxygen saturation and heart rate

vi. Capnograph recommended for moderate sedation, required for deep sedation or when direct patient visualization is not possible (ex. MRI, darkened room).

vii. EKG monitor: For moderate sedation, EKG is recommended in those patients with significant cardiovascular disease or when dysrhythmias are anticipated or detected.

EKG monitoring is recommended for all deep sedation.

d. Pharmacology: Refer to Institutional Pharmacy Formulary for sedation related pharmacological information.

e. Documentation

i. Procedural sedation information must be appropriately documented on the institutional EMR or paper form.

ii. Required documentation

1. Pre-sedation assessment including sedation plan, and reevaluation of the patient status immediately prior to the sedation medication administration.

2. Standardized pre-procedural "Time Out" to confirm patient identification, procedure and site of procedure (See Appendix D)

3. Name, dosage, time, and route of all medications and fluids given

4. Patient positioning

5. Insertion of any intravascular or airway devices

6. Intra-procedural Monitoring with Time-based documentation

a. Minimal sedation: Continuous pulse oximetry for heart rate and oxygenation plus direct observation assessing airway, respiratory and neurologic function.

b. Moderate sedation: The following should be documented per institutional policy (every 5 minutes recommended per ASA, every 10 minutes per AAP):

- i. Continuous pulse oximetry
 - ii. Heart rate
 - iii. Respiratory rate and effort
 - iv. Blood pressure unless doing so would interfere with the procedure (which should be documented with subsequent qualitative monitoring of cardiovascular function by direct observation)
 - v. Electrocardiogram (EKG) assessment is recommended in those patients with significant cardiovascular disease or when dysrhythmias are anticipated or detected.
 - vi. Capnography use may be considered when the practitioner is present with the patient, but it is strongly recommended when patients are physically separated from the caregiver (ex MRI).
- c. Deep sedation: Documentation every 5 minutes of the same qualities as in moderate sedation but with the addition of continuous capnography and EKG monitoring recommended for all patients.
7. Any complications, adverse reactions, or problems occurring during the sedation including treatments and patient's response to treatments.

B. Recovery Considerations

- a. The patient will remain on continuous monitoring and supportive oxygen therapy until stable.
- b. Vital signs, including heart rate, respiratory rate, blood pressure, level of consciousness and oxygen saturation are documented every 10-15 minutes until the patient meets discharge criteria.
- c. Preterm infants (less than 37 weeks gestation at birth) who are less than 60 weeks post-conceptual age (PCA) and full term infants (greater than 37 weeks gestation at birth) who are less than PCA of 48 weeks who have received sedation should be monitored for 12 hours post-sedation before being discharged from the monitored environment.
- d. For deep sedation, a post-anesthesia evaluation must be completed within 48 hours after the procedure when the patient is sufficiently recovered from the acute sedation by a practitioner qualified to administer deep sedation per state law/hospital policy.
 - i. The post-anesthesia evaluation should include:
 - 1. Respiratory function: respiratory rate, oxygen saturation, airway patency
 - 2. Cardiovascular function: heart rate, blood pressure
 - 3. Mental status
 - 4. Temperature
 - 5. Pain
 - 6. Nausea/vomiting and postoperative hydration status
 - 7. Complications
 - 8. Disposition
- e. A qualified LIP discharges the patient from the recovery area after achievement of standardized discharge criteria per institutional policy. (See Appendices C1-7)
- f. The patient should be returned to the pre-sedation standardized score with baseline vital signs and can be discharged when:
 - i. Easily awakened, appropriately oriented and/or returned to baseline
 - ii. Vital signs are stable
 - iii. There is no need for supplemental oxygen (or patient has returned to the baseline oxygen requirement)
 - iv. Nausea and vomiting are absent or well controlled
 - v. Pain is controlled

- vi. Discharge instructions are given to the person responsible for the care of the patient and are reviewed verbally. (See Appendix E)

C. Quality Monitoring

- a. Sedation patient care processes, adverse events, and outcomes should be reviewed regularly with appropriate action taken per institutional protocol

Links and References:

American Academy of Pediatrics, American Academy of Pediatric Dentistry Coté, C. J., Wilson, S., & Work Group on Sedation. (2006). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. *Pediatrics*, 118(6), 2587-2602.

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American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. (2002). Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology*. Apr;96(4):1004-17.

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Godwin, S. A., Burton, J. H., Gerardo, C. J., Hatten, B. W., Mace, S. E., Silvers, S. M., American College of Emergency Physicians. (2014). Clinical policy: procedural sedation and analgesia in the emergency department. *Annals of Emergency Medicine*, 63(2), 247-258.e18.

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Green, S. M., Roback, M. G., Kennedy, R. M., & Krauss, B. (2011). Clinical practice guideline for emergency department ketamine dissociative sedation: 2011 update. *Annals of Emergency Medicine*, 57(5), 449-461. doi:10.1016/j.annemergmed.2010.11.030

www.ncbi.nlm.nih.gov/pubmed/21256625

American Society for Anesthesiologists Guidelines for Credentialing Non-anesthesiologists for Moderate and Deep Sedation

<http://www.asahq.org/resources/standards-and-guidelines>

APPENDIX A
NPO GUIDELINES

Summary of Fasting Recommendations: Elective Procedures for Healthy Patients

Ingested Material Minimum Fasting Period

Clear liquids¹: 2 hours

Breast milk: 4 hours

Infant formula: 6 hours

Nonhuman milk²: 6 hours

Light meal³: 6 hours

Heavy meal⁴: 8 hours

1. Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.
2. Because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
3. A light meal typically consists of toast and clear liquids.
4. Examples of heavy meals include fried or fatty foods or meat which may prolong gastric emptying time. Additional fasting time (*e.g.*, 8 h or more) may be needed in these cases.
5. In emergency situations when NPO guidelines cannot be followed, the procedure should be delayed if possible. The increased risks of sedation should be weighed against the benefits. Consider consulting Anesthesia Services if the patient requires a protected airway.

Adapted from: *Anesthesiology* 2011;114 (3):495-511

APPENDIX B

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PHYSICAL STATUS SCORE

PS 1- A normal healthy patient

PS 2- A patient with mild systemic disease (ie controlled asthma/gastroesophageal reflux/hypertension/diabetes mellitus/malignancy)

PS 3- A patient with severe systemic disease (ie poorly controlled asthma/ gastroesophageal reflux/hypertension/diabetes mellitus/malignancy, morbid obesity)

PS 4- A patient with severe systemic disease that is a constant threat to life (ie status asthmaticus, cardiomyopathy, congestive heart failure)

PS 5- A moribund patient who is not expected to survive without the procedure

Reference: American Society of Anesthesiologists, “ASA Physical Status Classification System.” Last approved by the ASA House of Delegates on October 15, 2014.

APPENDIX C1
SEDATION SCALE/SCORE

Ramsay Sedation Scale

- 1 Patient is anxious and agitated or restless, or both
- 2 Patient is cooperative, oriented, and tranquil
- 3 Patient responds to commands only
- 4 Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
- 5 Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
- 6 Patient exhibits no response

Reference: *Critical Care* 2008, 12(Suppl 3):S2

APPENDIX C2

SEDATION SCALE/SCORE

Children's Hospital of Wisconsin Sedation Scale

- | |
|---|
| <p>6 Inadequate- anxious, agitated or in pain</p> <p>5 Minimal- spontaneously awake without stimulus</p> <p>4 Drowsy- eyes open or closed, but easily arouses to consciousness with verbal stimulus</p> <p>3 Moderate-deep- arouses to consciousness with moderate tactile or loud verbal stimulus</p> <p>2 Deep- arouses slowly to consciousness with sustained painful stimulus</p> <p>1 Deeper- arouses, but not to consciousness, with painful stimulus</p> <p>0 Anesthesia- unresponsive to painful stimulus</p> |
|---|

Reference: Pediatrics. 2002 Feb;109(2):236-43.

APPENDIX C3

SEDATION SCALE/SCORE

University of Michigan Sedation Scale

- 0 Awake and alert
- 1 Minimally sedated: tired/sleepy, appropriate response to verbal conversation and/or sound
- 2 Moderately sedated: somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command
- 3 Deeply sedated: deep sleep, arousable only with significant physical stimulation
- 4 Unarousable

Reference: Br J Anaesth. 2002 Feb;88(2):241-5.

APPENDIX C4

SEDATION SCALE/SCORE

Modified Aldrete Scoring System

ACTIVITY	Able to move all extremities voluntarily on command	2
	Able to move 2 extremities voluntarily on command, some weakness	1
	Unable to move extremities	0
RESPIRATION	Able to deep breathe and cough without assistance	2
	Requires airway assistance	1
	Apnea	0
CIRCULATION	Blood pressure and heart rate are within 20% of pre sedation level	2
	Blood pressure and heart rate are within 20-50% of pre sedation level	1
	Blood pressure and heart rate are less than 50% of pre sedation level	0
CONSCIOUSNESS	Fully awake, able to answer questions as appropriate	2
	Arousable with verbal stimulation	1
	Unresponsive	0
OXYGENATION	Able to maintain oxygen saturation >92 percent on room air	2
	Requires supplemental oxygen to maintain oxygen saturation >92 percent	1
	Oxygen saturation <92 percent even with supplemental oxygen	0

References:

Anesthesiology 2002;96:742

J Clin Anesth 1995;7:89-91

Anesthesia and Analgesia 1970;49:924-934

APPENDIX C5
SEDATION SCALE/SCORE

Post Anesthesia Discharge Scoring System (PADSS)

VITAL SIGNS	Within 20% of preoperative value	2
	20-40% of preoperative value	1
	>40% of preoperative value	0
ACTIVITY AND MENTAL STATUS	Oriented x 3 AND has a steady gait	2
	Oriented x 3 OR has a steady gait	1
	Neither	0
PAIN, NAUSEA, AND/OR VOMITING	Minimal	2
	Moderate	1
	Severe, requiring treatment	0
SURGICAL BLEEDING	Minimal	2
	Moderate, having required treatment	1
	Severe	0
INTAKE AND OUTPUT	Has had PO fluids AND voided	2
	Has had PO fluids OR voided	1
	Neither	0

Total PADSS score= 10

Score ≥ 9 are considered fit for discharge

Reference: J Clin Anesth. 1995 Sep; 7(6):500-6

APPENDIX C6

SEDATION SCALE/SCORE

Vancouver Sedative Scale

Response	Awake/alert	4
	Awake/drowsy	3
	Asleep/easily aroused	2
	Asleep/difficult to arouse	1
	Asleep/unable to arouse	0
	Responds fully to stimuli in an age appropriate manner	2
	Delayed response to stimuli	1
	Absent response to stimuli	0
	Alert facial expression	1
	Flat facial expression	0
Eyes	Bright eyes	1
	Dull eyes;glazed	0
	Looks “at you”	1
	Looks “through” you	0
	Accommodates	1
	Does not accommodate	0
	Recognition of stimulus	1
	Limited or no recognition of stimulus	0
	Purposeful and spontaneous eye movement	1
	Little or no spontaneous or purposeful eye movement	0
Movement	Spontaneous and varied central activity	4
	Spontaneous and varied peripheral activity	3

	Central activity in response to stimuli	2
	Peripheral activity in response to stimuli	1
	No movement	0
	Absence of tremor or ataxia	2
	Minor ataxia or tremor	1
	Major ataxia or tremor	0
	Coordinated spontaneous movement	2
	Weak/coarse spontaneous movement	1
	No purposeful spontaneous movement	0
	Shows age-appropriate manual dexterity	2
	Awkward or clumsy hand movement	1
	No fine hand movement	0

Maximum score=22 (fully awake)

Minimum score= 0

Reference: Can J Anaesth. 1994 Oct;41(10):913-8

APPENDIX C7

SEDATION SCALE/SCORE

Modified Maintenance of Wakefulness Test

- A simple visual observation of the time that the child is able to maintain wakefulness in a soporific environment (*i.e.*, dim, quiet room)
- Time is measured from when the the child awakens through the time the child seems to fall asleep again (*i.e.*, eyes closed, relaxed facial muscles, deepened regular respiratory pattern).
- Children are considered awake if they are able to open their eyes and respond appropriately to parents or caregivers.
- Children are considered ready for discharge with a MMWT of at least 20 minutes.

Reference: Malviya, S, Voepel-Lewis, T, Ludominsky, A, Marshall, J and Tait, A (2004). Can we improve the assessment of discharge readiness?, *Anesthesiology* 100: 218-224.

APPENDIX D

TIME OUT PROCEDURE

RN / SEDATION PROVIDER VERIFIES:

- Correct patient with verification of 2 forms of identification

- Brief statement of Medical History
- Procedure (Including indication)
- Site / Side
- Patient Weight
- Allergies
- NPO Status
- Emergency equipment

Sedation Plan

- Consent Form
- Risk of Difficult Airway
- Potential for challenges
- Medication doses
- Reversal medication doses (if applicable)

Reference: Adapted from several institutions' policies

APPENDIX E
DISCHARGE INSTRUCTIONS

Your child was sedated today and received the following medications: _____(med/dose/time). Although your child is now awake and ready to be discharged, he/she may still be affected by the medications. Please follow the guidelines below in caring for your child.

ACTIVITY- Your child may be sleepy, dizzy or less alert for the remainder of the day. Infants may not be able to hold their heads up without help, and toddlers/older children may be uncoordinated. Do NOT let your child walk around without being supervised. Do NOT let your child participate in any sports or other activities for the next 24 hours.

DIET- Your child may feel nauseous while the sedation medications are still in his/her system. You may give your child fluids to drink as instructed, and advance the diet as tolerated.

MEDICATIONS- Your child may continue with usual medications as scheduled.

SLEEP- Your child may be irritable or hyperactive when awake.

Take your child to the nearest Emergency Department for any of the following issues:

- a. Frequent vomiting (unable to keep fluids down)
- b. Difficulty breathing
- c. Difficulty waking your child up

I have read and understand these discharge instructions.

Parent/Guardian signature

Discharging RN signature

Date/Time

Reference: Adapted from several institutions' policies