Children's Hospital and Health System Patient Care Policy and Procedure

This policy applies to the following entity(s): Fox Valley Hospital Milwaukee Hospital Specialty Clinics

SUBJECT: Procedural Sedation

Table of Contents

Definitions	1
POLICY	3
STEPS IN MODERATE OR DEEP SEDATION	5
Sedation techniques with higher risk for complications include:	6
SEDATION MONITORING AND PERSONNEL REQUIREMENTS	11
References	13
APPENDIX 1:AMERICAN ACADEMY OF PEDIATRICS GUIDELINES	15
APPENDIX 2: AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS GUIDE	18
APPENDIX 3: Recommended Process for Procedural Sedation (Example)	20
APPENDIX 4:Sedation Privleges	21
Minimal sedation ("formally anxiolysis"):	21
Moderate sedation/analgesia ("conscious sedation")	21
Deep sedation/anesthesia	21
Appendix 5: Medications Commonly Used for Procedural Sedation (Based on Lexicomp© online resource	e) 23

Definitions

<u>Sedation Score:</u> The rationale for sedation scoring is to guide quantitative assessment of depth of sedation. The following scale is an adaptation of the Ramsey sedation scale for a wider range of sedation continuum.

Sedation Scoring Scale (based on the Ramsey Sedation Sc	cale)
---	-------

	MINIM	AL	MODERATE		DEEP	
6 Agitated, anxious, or in pain above baseline	5 Spontaneously awake without stimulus; may exhibit anxiolysis	4 Drowsy but easily arouses to consciousness to light tactile or verbal/tactile stimulus	3 Arouses to consciousness with moderate tactile or loud verbal stimulus	2 Arouses slowly to consciousness with sustained painful tactile stimulus	1 Arouses, but not consciousness, with painful stimulus	0 Unresponsive to painful stimulus

Minimal Sedation (Formerly anxiolysis):

Normally with a sedation score of 4 or 5. A drug-induced state during which patients respond normally to verbal commands, although cognitive function and coordination may be impaired. No interventions are required to maintain consciousness, and airway patency and spontaneous ventilation are adequate.

Moderate Sedation:

Normally associated with a sedation score of 3. A drug-induced state of depressed consciousness in which the patient responds purposefully to tactile or loud verbal stimuli. Interventions are typically not required to maintain a patent airway, and spontaneous ventilation is adequate.

Deep Sedation:

Normally associated with a sedation score of <3. A drug-induced state of depressed consciousness and decreased arousability in which the patient cannot be easily aroused to consciousness, but may respond following repeated intense, or sustained painful stimulation. Consciousness may not be maintained after cessation of stimulation. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained (in an otherwise healthy patient).

Anything less than 3 is deep sedation. There is no functional distinction between general anesthesia and deep sedation. General anesthesia predictably alters respiratory, cardiovascular, and autonomic function and usually requires specific monitoring and interventions for those effects.

Procedures:

Therapeutic and diagnostic procedures involving puncture or incision of the skin or insertion of an instrument or foreign material into the body including, but not limited to, percutaneous aspirations and biopsies, reduction of fractures, venipuncture, intravenous therapy, cardiac and vascular

catheterization, and endoscopies; diagnostic testing including, but not limited to, injection of radiographic contrast media, dental procedures, echocardiography, and neurophysiologic testing, infant and toddler pulmonary function testing, dressing changes and burn care.

<u>Continuous</u>: Without any interruption.

Vital Signs: Blood pressure, pulse rate, respiratory rate, and oxygen saturation.

Immediately Available: Able to be physically present and functional within two minutes.

Infant: A child that is less than 9 months of age (for the purpose of this policy and procedure).

Full-Term infant: A child that is greater than or equal to 37 weeks gestation at birth. **Pre-Term Infant:** A child that is less than 37 weeks gestation at birth.

Post Conceptual Age:

Gestational age in weeks plus the number of weeks of life the patient is on the day of the procedure (Example: a 34 week preemie who is 8 weeks old on day of procedure has a post conceptual age of 42 weeks).

Physician/Dentist Designee:

Licensed by the state and privileged by the hospital to act as an intermediary of a supervising member of the appropriately privileged medical/dental staff in accordance with written policies and protocols within their scope of practice e.g. physician assistant (PA), or nurse practitioner (NP).

CRM: Cardiac Respiratory Monitor

POLICY

Procedural sedation is the process of giving a sedative, hypnotic, or analgesic drug, by any route, which may result in partial loss of consciousness and/or protective reflexes in order to facilitate a diagnostic or therapeutic procedure.

This policy, therefore, does NOT apply to the following:

- Administration of analgesic, sedative, or hypnotic drugs for indications other than procedural sedation.
- \circ $\;$ Patients who have already undergone tracheal intubation and ventilation
- o Administrations of agents to facilitate airway management or tracheal intubation.
- Use of pre-medication prior to the administration of moderate sedation, deep sedation or general anesthesia for a procedure.

Milwaukee Campus: For patients going to Froedtert for sedation please see the policy: "Transporting and Monitoring Patients Going to Froedtert Hospital for Ancillary Services and Procedures."

Fox Valley Campus: For patients going to ThedaCare Regional Medical Center Neenah for sedation please see the policy: "Transporting Patients going to ThedaCare Regional Medical Center-Neenah (TCN) for Ancillary Services and Procedures/Surgery."

<u>Purposes</u>

- 1. To maximize patient safety and comfort during diagnostic and therapeutic procedures, with the understanding that pediatric patients may require sedation for minimally painful procedures to minimize psychological distress, provide safe conditions for the procedure, and improve the quality or outcome of the procedure;
- 2. To provide guidelines for assessment of risk prior to procedures to aid in planning sedation and recovery care;
- 3. To provide tools for assessment of level of sedation during and after the planned procedure;
- 4. To ensure that patients undergoing sedation for a procedure receive a consistent standard of care regardless of location.

Rationale

Unconsciousness is accompanied by physiologic deterioration and increased patient risk. Minimal sedation, moderate sedation, deep sedation, and general anesthesia are descriptions of points along a **continuum of unconsciousness** in which progressive loss of protective reflexes produces progressive increase in physiologic change and potential risk to the patient.

Therefore, application of these standards and monitoring requirements shall be based upon the **intended** state of the patient. If the patient's **actual** state of sedation exceeds the **intended** state, the standards and monitoring requirements for the **actual** state of sedation the patient reached are required.

- 1. Overall responsibility for procedural sedation lies with an appropriately privileged member of the medical/dental staff who must be immediately available during the procedure and recovery. The responsibility of patient monitoring, ordering, and medication administration may be delegated to another qualified individual, but the direction of sedation will be maintained by the appropriately privileged member of the medical/dental staff.
- 2. The appropriately privileged member of the medical/dental staff directing sedation must have clinical privileges as described in Appendix 4 of this policy and the appropriately privileged member of the medical/dental staff and their designee must be:
 - a. Trained in basic life support
 - b. Trained in the administration and effects of sedatives/analgesics.

Revised: 10/4/2023 Effective: 10/6/2023 Procedural Sedation/Process Owner: Manager of Imaging

- 3. The appropriately privileged member of the medical/dental staff directing deep sedation will also be trained in advanced airway management. Such training may be accomplished through ACLS (advanced cardiac life support), PALS (pediatric advanced life support), or similar advanced training, with approval of the chief of anesthesiology.
- 4. The person performing the procedure and the person assisting with the procedure must not be the person monitoring the patient.
- 5. All medications administered for the purpose of procedural sedation will be ordered by an appropriately privileged member of the medical/dental staff or their designee.

PROCEDURE

STEPS IN MODERATE OR DEEP SEDATION

- 1. A focused medical **history** and physical **exam** shall be performed by a physician or physician/designee (not the RN) prior to administering moderate or deep sedation and documented in the electronic medical record (EMR). History and physical must comply with requirements as outlined in the "Medical Staff Rules and Regulations".
- 2. A **pre-sedation assessment** must be performed within 48 hours prior to the procedure. (If the H&P meets all the requirements of the pre-sedation assessment as outlined below, it may be used to meet the pre-sedation assessment requirements).

The Pre-sedation assessment shall include the following:

- *health and risk assessment health history including allergies, current medications, current health problems, previous hospitalizations, previous sedation/anesthesia history, known pregnancy status, alcohol and illicit drug use
- *weight
- *American Society of Anesthesiologists (ASA) physical status
- *mental status
- *assessment of airway opening and patency
- *NPO status
- *Prematurity status of infants less than 9 months old
- respiratory status
- cardiovascular status

Items with a (*) may be delegated by the appropriately privileged member of the medical/dental staff or their physician designee to a clinician <u>who has demonstrated</u> <u>competency in pre-sedation assessment when the pre-sedation assessment is not also serving</u> <u>as the H&P</u>. The appropriately privileged member of the medical/dental staff or their physician designee is responsible to review all of the delegated items before ordering sedation.

3. An immediate pre-sedation assessment shall be performed and documented in the EMR

which at a minimum includes baseline vital signs immediately prior to administration of sedation.

4. For non-hospitalized or ambulatory clinic patients before procedure:

All Patients

- a. Verify that there is a responsible adult to accompany the patient home. If not, cancel procedure and reschedule patient for another time.
- b. Document that instructions have been given to the patient, or their parent/legal guardian, if appropriate, to avoid drinking alcohol, driving, operating heavy machinery (or other injury prone physical activity), or making any major decisions after the procedure for 24 hours.

Children in Child/Safety Seats (See Car Seat Safety):

- a. Provide special instructions to the responsible adult who will transport children home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction.
- b. Consider a longer period of observation, if the responsible person's ability to observe the child is limited (e.g., only 1 adult who also has to drive). This is especially important for infants and toddlers who have received medications with a known long half-life.
- 5. A **plan of care for sedation will be developed** by the appropriately privileged member of the medical/dental staff or their physician designee based on the assessment data, including documentation of patient risk, assignment of an ASA physical status (American Society of Anesthesiologists Classification of Physical Health) (Appendix 2), risk of procedure, and risk of planned sedative technique.

Patients at high risk for procedural sedation complications include patients with:

- a. inadequate NPO time (see Appendix 1)
- b. upper airway obstruction (e.g. stridor when awake or tonsilar hypertrophy) sleep apnea or significant snoring
- c. mandibular hypoplasia, craniofacial abnormalities, or history of difficult airway during anesthesia or sedation
- d. active vomiting, delayed gastric emptying
- e. significant gastro-esophageal reflux, particularly with history of aspiration
- f. preexisting significant neurologic dysfunction or depressed consciousness
- g. hypovolemia, cardiac disease, or other potential for alteration in perfusion
- h. pneumonia, reactive airway disease, or other disorder of gas exchange or pulmonary mechanics
- i. history of sedation failure
- j. ASA class 3 and 4

Sedation techniques with higher risk for complications include:

- a. deep sedation, regardless of intended depth or drugs administered
- b. non-elective sedation
- c. combination drug therapy, particularly opioids and hypnotics
- d. medications administered in large doses instead of titration
- e. use of high-potency or ultra-short duration drugs with low therapeutic index

Revised: 10/4/2023 Effective: 10/6/2023 Procedural Sedation/Process Owner: Manager of Imaging

- f. use of opioids for sedation instead of analgesia.
- 6. If the physician designee is ordering sedation, the appropriately privileged member of the medical/dental staff directing sedation and their physician designee evaluate the patient's sedation plan and pre-sedation assessment, addressing both patient and technique- specific factors and the appropriately privileged member of the medical/dental staff documents in the record agreement with the plan for sedation in the EMR.
- 7. Except for in emergency situations, **informed consent** for procedural sedation must be obtained from the patient, parent, or legal guardian by the appropriately privileged member of the medical/dental staff or their physician designee and documented in the pre-sedation assessment note in the EMR before the procedure. This consent may or may not be a part of the procedure itself.
- 8. Documentation of steps 1-8 shall be completed prior to medication administration in the EMR.
- 9. The sedation risk assessment, addressing both patient and technique-specific factors as described in # 2 above, shall be reviewed immediately prior to the administration of medication by the registered nurse or respiratory care practitioner and the appropriately privileged member of the medical/dental staff directing the sedation or physician designee.
- 10. For moderate sedation, the appropriately privileged member of the medical/dental staff directing sedation must be **immediately available**. For deep sedation, the appropriately privileged member of the medical/dental staff directing the sedation must be **present and available**.
- 11. Appropriate procedural sedation **equipment** must be immediately available and operational at all times during procedural sedation and recovery. Refer to grid: "Sedation Monitoring and Personnel Requirements" for application requirements.
- 12. If, at any time, **the sedation score is 2 or less** (unless deep sedation was planned), the appropriately privileged member of the medical/dental staff directing the sedation will be immediately notified and come to the bedside; intensified monitoring, support and interventions will be instituted as indicated.
- 13. Monitoring as outlined in the "Sedation Monitoring and Personnel Requirements Grid":
 - a. will begin when medication is given and continue at 5-minute intervals until sedation score of ≥ 4 post procedure, and then every 15 minutes until discharge criteria (identified below) are met.
 - b. The clinician responsible for monitoring the patient must be able to immediately meet the patient needs.
 - c. Vital signs must be monitored and recorded in the medical record per policy.
 - d. Providers may only order vital signs to be taken more frequently than the policy.
 - e. The registered nurse may delegate vital signs as outlined in the "Clinical Delegation by Registered Nurses" Policy. However, the RN must be present during procedure, evaluate all vital signs, and perform assessments at the required intervals.
- 15. All patients that received a **reversal agent** must be monitored for at least 90 minutes after the final administration of any reversal agent.
- 16. **Discharge Criteria**: **If the patient is not an infant (see below for infant requirements)**, the patient is discharged/discontinued from procedural sedation monitoring upon meeting <u>all</u> of the following discharge criteria:
- a. The time of maximum/peak effect of the medication (as listed in the Pediatric Dosage Revised: 10/4/2023 Effective: 10/6/2023

Handbook (Lexi Com) has passed

- b. If the patient received a reversal agent, the patient must be monitored for at least 90 minutes after the final administration of any reversal agent
- c. The sedation score is 4 or greater
- d. Cardiovascular and airway stability is established at pre-intervention status
- e. Oxygen saturation is at pre-intervention status
- f. Pain is adequately controlled
- g. Nausea/vomiting is controlled
- h. All post procedural orders have been completed

If above criteria are not met within 2 hours, the appropriately privileged member of the medical/dental staff directing the sedation is notified and the status for discharge is determined by the appropriately privileged member of the medical/dental staff.

17. Infant Monitoring Requirements (*See flow diagram below)

• At minimum all infants less than 9 months old require recovery for 2-hours after the maximum/peak effect of the medication (see Appendix 5). See below for detailed monitoring criteria.



- a. **Full-term infants** (A child that is greater than or equal to 37 weeks gestation at birth)and is now less than or equal to 44 weeks post conception age should stay for a minimum of 12 hours post procedure. Full-term infants who are greater than 44 weeks post-conception who have met discharge criteria may go home 2-hours after the maximum/peak effect of the medication with apnea-free recovery.
- b. Pre-term infants (A child that is less than 37 weeks gestation at birth) and is now less than or equal to 52 weeks post conception age should stay for a minimum of 12 hours post procedure. Preterm infants who are greater than 52 weeks post-conception and have met discharge criteria may be discharged home 2- hours after the maximum/peak effect of the medication with apnea-free recovery
- c. Any infant experiencing an episode of apnea greater than 20 seconds should be monitored for at least 12 hours and must be apnea free for 12 hours prior to discharge.
 - i. 12 hour time frame starts at the time the last medication is administered.
 - ii. Vital signs should be taken according to policy until discharge criteria are met, and then continue on routine basis per orders.
 - iii. Monitoring should include CR monitoring to continue until infant is discharged from care. (*Monitor may be removed if it impedes procedure and clinician is in attendance).
 - iv. If an apnea episode occurs, an apnea and bradycardia documentation should be completed in the electronic medical record.
- 18. **Post sedation teaching** and home care instructions as appropriate will be performed and documented in the EMR prior to discharge from hospital.
- 19. All moderate and deep sedation **documentation** is to be completed in the medical record.
 - a. Documentation shall include: the date and time of the start of sedation, time of conclusion of post- procedure care, the name of the appropriately privileged member of the medical/dental staff directing sedation, the NPO status of the patient, weight, allergies, significant coexisting conditions, significant risk factors noted above, and assignment to a higher or lower risk category based upon the ASA classification scheme (see Appendix 2).
 - b. A time-based record shall document the pain and sedation scores, vital signs and medication doses administered.
 - c. Adverse events to be documented include apnea or airway obstruction requiring intervention, vomiting, aspiration, over sedation, inadequate sedation or sedation failure, and inadequate pain control.
- 20. The provider responsible for the sedation is required to complete the following post sedation documentation in the EMR within 48 hours of sedation end:
- a. Post Sedation Note
- b. Sign off of complete sedation documentation (includes Sedation Narrator sign- off at CHW-Milwaukee)

SEDATION MONITORING AND PERSONNEL REQUIREMENTS

This grid summarizes equipment, monitoring, and personnel requirements for **intended** types of sedation. If the **actual** state of the patient deviates significantly from the intended end-point, **appropriate equipment and personnel MUST be made available for the actual state of sedation achieved.**

Sedation Monitoring	Minimal Sedation	Moderate Sedation	Deep Sedation
Physician / Dentist Privileges	No specific sedation privileges	Moderate Sedation Privileges. Online education and test	Deep Sedation Privileges
Physician/Dentist designee Education and Competencies	No requirements	Online education and test required for initial privileges	cannot order/direct deep sedation. Must meet requirements for moderate sedation if assisting with deep sedation.
Nursing/Qualified Care Provider Education & Competencies	 Medication administration competency BCLS 	 Medication administration competency BCLS 	 Medication administration competency BCLS Procedural sedation competency verified. In addition airway management and monitoring competencies acquired through the Neonatal Resuscitative Program(NRP),or Pediatric Advanced Life Support (PALS) Capnography competency verification.

Sedation Monitoring and Personnel Requirements	Minimal Sedation	Moderate Sedation	Deep Sedation
Presence of Physician/Dentist directing sedation	No	Immediately available (within 2 minutes)	Present and available
Individual responsible for monitoring (available from time of medication administration through recovery) *Person performing procedure must NOT be person monitoring	Available	Present during procedure Available to perform required monitoring from baseline (immediately pre- medication) until discharge criteria are met (see step 12)	Present during procedure Available to perform monitoring from baseline (immediately pre-medication) until discharge criteria are met (see step 12)
Pre-sedation Requirements	Vital signs and general assessment recommended. No consent needed	History and Physical, Pre-Sedation Assessment, Plan, And Consent	History and Physical, Pre-Sedation Assessment, Plan, And Consent
Equipment Set Up	Pulse oximeter recommended	 Suction Oxygen Bag & mask Pulse oximeter Non- invasive blood pressure monitor (NIBP) 	 Suction Oxygen Bag & mask Pulse oximeter NIBP Code cart immediately available

Sodation Monitoring	Minimal Sodation	Modorato Sodation	Doop Sodation
and Personnel		Moderate Sedation	
Requirements			
Monitoring: • Pulse Oximetry • Heart Rate • Respiratory Rate • NIBP • Sedation Score	If not continuously attended, Sedation Score every 15 minutes until discharge criteria are met Pulse Oximeter recommended	 NIBP* and Pulse Oximeter continuously applied. Pulse ox, HR, RR, BP* & sedation scores documented immediately prior to medication administration, every 5 minutes during procedure and until sedation score >= 4 post procedure; then every 15 minutes until discharge/discontinue monitoring criteria are met. All patients that received a reversal agent must be monitored for at least 90 minutes after the final administration of any reversal agent. *See Footnote 	 NIBP* and Pulse Oximeter continuously applied. Pulse ox, HR, RR, BP*& sedation scores documented immediately prior to medication administration, every 5 minutes during procedure and until sedation score >= 4 post procedure; then every 15 minutes until discharge/discontinue monitoring criteria are met. All patients that received a reversal agent must be monitored for at least 90 minutes after the final administration of any reversal agent. *See Footnote
Pain Score (using appropriate pain scale)	At the start and end of the procedure.	 At the start and the end of the procedure, and every 5 minutes while awake during procedure. After procedure, every 15 minutes until discharge 	• At the start and the end of procedure, then every 15 minutes until discharge criteria is met.
Continuous CRM	No	No, unless clinical indication (e.g. high risk patient or technique)	Continuously applied
Capnography	No	Recommended	Required
Post Sedation Requirements	None	Post-Sedation Note and Sedation Narrator Sign-off if applicable (not available at CW- Fox Valley)	Post-Sedation Note and Sedation Narrator Sign-off if applicable

*It is recognized that there may be circumstances when the patient's condition requires exception to the BP monitoring requirements, but at a minimum BP should be assessed and documented in the EMR immediately before the sedation is initiated, once the patient's sedation score is <4, and at the completion of the procedure. The person responsible for monitoring shall document in the EMR why the monitoring requirements were not followed.

References

- American Academy of Pediatrics and the American Academy of Pediatric Dentistry (2006). Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016February 14, 2020 www.aap.org
- Cote, C. J., & Wilson, S. (2006, December). Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: An update. *Pediatrics, 118*(6), 2587-2602.
- Cote, C. J., Zaslavsky, A., & Downes, J. J. (1995). Postoperative apnea in former preterm infants after inguinal hernior-rhaphy: A combined analysis. *Anesthesiology*, *82*(4), 809-822.
- Dalal, P. G., Murray, D., Cox, T., McAllister, J., & Snider, R. (2006, October). Sedation and anesthesia protocols used for magnetic resonance imaging studies in infants: Provider and pharmacologic considerations. *Pediatrics*, 103(4), 863-868.
- Harvey, A. J., & Morton, N. S. (2007). Management of procedural pain in children. *Archives of Disease in Childhood- Education and Practice*, *92*, 20-26.
- Hoffman, G. M., Nowakowski, R., Troshynski, T. J., Berens, R. J., & Weisman, S. J. (2002, February). Risk reduction in pediatric procedural sedation by application of American Academy of Pediatric/ American Society of Anesthesiologists process model. *Pediatrics, 109*(2), 236-243.
- King, W. K., Stockwell, J. A., DwGuzman, M. A., Simon, H. K., & Khan, N. S. (2006, June). Evaluation of a pediatric-sedation service for common diagnostic procedures. *Society for Academic Emergency Medicine*, 13(6), 673-676.
- Malviya, S., Swartz, J., & Lerman, J. (1993). Are all preterm infants younger than 60 weeks postconceptual age at risk for postanesthetic apnea? *Anesthesiology*.
- The Joint Commission *Comprehensive accreditation manual for hospitals: The official handbook.* : Oakbrook Terrace. (PC.03.01.01 through PC.03.01.07, PI.01.01.01,RC.01.02.03,))
- Walther-Larsen, S., & Rasmussen, L. S. (2006, April). The former preterm infant and risk of post-operative apnea: Recommendations for management. *ACTA Anesthesiology Scandinavia, 50,* 888-893.

Association of PeriOperative Registered Nurses Standards (AORN) (2013), Recommended Practices.

Practice guidelines for sedation and analgesia by non-anesthesiologists. (Approved by the house of delegates on October 25, 1995, and last amended on October 17, 2001.)

No 12.8, American Nurses Association Board of Directors Policy/Position, September 6, 1991, "Endorsement of Position Statement on the Role of the Registered Nurse (RN) in the Management of Patients Receiving IV Conscious Sedation for Short-Term Therapeutic, Diagnostic, or Surgical Procedures. Source: ANA Board of Directors".

AANA: Considerations for Policy Guidelines for Registered Nurses Engaged in the Administration of Sedation and Analgesia,

http://www.aana.com/resources.aspx?ucNavMenu_TSMenuTargetID=51&ucNavMenu_TSMenuTargetType =4&ucNavMenu_TSMenuID=6&id=707, Accessed 2/13/08

Related Children's Wisconsin (CHW) Patient Care Policies:

Pain Assessment and Management

Assessment, Reassessment, Documentation of a Patient Monitoring: Cardio Respiratory and Pulse Oximetry Devices Transport of Patient within the Hospital

Approved by the Joint Clinical Practice Council August 21, 2023 Milwaukee Medical Executive Committee October 2, 2023 Fox Valley Medical Executive Committee October 4, 2023

APPENDIX 1 AMERICAN ACADEMY OF PEDIATRICS GUIDELINES

AAP guidelines for NPO status before elective procedures (2006):

- Sedative and analgesic medications tend to impair airway reflexes in proportion to the degree of sedation achieved. Patients may be at increased risk of aspirating gastric contents should regurgitation occur.
- For elective procedures, this risk may be minimized by allowing sufficient time for gastric emptying before the procedure begins.
- In emergent situations or with impaired gastric emptying (bowel obstruction, pregnancy, opioids, pain), pulmonary aspiration risk should be considered in determining timing of the procedure and target level of sedation. An emergency patient may require airway protection prior to sedation.

Gastric emptying may be influenced by many factors, including anxiety, pain, abnormal autonomic function (e.g., diabetes), pregnancy, and mechanical obstruction. Therefore, the suggestions listed do not guarantee that complete gastric emptying has occurred. Unless contraindicated, pediatric patients should be offered clear liquids until 2-3 hours before sedation to minimize the risk of dehydration.

Appropriate Intake of Food and Liquids Before Elective Sedation				
Ingested Material	Minimum Fasting Period (hours)			
Clear Liquids: water, fruit juices without pulp, carbonated	2			
beverages, clear tea, black coffee				
Breast milk	4			
Infant Formula	6			
Nonhuman milk: because nonhuman milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period	6			
Light meal : 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	6			

Pre Sedation Fasting Recommendations (2006 AAP guidelines) (1999 ASA guidelines)

AAP definitions of sedation continuum (2006):

- **Minimal sedation** (formerly anxiolysis): 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 (formerly conscious sedation or sedation/analgesia): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands (e.g., "open your eyes," either alone or accompanied by light tactile stimulation, such as a light tap on the shoulder or face, not a sternal rub). For older patients, this level of sedation implies an interactive state; for younger patients, age appropriate behaviors (e.g., crying) occur and are expected. Reflex withdrawal, although a normal response to a painful stimulus, is not considered as the only age-appropriate purposeful response (i.e., it must be accompanied by another response, such as pushing away the painful stimulus, to confirm a higher cognitive function). With moderate sedation, no intervention is required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. However, in the case of procedures that may themselves cause airway obstruction (e.g., dental or endoscopic), the practitioner must recognize an obstruction and assist the patient in opening the airway. If the patient is not making spontaneous efforts to open their airway to relieve the obstruction, then the patient should be considered to be deeply sedated.
- **Deep sedation** (deep sedation/analgesia): a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully (see discussion of reflex withdrawal above) after repeated verbal or painful stimulation (e.g., purposefully pushing away the noxious stimuli). 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. A state of deep sedation may be accompanied by partial or complete loss of protective airway reflexes.
- **General anesthesia**: 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.

APPENDIX 2:

AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS GUIDE

- **ASA1:** A patient with localized pathology related to the procedure being performed, without systemic manifestations
- ASA 2: A patient with mild systemic manifestations of disease, which may or may not be caused by the pathology related to the procedure, which is well-controlled and which causes minimal limitation in life style or physical activity (e.g., asthma at baseline with basically normal peak flow rate, with or without medication; restrictive ASD or VSD without any evidence of congestive heart failure or pulmonary hypertension and on no medication)
- ASA 3: A patient with systemic disease which results in a significant impairment in physical activity or life style (e.g., poorly controlled asthma with significantly reduced peak flow rate; static encephalopathy with seizures and tube feeding without reflux; congenital cardiac disease with controlled congestive heart failure or desaturation; acute lymphoblastic leukemia in remission on maintenance chemotherapy; chronic renal failure with routine dialysis and normal electrolytes and hypertension moderately controlled with medication; insulin-dependent diabetes)
- ASA 4: A patient with severe disease, which is a threat to life (e.g., a patient on inotropic therapy, requiring ventilatory assistance, with a recent head injury and alteration of consciousness, septic shock, severe dehydration and hypovolemic shock)
- **ASA 5:** A moribund patient who may die with or without the procedure
- **ASA 6:** A brain-death patient with cardiopulmonary function maintained for organ donation
- **E modifier:** Emergency status with need for procedure without sufficient time for adequate treatment of physiologic risk factors including insufficient fasting time

ASA Physical Status Guide

LOWE	RRISK	HIGHER RISK				
ASA1	ASA2	ASA3	ASA4	ASA5	ASA6	Emergency
Local pathology without systemic manifestations (Example, healthy child with abscess)	Mild systemic disease that may or may not be related to the pathology (Example, well- controlled asthma or ASD heart defect without CHF or medications)	Systemic disease with significant impairment in physical state (Example, poorly controlled asthma, chronic renal failure, or insulin- dependent diabetes)	Severe systemic disease which is life- threatening (Example, vent- dependent, septic shock, head injury with altered LOC)	Moribund patient who may die with or without the procedure	A brain- death patient sustaine d for organ donation	Needs the procedure without sufficient time for adequate treatment of physical risk factors, including inadequate NPO status

APPENDIX 3:

Recommended Process for Procedural Sedation (Example)

Pharmacologic Rationale:

These recommendations rely on the actions of a short-acting benzodiazepine (usually midazolam) to achieve sedation, anxiolysis, possibly amnesia, and the prevention of avoidance learning. Even though benzodiazepines have no analgesic qualities, patients prefer them to opioids for short painful procedures.

There is no dose of opioid medication, which will prevent pain and patient movement for procedures without the probability of apnea. Local anesthesia should be used where possible. Therefore, the mainstay of pharmacotherapy for procedural sedation is a benzodiazepine.

Moderate Sedation:

- a. History, physical, risk assessment and consent completed
- b. Prepare area and equipment
- c. Oral premedication according to orders
- d. Begin patient monitoring and assessment
- e. Establish IV access if further sedation required
- f. Administer opioid (if painful procedure not amenable to local anesthesia) to endpoint of minimal sedation. DO NOT ADMINISTER OPIOID TO CAUSE SEDATION OR UNCONSCIOUSNESS.
 Wait 5-15 minutes, depending on opioid, for full effect to occur
- g. Titration of IV midazolam (if no oral midazolam premedication given) as necessary until patient is relaxed but awake or easily arousable (sedation score of 4)
- h. Administer local anesthetic if possible
- i. Begin procedure
- j. Continual monitoring of sedation score and physiologic responses according to policy throughout recovery

Deep Sedation (Anesthesia Standards apply):

- a. History, physical, risk assessment and consent completed
- b. Prepare area and equipment for deep sedation
- c. Oral premedication according to orders
- d. Begin patient monitoring and assessment
- e. Establish IV access if further sedation required
- f. Administer opioid (if painful procedure not amenable to local anesthesia) to endpoint of minimal sedation. DO NOT ADMINISTER OPIOID TO CAUSE SEDATION OR UNCONSCIOUSNESS. Wait 5-15 minutes, depending on opioid, for full effect to occur
- g. Titration of IV midazolam (if no oral midazolam premedication given) until patient is relaxed but awake or easily arousable (sedation score of 4)
- h. Subsequent titration of midazolam or hypnotic drug (methohexital or pentobarbital) until patient is more deeply sedated (sedation score of 3)
- i. Administer local anesthetic if possible
- j. Begin procedure
- k. Continual monitoring of sedation score and physiologic responses including all vital signs according to policy throughout recovery

APPENDIX 4:

SEDATION PRIVILEGES

Rationale:

<u>The use of sedative/analgesic medications to facilitate diagnostic or therapeutic procedures is often</u> desirable and necessary for optimal patient care. However, risk of physiologic deterioration and adverse events is increased with progressive levels of sedation. Standards for sedation and anesthesia care apply when patients receive, in any setting, *moderate or deep sedation,* as well as general, spinal, or other major regional anesthesia. Please understand the following definitions:

Minimal sedation ("formally anxiolysis"):

"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/analgesia ("conscious sedation")

"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 (in an otherwise healthy patient)."

Deep sedation/anesthesia

"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 (in an otherwise healthy patient)."

Privileges for *minimal sedation* are considered core privileges. Privileges for *moderate and deep sedation* will be granted to physicians/dentists whose practice requires it, after documentation of appropriate cognitive and technical skills as delineated below.

Privileges for Major Sedation (Moderate and Deep)

A. Core Requirements:

- Applicant has read and understands the CHW Procedural Sedation Policy, AAP Guidelines for procedural sedation, and CHW drug dose guideline.
- Applicant will document procedural sedation using the CHW form, agree to participate in QA/QI activities related to procedural sedation.

B. Training and Experience:

Please document specific training and experience related to management of procedural sedation, administration and management of sedative/analgesic drug effects and complications, such as: cardio- respiratory support training, BLS, ACLS, PALS or other ALS certification, or procedural sedation workshops.

Type of Training/Experience related to Sedation

Date

1. Management of moderate sedation: accessible practice or training history reviewed by

- department chief with input from section chief (date and initial):
- 2. Management of deep sedation: demonstration of airway & cardio respiratory support skills approved by anesthesia chief or designee (date and initial):

D. Personal Attestation

C. Competency Verification:

- I am proficient in application of maneuvers to maintain airway patency and in performance of bag-mask ventilation.
- I have read and agree to adhere to the Children's Hospital of Wisconsin Procedural Sedation Policy and am physically and mentally capable of carrying out procedural sedation.
- I have acquired and will maintain the necessary technical and cognitive skills to successfully • manage the requested privileges for procedural sedation in pediatric patients.
- I agree to the QI process by participation in periodic review of documentation, patient • assessment, procedural sedation techniques, and outcomes.

I request	privileges	for moderate	sedation
-----------	------------	--------------	----------

I request privileges for deep sedation as described above, which includes moderate sedation

Signature	Date		
Anesthesia Chief (or delegate) Recommendation:	RecommendedNot recommended		
Signature (Anesthesia Chief)	Date		
Department Chief Recommendation:Recomm	nendedNot recommended		

Signature (Department Chief)

Date

Procedures for which you anticipate using sedation

Appendix 5

<u>Medications Commonly Used for Procedural Sedation</u> (Based on Lexicomp© online resource)

Opioid Medication	Route	Onset	Peak	Duration	Reversal
D			15.00		
Dexmedetomidine	IV	5-10 min	15-30 min	1 – 2 hours	none
Fentanvl	IV	1-2 min.	3 – 5 min.	30 – 45 min.	Naloxone
Fentanyl	Intranasal	5 – 15 min.	20 – 30 min.	1 – 2 hours	Naloxone
Ketamine	IM	10 – 15 min	15-30	15 – 30	None
Ketamine	IV	Within 30	minutes 1-2 min.	5 – 60 minutes	None
Ketamine	PO	15-20 min.	20-30 min.	45-60 min.	None
				(recoverv	
Methohexital (Brevital)	IV	30 - 60	Less than 5	2-3 hours) 10 – 20 min.	none
Midazolam	N/	seconds	min. 3 5 min	30 15 min	Elumazonil
Midazolam		1-2 min.	3 - 5 min.	1 - 2 hours	Flumazenii
Midazolam	F U Intranasal	5 - 15 min	10 min	1 - 2 10013 30 - 60 min	Flumazenii
Morphine	IV	5 - 10 min	15 min	90 minutes - 4	Naloyone
Morphine		0 – 10 mm.		boure	Naioxone
				nouis	
Pentobarbital	IV	1 min.	5 – 10 min.	15 min – 4	None
(Nembutal)				hours	
Pentobarbital	PO	15 – 60 min.	30 – 90 min.	1 – 4 hours	None
(Nembutal)					
Propofol	IV	Within 30	20 to 50	3 – 10	None
		seconds	seconds	minutes	
			depending of	depending	
			rate of administration	on dose	

*For more information see the CHW intranet > Clinical Resources > JITs and Quick References > Procedural Sedation Information > Pediatric Sedation Pocket Reference