

TEXAS CHILDREN'S HOSPITAL
EVIDENCE-BASED OUTCOMES CENTER
Procedural Sedation
Evidence-Based Guideline

Definition: The purpose of this evidence-based guideline is to standardize care for patients undergoing procedural sedation receiving minimal, moderate, or deep sedation for acute diagnostic, therapeutic or minor surgical procedures outside the OR at Texas Children's Hospital (TCH). The goal for all patients is to minimize physical discomfort; minimize negative psychological response to treatment by providing sedation and analgesia. ⁽¹⁾ Pharmacological and non-pharmacological interventions (i.e., cognitive-behavioral interventions: CBI) are important components of a procedural sedation program.

Inclusion Criteria

- All patients treated at TCH undergoing any sedation (minimal, moderate, or deep) for procedures that cause pain, distress and/or discomfort.
- Patients admitted to the Pavilion for Women (PFW) or Adult Congenital Heart Disease (ACHD) unit

Exclusion Criteria

All patients who will require general anesthesia for procedures
Pregnancy

Guiding Principles⁽²⁻⁴⁾

Maximize comfort and minimize pain and distress. The ideal goal of pain management is to make the procedure comfortable for the patient and family. (See Table 6)

Use non-pharmacologic interventions as an adjunct to pharmacologic interventions. *Non-pharmacologic* techniques (i.e., CBI) should be utilized and taught to every patient who is developmentally able to use these strategies to increase comfort and decrease pain and distress. (See Table 7 and Table 8)

Prepare the patient and caregivers. The key to managing procedure-related pain and distress is preparation. This begins with the patient and/or caregivers receiving developmentally appropriate information regarding what to expect and stress-reducing techniques. Patient and/or families should be involved in choices offered for pharmacologic and non-pharmacologic interventions for procedures.

Assure provider competency in performing procedures and sedation. Procedures and sedation must be performed by persons with sufficient technical expertise or by providers directly supervised by experts who are competent in performing the procedures and sedation.

Use appropriate monitoring to assure safety. Sedation should be administered in a monitored setting with resuscitative drugs and equipment available. In procedures requiring moderate and deep sedation two licensed independent practitioners must be present: typically one to perform the procedure and one to administer medications and monitor the patient.

Patient Evaluation ⁽⁵⁾

Evaluate patient and determine the need to utilize sedation for a procedure

- Evaluate injury/condition and urgency of procedure needing to be performed.
- Obtain a comprehensive history to include:
 - Age of patient
 - Underlying medical conditions (e.g., syndromes, sleep apnea)
 - Allergies
 - Neurologic/Mental status
 - Previous reactions/responses to sedation
 - Previous experience with painful conditions
 - Current prescriptions, over-the-counter and herbal medications/supplements
 - Body mass index (BMI) - if feasible
 - History of prematurity for children
 - Pregnancy status if applicable
 - History of tobacco, alcohol, or substance use if applicable
- Determine an ASA Physical Status Classification (See Table 1) Perform a focused physical examination:
 - Vital signs
 - Auscultation of heart and lung sounds
 - Specific evaluation of the airway to determine likelihood of airway compromise
- General Assessment
 - State of dentition/presence of loose teeth
 - Presence of mouth breathing, nasal speech or snoring usually indicates adenoidal or tonsillar hypertrophy, and such patients have an increased incidence of airway obstruction when sedated.
 - Neck mobility
- Considerations for adult patients
 - Size/placement of mandible, tongue size, and mouth opening
 - General guideline for adequate adult airway positioning: (1) Able to open mouth sufficiently to vertically place ≥ 3 finger width; (2) Distance from tip of chin to neck-mandible junction is ≥ 3 finger widths
- Anesthesiology consultation is recommended for the patient presenting with the following:
 - ASA Class III to V (exception for patients in intensive care units)
 - A **severe** problem/injury
 - Complex medical condition(s)
 - Potentially difficult airway (e.g., short neck, small mandible, large tongue, tracheomalacia, laryngomalacia, a history of difficult intubation, congenital anomalies, craniofacial injuries, hydrocephalus, moderate-to-severe tonsillar hypertrophy)
- Choose anticipated category/level of sedation (minimal, moderate or deep) based on the procedure (See Table 2), level of pain, age and psychological status of patient.
- Assess the timing and nature of oral intake. (See Table 3) Adult fasting recommendations based off American Society of Anesthesiologist guidelines.

Table 1. ASA Physical Status Classification ^(3,6)		
ASA CLASS	DESCRIPTION	EXAMPLE
Class I	Normal, healthy patient	
Class II	Patient w/ mild systemic disease	Controlled asthma
Class III	Patient w/ severe systemic disease	Patient who is actively wheezing
Class IV	Patient w/ severe systemic disease that is a constant threat to life	Patient with status asthmaticus
Class V	A moribund patient who is not expected to survive without the procedure	Patient with severe cardiomyopathy requiring heart transplantation

Table 2. Levels of Sedation ⁽⁴⁻⁷⁾
Minimal Sedation (anxiolysis)
Patient responds normally to verbal commands. Cognitive function may be impaired. Respiratory and cardiovascular systems unaffected. Decreases anxiety and/or facilitates coping skills.
Moderate Sedation (previously called conscious sedation)
Patient responds to verbal commands but may not respond to light or tactile stimulation. Cognitive function is impaired. Respiratory function adequate; cardiovascular unaffected. Level of consciousness is moderately depressed.
Deep Sedation
Patient cannot be easily aroused except with repeated or painful stimuli. Ability to maintain airway may be impaired . Spontaneous ventilation may be impaired ; cardiovascular function is maintained. May require assistance with maintaining a patent airway.
General Anesthesia
Loss of consciousness, patient cannot be aroused with painful stimuli. Airway cannot be maintained adequately and ventilation is impaired. Cardiovascular function may be impaired.

For patients presenting to the Emergency Center, please see page 12 for specific recommendations regarding fasting guidelines for **emergent and urgent procedures** (i.e., procedures that need to be completed in 3 hours).

Table 3. Moderate and Deep Sedation [^] Fasting Guidelines for Patients Requiring a Semi-Urgent/Non-Urgent/Elective Procedure ^{**}			
Ingested Material	Child Minimum Fasting Period (h)	Adult Minimum Fasting Period (h)	Examples
Clear Liquids	1	2	Any liquid you can see through (e.g., Apple juice, water, pedialyte, black coffee, tea with no additives)
Breast Milk	4	4	
Infant formula	6	6	
Non-human milk	6	6	
Light meal	6	6	Any food with low fat and protein content (e.g., toast, crackers, jam, cereal)
Heavy meal	8	8	All fatty or fried foods, meat, cheese, ice cream
Medications	Usual Time with sip of water	Usual Time with sip of water	EXCEPTIONS: Hold ACE inhibitors, ARBs [†] and Metformin on day of surgery; Give white liquid antacid 8 hours prior

[†]ARBs = angiotensin receptor blockers

^{**}Patients receiving 30-70% nitrous oxide without additional sedatives or narcotics for procedural sedation outside the operating room do not have fasting requirements prior to procedure.

[^]Patients receiving minimal sedation are not required to fast.

Optional Additional Assessment

[Mallampati Classification](#) to assess for a difficult airway more prone to obstruction, difficult ventilation or difficult intubation. The [3-3-2 Rule](#) can be used to predict difficult intubation.

Critical Points of Evidence*

Evidence Supports

Pharmacological Interventions for Minimal, Moderate, and Deep Sedation

- Intranasal dexmedetomidine is safe and effective to provide minimal and moderate sedation during non-invasive/painless procedures or painful procedures with the use of a topical anesthetic for patients greater than or equal to 1 month of age. – Strong recommendation, low quality evidence (18-33)
- Choral hydrate should continue to be administered to provide moderate sedation in patients requiring pulmonary function testing. – Strong recommendation, low quality evidence (34-36)
- Intranasal midazolam is safe and effective to provide minimal sedation during non-invasive/painless procedures. – Strong recommendation, low quality evidence (37-48)
- Nitrous oxide dosed at 50% continuous flow is safe and effective when used as the sole agent for minimal sedation in patients greater than 1 year of age. – Strong recommendation, low quality evidence (54-69)
- Nitrous oxide dosed at 50% continuous flow is safer and more effective than 70% nitrous oxide for minimal sedation in patients greater than 1 year of age. – Strong recommendation, low quality evidence (70-72)
- Intranasal midazolam should be the primary sedative agent for procedural sedation in neonates and former premature infants without intravenous access – Strong recommendation, very low quality evidence (24,25,29,31,33,38,40,41,73,74)

Pharmacological Procedural Pain Management

- Instill 2% lidocaine gel into the urethra before urinary catheterization for children >2 years old. – Strong recommendation, moderate quality evidence (75-78)
- IV morphine is effective for pain reduction for extremity fracture reduction. – Strong recommendation, low quality evidence (79-81)
- Intranasal fentanyl is safe and effective to reduce moderate to severe pain. – Strong recommendation, moderate quality evidence (80,82-87)
- Morphine and/or LMX cream should be administered for chest tube removal. – Strong recommendation, low quality evidence (123-125)
- Subcutaneous lidocaine should be administered before drain removal. – Strong recommendation, very low quality evidence (126)
- Oral morphine and/or fentanyl is effective for pain relief for burn dressing changes. – Strong recommendation, low quality evidence (82,127-130)
- Oral sucrose should be administered for insertion of urinary catheters in infants younger than 90 days. – Strong recommendation, low quality evidence (131)
- A topical local anesthesia (i.e., LET, EMLA cream) should be used to decrease the pain of local anesthetic injection in minor/simple lacerations. – Strong recommendation, low quality evidence (132-137)
- Intranasal ketamine is safe and effective in reducing pain and preprocedure anxiety. – Weak recommendation, low quality evidence (138-141)

Pharmacological Interventions for Discomfort

- Ondansetron (Zofran) should be considered to prevent and decrease medication (ketamine) related vomiting in patients ≥5 years old. – Strong recommendation, low quality evidence (88)

Fasting Requirements

- Evaluation of oral intake for patients admitted to the **Emergency Department** requiring an urgent procedure should include timing and nature of intake in the 3 h prior to the procedure. Fasting time for patients **with risk factors** for aspiration receiving urgent procedures is 3 hours for milk, breast milk, infant formula, and solids. – Strong recommendation, low quality evidence (89-94)
- Patients **without risk factors** for aspiration requiring sedation for urgent procedures in the **Emergency Department** should not have sedation withheld based on fasting times. – Strong recommendation, low quality evidence (89,95-101)
Remarks: Risk factors include severe systemic disease, moderate to severe obesity, obstructive sleep apnea, airway abnormalities, age 12 months or less, hyperemesis, esophageal disorders, and/or bowel obstruction. Higher risk procedures include bronchoscopy, upper endoscopy, propofol as the principle sedative, and/or procedures with an anticipated need for assisted ventilation or other airway management. (See Table 9)
- Patients receiving minimal sedation for procedures outside of the operating room *do not need to adhere to preoperative fasting requirements* prior to procedures. – Strong recommendation, low quality evidence (5,89,91,93,102,103)
- Patients receiving 30-70% nitrous oxide **without additional sedatives or narcotics** for procedural sedation outside the OR should not have fasting requirements prior to the procedure. – Strong recommendation, low quality evidence (104-108)

Monitoring

- Capnography effectively evaluates ventilation during procedures requiring moderate and deep sedation. – Strong recommendation, low quality evidence (5,109-113)

Trained Personnel

- Nitrous oxide dosed at 50% continuous flow is safe for administration by RNs with documented competency as the sole agent for minor procedures less than 30 minutes in patients greater than 1 year of age. – Strong recommendation, low quality evidence. (118-120)

Evidence Lacking/Inconclusive

Pharmacological Interventions for Minimal, Moderate, and Deep Sedation

- Intranasal fentanyl, as a single agent, is safe and effective for moderate sedation. – Weak recommendation, low quality evidence (82,85,86)
- Oral pentobarbital is safe and effective to provide moderate sedation during non-invasive/painless procedures. – Weak recommendation, low quality evidence (49,121,122)

Recommendations Adopted/Adapted from Texas Children’s Hospital Policy

- Pediatric patients receiving moderate or deep sedation outside of the operating room for **semi-urgent, non-urgent, and/or elective procedures** should have one-hour of clear liquid fasting **in addition to** standard breast milk, milk, formula and solid food fasting. (5,104,142-152)

Remarks: This recommendation was adopted from the Texas Children’s Hospital Anesthesia department policy for clear liquid fasting prior to general anesthesia for pediatric patients.

*NOTE: The references cited represent the entire body of evidence reviewed to make each recommendation.

Condition-Specific Elements of Clinical Management

Key components to procedural sedation management include effective patient and family education and psychological preparation for sedation, analgesia and the procedure. To minimize complications from sedation and/or analgesia, the appropriate level of sedation (minimal, moderate, and deep) and corresponding drug(s) and dosages are carefully chosen. Medications are administered in the proper setting with patient evaluation and monitoring before, during, and after their use. It is important to understand the different levels of sedation to maintain safety for the patient (See Table 2). (6-7,153) The selection of the fewest number of drugs and matching drug selection to the type and goal of the procedure are essential for safe practice. (148,149) When performing procedures, providers with emergency medicine and/or advance life support training may safely administer medications for minimal and moderate sedation. (114-118) It is also important for individuals performing the procedures to be skilled in both non-pharmacologic techniques (e.g., education, CBI, distraction) and pharmacological interventions.

- Use “teachable moments” - times when family members are most likely to accept new information (e.g., when a member asks a question or when symptoms are present).
- Inform parents and/or caregivers of their supportive role and typical responses of patients undergoing the procedure.
- Encourage and facilitate parent and/or caregivers involvement in the support of the patient.
- Parents/Families should be given the option of remaining at bedside during invasive procedures and supported in their decision.
- Inform parents/guardians that two adults are encouraged to accompany patients riding in car seats home after discharge; one to operate vehicle and one to monitor patient.

Psychological Preparation (157,164)

- Assess patient’s present understanding.
- Consider the patient’s developmental age and coping style when deciding how much time in advance to prepare.
- Keep information short and concrete in addition to utilizing visual aids to describe procedure.
- Emphasize sensory aspects of procedure- what patient will feel, see, hear, smell and touch.
- Emphasize what patient can do during procedure (e.g., lie still, count out loud, squeeze a hand, hug a doll).
- Give the patient choices where choices are allowed.
- Be honest with patient about unpleasant aspects of a procedure; avoid creating undue concern.
- Introduce anxiety-laden information last (e.g., starting a PIV).
- Allow for ample discussion and role rehearsal to prevent information overload, increase comfort with sequence of events and ensure adequate feedback.
- Emphasize end of procedure and any pleasurable events afterward (e.g., going home, seeing parents and/or caregiver).
- Provide a positive ending, praising efforts of cooperation and coping.
- Many procedures can be performed without sedation when the patient/family is prepared using the guiding principles outlined on in Tables 7 and 8.
- CBI is effective in helping patients through procedures.
- Allow patients to sit up when possible since it is less threatening than forcing them to lie down in a supine position.

Considerations for Children or those with Special Healthcare Needs

In December 2016, the U.S. Food and Drug Administration (FDA) issued a safety announcement regarding the potential effects of prolonged (>3 hours) or repeated anesthetics or sedations on patients younger than 3 years of age or in pregnant women during their third trimester. Recent studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic/sedation exposure affects patients’ brain development. Healthcare providers should speak with parents/guardians about the risks, benefits and timing of procedures requiring sedation and anesthesia. (156)

Non-pharmacological Interventions

- Request to see Child Life for coping techniques, procedural teaching, and psychosocial support.

Parent and Family Teaching (5,157-163)

- Establish rapport; reduce anxiety and fear.
- Assess what family members know and expect to learn, learning style and their concerns before teaching.
- Use a variety of teaching materials and common words (e.g., hands-on, lecture, demonstration, video, written material).
- Introduce most important information first.
- Keep information short and concrete.
- Evaluate teaching by eliciting feedback, repeat as needed.

Pre-procedure Preparation

Informed Consent

Prior to the administration of any level of sedation, the provider or their authorized designee will discuss the sedation plan and its associated risks, benefits, and alternatives with the parents/guardians of children and patient (if an adult or as

appropriate) and answer all questions. For minimal sedation, this may simply be a verbal discussion and agreement, and such discussion and agreement will be documented in the patient medical record. For moderate sedation and deep sedation, informed consent will also be documented via the parent/legal guardian or patient if an adult signing the TCH sedation informed consent form.

Room Preparation (5-6)

- Before starting any procedure, consider the age of the patient, type of procedure, and coping style of the patient when choosing between the treatment room and the patient's room.
- Use of the treatment room is recommended for patients experiencing invasive procedures (e.g., Lumbar Puncture, Bone Marrow Aspiration) and for younger patients (e.g., ≤6 years). Use of the treatment room should be decided by the patient and/or caregiver for less invasive procedures AND/OR for older patients (e.g., >7 years).
- Ensure that quiet play materials are available (e.g., books, crayons, paper).
- Minimize the amount of visible medical equipment.
- Minimize the discussions and use of threatening language during the procedure.
- Patients should be brought to the treatment room when the clinician is prepared to start the procedure.
- Before starting any procedure, ensure the following emergency equipment (e.g., Code/Crash Cart with defibrillator) is immediately available:
 - Pulse oximeter
 - Cardiac monitor
 - Sphygmomanometer or automatic blood pressure equipment with appropriate size cuffs
 - Capnography for moderate and deep sedation
 - Age and size appropriate bag-valve mask with O₂ reservoir (Ambu Bag)
 - Age and size appropriate suction apparatus and catheter(s)
 - One 10 mL syringe to inflate the ETT balloon (**for a cuffed ETT**) after tube placement
 - Proper size advanced airway (e.g., ETT, oral/nasal airway, LMA)
 - Proper size stylette
 - Functioning laryngoscope and appropriate size blade
 - Secondary confirmation device (capnograph, colorimetric, carbon dioxide [CO₂] detector)
 - Tape or other device to secure ETT
 - Equipment for IV access if there is not a patent IV in place
 - Functioning flowmeter with adequate oxygen supply
 - Emergency cart

Procedure

All team members participating in the procedure must use Universal Protocol prior to the start of invasive procedures

Pharmacological interventions

- Administer sedation and/or analgesia appropriate for clinical condition and procedure (e.g., pain related to fracture, laceration). See Table 5.
- Initiate Procedural Pain Protocol (e.g., PIV, venipuncture, port-a-cath, IM, arterial, AV Graft/AV Fistula access)

Analgesia for Specific Procedures

- Instill 2% lidocaine topical into the urethra before urinary catheterization for patients >2 years old. (75-78)
- Use IV morphine for pain reduction for extremity fractures. (79-81)

- Oral Sucrose per the Procedural Pain Protocol is an effective agent in reducing the pain response in infants ≤3 months who are undergoing minor acute painful procedures.
- Topical adjuncts (i.e. cooling spray, Pain Ease[®]) and/or local anesthetics to decrease pain for any type of needle puncture.

Administration of Intranasal Medications

- In order to ensure the most effective drug administration, all intranasal medications for sedation should be administered using an atomization device. The atomization device will be dispensed by the pharmacy department with all intranasal medications for sedation.
- The total volume of each dose should be equally divided between both nares, with a max volume of 1 mL per nare. The pharmacy will overfill the syringe by 0.1 mL to account for the dead space in the atomizer. Do not add an additional air pocket in the syringe.
- Below are brief instructions on the use of atomization devices to deliver intranasal medications.
 - While holding the patient's head stable, place the tip of the atomization device into the nostril aiming up and out toward the top of the ear.
 - Compress the plunger to deliver half of the medication.
 - Repeat this process in the opposite nostril to administer the remainder of the medication.

Monitoring and Documentation during the Procedure (3-6,109-113,165)

- A minimum of two health care providers must be present throughout the procedure: typically, one performing the procedure and one administering medication and directly and continuously monitoring the patient.
- Prior to minimal, moderate, and deep sedation, documentation will include a baseline Modified Aldrete Score for patients expected to recover in the post anesthesia care unit (see Table 4) and a baseline physiological assessment for all patients including: (3-6,104-108,153)
 - Heart rate
 - Blood pressure
 - Respiratory rate
 - Skin color
 - O₂ saturation

Minimal sedation: (3-6,165)

- Obtain IV access if necessary
- Monitor patient continuously on pulse oximetry during the procedure.
- Document the following items:
 - HR, pulse oximetry O₂ saturations and level of sedation at least every 15 minutes
 - HR, RR, BP, and pulse oximetry O₂ saturation pre- and post-procedure.

Moderate sedation: (3-6,109-113,165)

- Obtain and maintain IV access if sedation is given via the IV route
- If sedation is given by a non-IV route, practitioner should decide if an IV is needed on a case-by-case basis. If an IV is not placed, an individual with skills to establish IV access should be immediately available.
- Monitor continuously and document the following items every 5-10 min:
 - level of sedation
 - status of the procedure (e.g., procedure not yet started, procedure in progress, and procedure completed)
 - physiological status including HR, RR, BP, and pulse oximetry O₂ saturation

- Capnography to measure ETCO₂ to assess ventilation (Other methods to monitor ventilation may be used in the neonatal population)
- Monitor EKG rhythm in patients with significant cardiovascular disease or patients at increased risk of dysrhythmias during the procedure.
- Capnography or pretracheal/precordial stethoscope should be used to monitor ventilation during moderate sedation. Capnography may not be feasible with the use of nitrous oxide. If excessive patient agitation/lack of cooperation or procedure-related factors prohibit use of capnography or pretracheal/precordial stethoscopes, this situation should be documented. (Other methods to monitor ventilation may be used in the neonatal population)
- If blood pressure monitoring interferes with sedation or procedure, document as such and clinically monitor patient.
- Consider supplemental oxygen unless specifically contraindicated for a particular patient or procedure.
- In adult patients, if the maximum cumulative dose of medication has been administered and the patient has not reached the desired level of sedation, stop the procedure and call the Anesthesia GOAT. For adult patients in the PFW, notify the PFW Pre-Assessment Testing Area for an anesthesiologist consultation.

Deep Sedation: (3-6,109-113,165)

- Obtain and maintain IV access
- Monitor continuously and document the following items every 5 min:
 - Level of sedation
 - Physiological status including HR, RR, BP, and pulse oximetry O₂ saturation
 - Capnography to measure ETCO₂ to assess ventilation
 - EKG rhythm
- Capnography or pretracheal/precordial stethoscope should be used to monitor ventilation during deep sedation. Capnography may not be feasible with the use of nitrous oxide. If excessive patient agitation/lack of cooperation or procedure-related factors prohibit use of capnography or pretracheal/precordial stethoscopes, this situation should be documented.
- If blood pressure monitoring interferes with sedation or procedure, document as such and clinically monitor patient.
- Administer supplemental oxygen unless specifically contraindicated for a particular patient or procedure.
- The sedating provider must be a credentialed physician to provide deep sedation.
- Note the use of propofol is restricted to Anesthesiology and physicians who have secondary appointment under Pediatric Anesthesiology.

Post-procedure Recovery (5)

Physiological status will be continuously monitored and documented every 5 to 15 minutes after last medication administration until the patient meets discharge criteria with the exception of recovery from administration of ≤50% nitrous oxide alone.

Discharge Criteria (3,165,166)

The following must be achieved and maintained prior to discharge or transfer:

- A patent airway without respiratory depression
- Return to baseline vital signs
- Return to baseline motor function
- Return to baseline level of consciousness
- Adequate hydration, absence of nausea and vomiting

- Adequate pain control
- Discharge or transfer **may** occur 30 minutes after final medication administration if **all** discharge criteria are met.
- Modified Aldrete Score at discharge must have returned to baseline (pre-sedation) level.
- Full term infants less than 1 month old or premature infants less than 52 weeks post conceptual age will be observed for minimum of 12 apnea free hours following the administration of sedation.

Comfort

- Administer analgesia appropriate for clinical findings
- Administer ondansetron if indicated, to decrease and prevent medication related nausea/vomiting (88)
- Discharge readiness after sedation will be measured by utilizing the Modified Aldrete Scoring System (167)

Table 4. Modified Aldrete Scoring System		Sedation Score
Activity	Able to move 4 extremities	2
	Able to move 2 extremities	1
	Able to move 0	0
Respiration	Regular, able to deep breathe/cough freely	2
	Dyspnea, limited & obstructed breathing	1
	Apneic	0
Circulation	B/P +/-0-20 mmHG pre procedure level	2
	B/P +/-0-25 mmHG pre procedure level	1
	B/P +/- greater than 25 mmHG pre procedure level	0
Level of Consciousness	Fully awake	2
	Arousable on calling	1
	Not responding	0
O ₂ Saturation	Able to maintain O ₂ saturation > 92% on room air	2
	Needs O ₂ inhalation to maintain O ₂ saturation >90%	1
	O ₂ saturation <90% even with O ₂ supplementation	0

Special Considerations

Reversal Agents (3,168)

- Naloxone (Narcan) and/or flumazenil (Romazicon) may be needed to reverse the adverse effects of opioids or benzodiazepines
- Before using reversal agents, stimulate patient to deep breathe, give blow by oxygen and if necessary provide positive pressure bag and mask ventilation if spontaneous ventilation is inadequate or if oxygen saturation remains below 92%
- If naloxone (Narcan) or flumazenil (Romazicon) is administered, monitoring will continue for an additional 2 hours

Procedural Sedation for Neonates

- The monitoring for minimal, moderate and deep sedation for neonates will be according to the policy with the following changes:
 - Capnography will not be recommended in the neonatal population for monitoring during and after procedural sedation. The adequacy of ventilation will be monitored by clinical signs and symptoms, auscultation, chest movement, blood gases or x-ray as deemed necessary by the clinician.
- For analgesia during procedures on neonates, acetaminophen, ibuprofen, fentanyl and morphine can be considered.

Measures

Outcome

- Depth of sedation (i.e., minimal, moderate, deep)
- # of patients receiving mild/moderate/deep sedation
- # of patients at-risk for sedation identified
- Appropriate type/dose of moderate sedation agents (i.e., midazolam and fentanyl)
- Incidence/Type/Venue of reversal agent(s) administration
- Incidence/Type/Venue of adverse events
- Failed sedation

Process

- Appropriate level of sedation administered based on the type of procedure, clinical characteristics
- # of Anesthesiology consults for at-risk patients
- Utilization of clinical guideline for painful procedure
- # of cases per unit (EC, Acute Care)
- # of procedures delayed due to NPO status
- # of Child Life consults

Table 5. Medications for Procedural Sedation (1)

Practitioner should seek the assistance of an Anesthesiologist if the patient has received the max cumulative dose without achieving the desired level of sedation. Practitioner should be aware that the combination of sedatives and analgesics could result in an increased level of sedation. Use of more than one sedative or analgesic is never minimal sedation.

Medications for Sedation						
Drug (Route) Onset [O] Duration [Dur]	Dosing			Common Adverse Reactions	Comments	Cost†
	Minimal Sedation ¹	Moderate Sedation ¹	Deep Sedation ²			
<i>Sedative (hypnotics)</i>						
Chloral hydrate (Oral) O: 15-60 min Dur: 60-120 min	N/A	ONLY Infants prior to PFT testing: initial dose: 80 mg/kg/dose ONCE; an additional dose of 20 mg/kg/DOSE may be given in 30 minutes if adequate sedation is not achieved after the first dose; MAX cum dose 100 mg/kg or 1000 mg	N/A	Gastric mucosal irritation, N/V, H/A	Effects unreliable in age > 3 yrs. Contraindicated in severe cardiac disease, renal/hepatic failure. Restricted to sedation for infant pulmonary function testing.	\$
Dexmedetomidine (IV) O: 5-10 min Dur: 60-120 min	N/A	Children Bolus (Give over 10 min): 2-3 mcg/kg once Infusion: 1-2 mcg/kg/h MAX dose: 2 mcg/kg/h Adults: Bolus (Give over 10 min): 0.5-1 mcg/kg Infusion: 0.2-1 mcg/kg/hr MAX dose: 1.5 mcg/kg/hr	Contact Anesthesiologist ³	↓HR, ↓BP atrial fibrillation	Relative contraindication with heart block, severe renal or hepatic impairment, or concomitant use of beta blockers. Use restricted to procedural sedation (per EBOC guideline) and MIBG administration and the use in following areas: TCH and PFW OR and critical care areas.	\$\$
Dexmedetomidine (IN) O: 15-25 min Dur: ~ 85 min	Children ≥1 months of age: 1 - 2 mcg/kg/dose once MAX 200 mcg (100 mcg per nare)	Children ≥1 months of age: 3 - 4 mcg/kg/dose MAX 200 mcg (100 mcg per nare); an additional dose of 1 mcg/kg may be administered in 30 minutes if necessary; MAX cumulative dose 4 mcg/kg	N/A	↓HR, ↓BP	Relative contraindication with heart block, severe renal or hepatic impairment, or concomitant use of beta blockers.	\$\$
Diazepam (IV) O: 1-3 min Dur: 20-120 min	Children and Adults: 0.04-0.1 mg/kg/dose MAX single dose: 10 mg	Children and Adults: 0.04-0.2 mg/kg/dose MAX cum.dose:0.6 mg/kg or 10 mg	Contact Anesthesiologist ³	Thrombophlebitis, ↓BP, ↓HR, respiratory depression	Reduce dose when used in combination with opioids.	\$\$
Etomidate (IV) O: < 1 min Dur: 5-15 min	N/A	Children > 10 yrs and Adults: 0.1-0.3 mg/kg/dose Repeat doses may be needed	Contact Anesthesiologist ³	Respiratory depression, myoclonus, N/V, adrenal suppression	Avoid use if suspect patient is septic. Physician must be present for administration	\$\$
LORazepam (IV) O: 15-20 min Dur: 8-12 h	Infants and Children <12 yrs: 0.01-0.03 mg/kg/dose MAX cum. dose: 2 mg Children ≥ 12 yrs or >50 kg: 0.05 mg/kg/dose Adults: 1-2 mg/dose MAX cum. dose: 4 mg	N/A	Contact Anesthesiologist ³	Respiratory depression, blurred vision, hallucinations, restlessness	Reduce dose when used in combination w/ opioids. Use with caution in patients with renal/liver impairment.	\$
Midazolam (IV) O: 2-3 min Dur: 60 min	Neonates: 0.05 mg/kg/dose Infants and Children: 0.05-0.1 mg/kg/dose Adults: 1-2 mg/dose MAX single dose: 5 mg	Infants and Children 0.05-0.1 mg/kg/dose, dose may be repeated once in 2-3 minutes if needed. Adults: 2-4 mg/dose MAX cum. dose: 10 mg	Contact Anesthesiologist ³			
Midazolam (Intranasal)* O: 10-15 min Dur: 45-60 min	Neonates: 0.2 mg/kg/dose Infants, Children, and Adults: 0.2 – 0.4 mg/kg/dose MAX dose: 10 mg (5 mg per nare)	Infants, Children, and Adults: 0.5 mg/kg/dose MAX dose: 10 mg (5 mg per nare)	Contact Anesthesiologist ³	Respiratory depression, blurred vision, H/A, N/V	Reduce dose when used in combination w/ opioids. May produce paradoxical excitement.	\$
Midazolam (Oral) O: 15-30 min Dur: 60-90 min	Neonates: 0.5 mg/kg/dose Infants, Children and Adults: 0.25-0.5 mg/kg once MAX single dose: 20 mg	Infants, Children and Adults: 0.25-0.5 mg/kg/dose, may give additional dose once after 20-30 minutes if necessary MAX cum. dose: 20 mg	Contact Anesthesiologist ³			
Nitrous Oxide (INH)* O: 2-5 min Dur: 3-5 min after discontinuation of continuous administration	Children > 1 year: ≤50% N ₂ O	Children > 1 year: 51-70% N ₂ O; any concentration combined with other sedative/analgesic medications except local anesthesia	N/A	Nausea/vomiting, Headache, dizziness, confusion, CNS excitation,	Continuous administration required. Maximum duration of administration 30 minutes	\$\$
PENTObarbitol (IV) O: 1-5 min Dur: 15-45 min	N/A	Infants ≥ 6 months and Children: 1-3 mg/kg/dose MAX cum. dose: 6 mg/kg or 200 mg, whichever is less	Contact Anesthesiologist ³	↓HR, ↓BP, thrombophlebitis, laryngospasm, respiratory depression	May produce paradoxical excitement. Avoid in patients w/ porphyria.	\$\$\$\$

PENTObarbitol (Oral) O: 20 min Dur: 30-90 min	N/A	Infants and Children: 4mg/kg initial dose; may repeat dose 2mg/kg if needed MAX cum. dose: 6mg/kg or 200mg whichever is less	N/A	↓HR, ↓BP, thrombophlebitis, laryngospasm, respiratory depression	May produce paradoxical excitement. Avoid in patients w/ porphyria.	\$\$\$\$
Propofol (IV) O: < 1 min Dur: 5-15 min	N/A	N/A	Bolus: 0.5 -1 mg/kg/dose Infusion: 50-100 mcg/kg/min MAX: 200 mcg/kg/min	↓BP, respiratory depression, injection site pain	Avoid in patients w/ egg or soy allergies. Highly lipophilic. Physician must be present for administration. Note: Restricted to Anesthesiology and Physicians with deep sedation privileges	\$
Medications for Analgesia						
Drug (Route) Onset [O] Duration [Dur]	Dosing		Common Adverse Reactions	Comments		Cost†
Analgesics						
Fentanyl** (IV) O: 1-5 min 30-60 min	Neonates: 1 mcg/kg/dose administered over 5 mins Infants and Children < 12 yrs: 1-2 mcg/kg/dose, may repeat in 5 min if needed MAX cum. dose: 50 mcg Children ≥ 12 yrs and < 50 kg: 0.5-1 mcg/kg/dose or 25-50 mcg/dose, may repeat in 5 min if needed MAX cum. dose: 100 mcg Children ≥ 50 kg and Adults: 0.5-1 mcg/kg/dose or 50-75 mcg/dose, may repeat in 5 min if needed MAX cum. dose: 300 mcg		Respiratory depression, apnea, ↓BP, ↓HR, seizures, delirium	Reduce dose when combined w/ benzodiazepines. Avoid rapid IV administration due to risk of chest wall rigidity. Use lowest dose in opioid naïve patients.		\$
Fentanyl (IN)[^] O: 7-20 min Dur: ~60 min	Children ≥ 1 yr and Adults: 1.5-2 mcg/kg/dose once MAX 100 mcg (50 mcg per nare)		Nasal irritation, respiratory depression, apnea, ↓BP, ↓HR, seizures, delirium	Administer with an atomization device. Reduce dose when combined w/ benzodiazepines. Use lowest dose in opioid naïve patients.		\$
Morphine (IV) O: 5-10 min Dur: 120-300 min	Neonates: 0.01 to 0.1 mg/kg/dose MAX cum. dose: 0.1 mg/kg Infants and Children: 0.1-0.2 mg/kg/dose Adults: 2-4 mg/DOSE MAX Infants: 2 mg/dose; Children 1-6 years: 4 mg/dose; Children ≥7 years and adolescents: 6 mg/dose Adults: Max cum. dose: 10 mg		Respiratory depression, apnea, ↓BP, ↓HR, seizures, delirium	Reduce dose when used in combination w/ benzodiazepines. Use lowest dose in opioid naïve patients.		\$
Dissociative – Moderate Sedation Monitoring Needed						
Drug (Route) Onset [O] (min) Duration [Dur] (min)	Dosing		Common Adverse Reactions	Comments		Cost†
Ketamine (IV) O: 1 min Dur: 5-10 min	Children: 1-2 mg/kg/dose administered over 60 seconds, an additional dose of 0.5-1 mg/kg/dose may be administered if necessary Adults: 1-2 mg/kg/dose administered over 60 seconds, an additional dose of 0.5-1 mg/kg/dose may be administered if necessary		Arrhythmia, ↓HR, ↑↓BP, ↑ICP, N/V, pain at injection site, airway obstruction, laryngospasm, respiratory depression	Contraindicated in children < 3 months or known/suspected psychosis. Provider must be present for administration of ketamine for procedural sedation for patients without an advanced airway and/or mechanically ventilated in a critical care setting.		\$
Ketamine (IM) O: 3-4 min Dur: 12-25 min	Children and Adults: 3-5 mg/kg/dose once		Dizziness, feeling of unreality, nausea/vomiting, changes in hearing, mood change, bad taste	Contraindicated in children < 3 months or known/suspected psychosis. Provider must be present for administration of ketamine for procedural sedation for patients without an advanced airway and/or mechanically ventilated in a critical care setting.		\$
Ketamine (IN)[^] O: 10-15 min Dur: up to 60 min	Children ≥ 2 yrs and Adults: 0.5-0.8 mg/kg/dose; May give second dose in 10-15 min if needed: 0.5 mg/kg/dose once MAX cum. dose: 100 mg (50 mg per nare)		Dizziness, feeling of unreality, nausea/vomiting, changes in hearing, mood change, bad taste	Provider must be present for administration of ketamine for procedural sedation for patients without an advanced airway and/or mechanically ventilated in a critical care setting.		\$
Medications for Reversal of Sedation						
Drug: Indication Onset [O] Duration [Dur]	Dosing		Adverse Reactions	Comments		
Reversal Agent for Benzodiazepines						
Flumazenil: Benzodiazepine (i.e., Diazepam, Lorazepam, Midazolam) reversal O: 1-3 min Dur: < 60 min	Neonates, Infants and Children: Initial dose: 0.01 mg/kg (MAX: 0.2 mg). If needed, repeat 30-45 sec after initial dose, then every 1 min MAX cum. dose: 0.05 mg/kg or 1 mg whichever is less Adults: Initial dose: 0.2 mg. If needed, repeat 30-45 sec after initial dose, then every 1 min MAX cum. dose: 1 mg		N/V, dizziness, agitation, blurred vision, dyspnea, hyperventilation, vasodilation, pain at injection site	Administer through a freely running intravenous infusion into a large vein to minimize pain at injection site.		
Reversal Agent for Opioids						
Naloxone: Opioid (i.e., Fentanyl, Morphine) reversal O: 2 min Dur: 30-120 min	Birth to 5 years or < 20 kg: Partial Reversal: 0.001 – 0.02 mg/kg. If needed, repeat every 2-3 min Full Reversal: Initial dose: 0.1 mg/kg. If needed, repeat every 2-3 min > 5 years or ≥ 20 kg and Adults: Partial Reversal: 0.02-0.2 mg. If needed, repeat every 2-3 minutes Full Reversal: 0.4-2 mg. If needed, repeat every 2-3 minutes		Adverse reactions occur due to reversal (withdrawal) of opioid analgesia and sedation	Half-life shorter than most opioids, likely to need repeated doses every 20-60 min. Continuous infusions may be required.		

*Neonates/Infants: Refer to the Neonatal Medications for Sedation table for more information on analgesia for painful procedures in neonates. ^ Refer to administration instructions on page 5 for intranasal medications. † See the Nitrous Oxide Administration Protocol for additional information on this medication.

Practitioner should seek the assistance of an anesthesiologist if the patient has received the max cumulative dose without achieving the desired level of sedation. The practitioner should call the Anesthesia GOAT to determine the availability of an anesthesiologist. If an anesthesiologist is not available, the procedure should be aborted and rescheduled with general anesthesia. For adult patients in the PFW, notify the PFW Pre-Assessment Testing Area for an anesthesiologist consultation.

†Medication Cost: \$ - <\$10; \$\$ - \$10-100; \$\$\$ - >\$100-1000; \$\$\$\$ - >\$1000

Table 6. Developmental Understanding of Pain

PREOPERATIONAL THOUGHT (2-7 Yr)
<p>Relates to pain primarily as physical, concrete experience Thinks in terms of magical disappearance of pain May view pain as punishment for wrongdoing Tends to hold someone accountable for own pain and may strike out at person</p>
CONCRETE OPERATIONAL THOUGHT (7-12 Yr)
<p>Relates to pain physically (e.g., headache, stomachache) Is able to perceive psychological pain (e.g., someone dying) Fears bodily harm and annihilation (body destruction and death) May view pain as punishment for wrongdoing</p>
FORMAL OPERATIONAL THOUGHT (≥ 12 Yr)
<p>Is able to give reason for pain (e.g., fell and hit nerve) Perceives several types of psychological pain Has limited life experiences to cope with pain as adult might cope despite mature understanding of pain Fears losing control during painful experience</p>

Table 7. Developmentally Appropriate Non-Pharmacologic Techniques for Children

Age Range	Techniques
Infants (0-12 months)	Parent's voice (e.g., talking, singing on tape), touching (e.g., holding and rocking), pacifier, music, swaddling, massage
Toddlers (12-36 months)	Same as infants in addition to: Pinwheels, storytelling, peek-a-boo, busy box
Preschoolers (3-5 years)	Pinwheels, party blowers, feathers, pop-up books, storytelling, comfort item, music, singing, manipulatives
School-agers (6-12 years)	Electronic toys (e.g., Nintendo DS, PSP, iPod), pop-up books, I Spy books, participation in procedure, imagery, storytelling, breathing techniques, muscle relaxation
Adolescents (13-18 years)	Music, comedy tapes, imagery, massage, muscle relaxation, TV, video, other electronics

Table 8. Description of Specific Cognitive-Behavioral Interventions (CBI) for Children

<p>Distraction</p> <ul style="list-style-type: none">• Involve child in play; use radio, tape recorder, CD player, or computer game; have child sing or use rhythmic breathing.• Have child take a deep breath and blow it out until told to stop.• Have child blow pinwheel to “blow the hurt away.”• Have child concentrate on yelling or saying “ouch,” with instructions to “yell as loud or soft as you feel it hurt; that way I know what’s happening.”• Have child look through kaleidoscope (type with glitter suspended in fluid-filled tube) and encourage him or her to concentrate by asking, “Do you see the different designs?”• Use humor, such as watching cartoons, telling jokes or funny stories, or acting silly with child.• Have child read, play games, or visit with friends.
<p>Relaxation</p> <p>With an infant or young child:</p> <ul style="list-style-type: none">• Hold in a comfortable, well-supported position, such as vertically against the chest and shoulder.• Rock in a wide, rhythmic arc in a rocking chair or sway back and forth, rather than bouncing child.• Repeat one or two words softly, such as “Mommy’s here.” <p>With a slightly older child:</p> <ul style="list-style-type: none">• Ask child to take a deep breath and “go limp as a rag doll” while exhaling slowly; then ask child to yawn (demonstrate if needed).• Help child assume a comfortable position (e.g., pillow under neck and knees).• Begin progressive relaxation: starting with the toes, systematically instruct child to let each body part “go limp” or “feel heavy”; if child has difficulty relaxing, instruct child to tense or tighten each body part and then relax it.• Allow child to keep eyes open, since children may respond better if eyes are open rather than closed during relaxation.
<p>Guided Imagery</p> <ul style="list-style-type: none">• Have child identify some highly pleasurable real or imaginary experience.• Have child describe details of the event, including as many senses as possible (e.g., “feel the cool breezes”, “see the beautiful colors”, “hear the pleasant music”).• Have child write down or tape record script.• Encourage child to concentrate only on the pleasurable event during the painful time; enhance the image by recalling specific details through reading the script or playing the tape.• Combine with relaxation and rhythmic breathing.
<p>Thought Stopping</p> <ul style="list-style-type: none">• Identify positive facts about the painful event (e.g., “It does not last long”).• Identify reassuring information (e.g., “If I think about something else, it does not hurt as much”).• Condense positive and reassuring facts into a set of brief statements and have child memorize them (e.g., “Short procedure, good veins, little hurt, nice nurse, go home”).• Have child repeat the memorized statements whenever thinking about or experiencing the painful event.
<p>Behavioral Contracting</p> <p>Informal—May be used with children as young as 4 or 5 years of age:</p> <ul style="list-style-type: none">• Use stars, tokens, or cartoon character stickers as rewards.• Give a child who is uncooperative or procrastinating during a procedure a limited time (measured by a visible timer) to complete the procedure.• Proceed as needed if child is unable to comply.• Reinforce cooperation with a reward if the procedure is accomplished within specified time. <p>Formal—Use written contract, which includes:</p> <ul style="list-style-type: none">• Realistic (seems possible) goal or desired behavior• Measurable behavior (e.g., agrees not to hit anyone during procedures)• Contract written, dated, and signed by all persons involved in any of the agreements• Identified rewards or consequences that are reinforcing• Goals that can be evaluated• Commitment and compromise requirements for both parties (e.g., while timer is used, nurse will not nag or prod child to complete procedure)

Patients Presenting to the Emergency Center requiring an Emergent or Urgent Procedure

Patients presenting to the Emergency Center may require procedures that need to be performed as soon as possible. Table 9 outlines the types of procedures and their minimal fasting guidelines.

Note: Patients receiving minimal sedation do not require fasting. Patients receiving 30-70% nitrous oxide **without additional sedatives or narcotics** for procedural sedation outside the operating room should not have fasting requirements prior to the procedure.

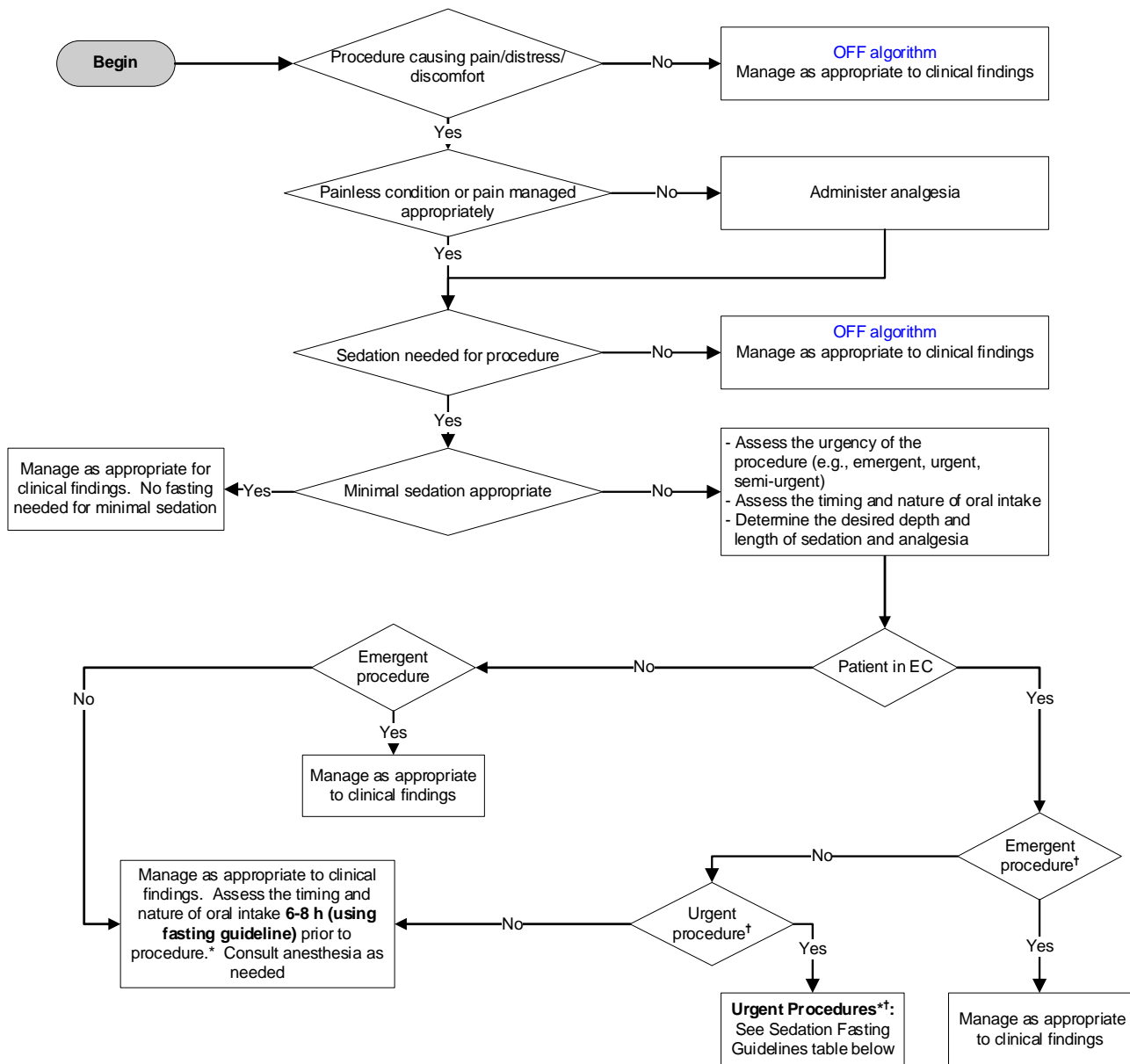
All other procedure-related practice recommendations included in the clinical guideline should be followed as clinically indicated regardless of the degree of procedural urgency.

Table 9. Degree of Procedural Urgency in the Emergency Center ⁽¹⁰¹⁾

Procedure Type	Patient Risk Factors	Recommended Fasting				
Emergent Procedures <ul style="list-style-type: none"> • Cardioversion for life-threatening dysrhythmia • Reduction of a markedly angulated fracture or dislocation with soft tissue or neurovascular compromise • Chest tube placement for tension pneumothorax • Intractable pain or suffering • Testicular torsion • Paraphimosis reduction • Reduction of an incarcerated hernia • Penile zipper injury • Neuroimaging for trauma/cord compression/sudden blindness/suspected stroke • Intubation • Laceration requiring an emergent repair for vascular control 	All patients included	No delay in sedation based upon fasting times				
		Urgent Procedures <ul style="list-style-type: none"> • Care of wounds and lacerations • Animal and human bites • Abscess I&D • Fracture reduction • Joint dislocation • LP • Chest tube placement • Thoracocentesis • Arthrocentesis • Neck imaging • Oropharyngeal foreign body removal 	Patients with NO Risk Factors listed below	Ingested Food		
				Clear liquids		0
				Breast Milk, Infant Formula, Non-Human milk		0
		Light or Heavy Meal		0		
	Patients with Risk Factors for Aspiration <ul style="list-style-type: none"> • Severe systemic disease • Moderate to severe obesity • Obstructive sleep apnea • Airway abnormalities • Age 12 months or less • Hiatal Hernia • Hyperemesis • esophageal disorders • Bowel obstruction 	Ingested Food				
		Clear liquids		0		
		Breast Milk, Infant Formula, Non-Human milk		3		
		Light or Heavy Meal		3		

^Patients requiring minimal sedation do not require fasting. Patients receiving 30-70% nitrous oxide without additional sedatives or narcotics for procedural sedation outside the operating room should not have fasting requirements prior to the procedure.

TCH Evidence-Based Outcomes Center Fasting Algorithm for Patients Requiring a Procedure



Moderate and Deep Sedation Fasting Guidelines*				
Ingested Food	Minimum Fasting Period		EC Urgent Procedure Risk Factors* Present	EC Urgent Procedure NO Risk Factors*
	Child Non-urgent/ Semi-urgent Urgent Procedures Outside the EC	Adult Non-urgent/ Semi-urgent Urgent Procedures Outside the EC		
Clear Liquids	1 hour	2 hours	0 hours	Sedation should not be withheld for fasting times
Breast Milk	4 hours	4 hours	3 hours	
Infant Formula	6 hours	6 hours	3 hours	
Non-Human Milk	6 hours	6 hours	3 hours	
Light Snack (plain toast/clear)	6 hours	6 hours	3 hours	
Heavy Snack (Fried/ Fatty Foods)	8 hours	8 hours	3 hours	

*Risk factors for aspiration include severe systemic disease, moderate to severe obesity, obstructive sleep apnea, airway abnormalities, age 12 months or less, hiatal hernia, hyperemesis, esophageal disorders, and bowel obstruction. Procedures that are high risk for aspiration include bronchoscopy, upper endoscopy, propofol principle sedative, and/or anticipated need for assisted ventilation or other airway management.

*Patients receiving 30-70% nitrous oxide **without additional sedatives or narcotics** for procedural sedation outside the operating room should not have fasting requirements prior to the procedure.

Clinical standards are developed for 80% of the patient population with a particular disease. Each practitioner must use his/her clinical judgment in the management of any specific patient.

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Clinical Standards Preparation

This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children's Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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No relevant financial or intellectual conflicts to report.

Development Process

This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
 - PICO questions established
 - Evidence search confirmed with content experts
2. Review of Existing External Guidelines
 - American Society of Anesthesiologists guideline for Preoperative Fasting and use of pharmacologic agents to reduce the risk of pulmonary aspiration, American Society of Anesthesiologists Practice guideline for Sedation and Analgesia by Non-Anesthesiologists, American College of Radiology Practice Guideline for Pediatric Sedation/Analgesia, American Academy of Pediatrics Guideline for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures, Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation in Children, Practice Guidelines for Moderate Procedural Sedation and Analgesia, Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: An updated report, Perioperative fasting in adults and children: Guidelines from the European Society of Anaesthesiology, Consensus statement on clear fluids fasting for elective pediatric general anesthesia, Canadian Pediatric Anesthesia Society statement on clear fluid fasting for elective pediatric anesthesia, Choosing wisely in pediatric anesthesia: An interpretation from the German Scientific Working Group of Paediatric Anaesthesia (WAKKA), Pre-procedure information-important instructions about eating and drinking before anesthesia or sedation, Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department, An International

- Multidisciplinary Consensus Statement on Fasting Before Procedural Sedation in Adults and Children
3. Literature Review of Relevant Evidence
 - Searched: PubMed, Cochrane, CINAHL
 4. Critically Analyze the Evidence
 - Four systematic reviews /meta-analyses, fifty-two randomized controlled trials (RCTs), and eighty-two non-randomized studies
 5. Summarize the Evidence
 - Materials used in the development of the guideline, evidence summary, and order sets are maintained in a Procedural Sedation evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence

Published clinical guidelines were evaluated for this review using the **AGREE II** criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence *in support of* or *against* specific interventions and identifies where evidence is *lacking/inconclusive*. The following categories describe how research findings provide support for treatment interventions.

“Evidence Supports” provides evidence to support an intervention

“Evidence Against” provides evidence against an intervention.

“Evidence Lacking/Inconclusive” indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn *from the evidence*.

The **GRADE** criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	Type of Evidence
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate	Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
Low	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

Recommendations

Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in procedural sedation outside of the operating room in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process

Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children's Hospital. Content Expert Teams are involved with every review and update.

Disclaimer

Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner should use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient's family, to make the ultimate judgment regarding care.

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