Texas Children's Hospital

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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 children 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 children treated at TCH undergoing any sedation (minimal, moderate, or deep) for procedures that cause pain, distress and/or discomfort.

Exclusion Criteria

All children who 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 child and parents. See Table 7, Developmental Understanding of Pain.

Use non-pharmacologic interventions as an adjunct to pharmacologic interventions. *Non-pharmacologic* techniques (i.e., CBI) should be utilized and taught to every child who is developmentally able to use these strategies to increase comfort and decrease pain and distress. See Table 8, Developmentally Appropriate Non-Pharmacologic Techniques. Also see Table 9, Description of Specific CBI.

Prepare the child and family. The key to managing procedure-related pain and distress is preparation. This begins with the parents and child receiving developmentally appropriate information regarding what to expect and stress-reducing techniques. 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: 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 child
  - 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
  - Pregnancy status
- Determine an ASA Physical Status Classification (See Table 1. ASA Physical Status Classification). Perform a focused physical examination to include:
  - Vital signs
  - Auscultation of heart and lung sounds
  - Specific evaluation of the airway to determine likelihood of airway compromise
- Anesthesiology consultation is recommended for the child 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, level of pain, age and psychological status of child and/or family (See Table 2. Categories of Sedation).
- Assess the timing and nature of oral intake. (See Table 3. Minimal, Moderate and Deep Sedation Fasting Guidelines for Children Requiring a Semi-Urgent/Non-Urgent/Elective Procedure).

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	Child who is actively wheezing
Class IV	Patient w/ severe systemic disease that is a constant threat to life	Child with status asthmaticus
Class V	A moribund patient who is not expected to survive without the procedure	Child 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 children 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 Children Requiring a Semi-Urgent/Non-Urgent/Elective Procedure**		
Ingested Material	**Minimum Fasting Period (h)**	**Examples**
Clear Liquids	2	Any liquid you can see through (e.g., Apple juice, water, pedialyte)
Breast Milk	4	
Infant formula	6	
Non-human milk	6	
Light meal	6	Any food with low fat and protein content (e.g., toast, crackers, jam, cereal)
Heavy meal	8	All fatty or fried foods, meat, cheese, ice cream
Medications	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.

Critical Points of Evidence*

Evidence Supports

Non-Pharmacological Treatment of Pain, Anxiety and/or Discomfort

- Treatment of pain and anxiety for initial procedures should be maximized to reduce development of anticipatory distress procedures. – Strong recommendation, moderate quality evidence [2-4,8]
- CBI should be combined with sedation and analgesia. – Strong recommendation, moderate quality evidence [2-4,8]
- CBI should be utilized to support children through painful procedures. – Strong recommendation, moderate quality evidence [9-15]
- Child/family should be prepared prior, during, and after procedures. – Strong recommendation, moderate quality evidence [16]
- Children should be effectively prepared by providing developmentally appropriate information, encouraging emotional expression and developing a trusting relationship. – Strong recommendation, moderate quality evidence [16-17]

Parental/Family Presence

- Parents/Families should be given the option of remaining at bedside during invasive procedures and supported in their decision. – Strong recommendation, low quality evidence [18-19]

Suggested Pharmacological Agents for Pediatric Patients

Call Mobile Sedation Service via the page operator for questions regarding the use of sedation medications	
Minimal Sedation	
Procedure length <30 min	**Procedure length 30-60 min**
PO/IV/IN Midazolam 50% Nitrous Oxide	**IN Dexmedetomidine† PO/IV/IN Midazolam**

*Agents were decided upon based on expert consensus. Evidence was reviewed on individual effectiveness and safety of medications
†Use restricted to CVICU, PICU, DI, EC, Sedating Ambulatory Units and Mobile Sedation Unit
*Pain management is essential in suspected painful procedures. Refer to Pain Management Guidelines for more information on analgesia for painful procedures.
≠See Medications for Sedation table for neonatal dosing of suggested pharmacological agents for the neonatal population

Minimal Sedation

- PO/IV/IN Midazolam or 50% Nitrous Oxide should be considered for use in pediatric patients requiring minimal sedation for painless procedures less than 30 minutes. – Consensus recommendation
- IN Dexmedetomidine or PO/IV/IN Midazolam should be considered for use in pediatric patients requiring minimal sedation for painless and/or painful procedures with the use of topical anesthetic lasting 30 minutes to 1 hour. – Consensus recommendation

Call Mobile Sedation Service via the page operator for questions regarding the use of sedation medications	
Moderate Sedation	
Painless Procedure	**IV/IN Dexmedetomidine†** **IV/IN Midazolam** **IV Pentobarbital**
Painful Procedure	**IN/IV Dexmedetomidine† (with local anesthetic)** **IM/IV Ketamine** **IV Etomidate^**

*Agents were decided upon based on expert consensus. Evidence was reviewed on individual effectiveness and safety of medications
†Use restricted for IV route to CVICU, PICU, DI, EC and Mobile Sedation Unit; Use restricted for IN route to previously named units and Ambulatory Sedating Clinics.
^Physician must administer Etomidate
≠See Medications for Sedation table for neonatal dosing of suggested pharmacological agents for the neonatal population

Moderate Sedation

- IV/IN Dexmedetomidine, IV/IN midazolam, or IV Pentobarbital should be considered for pediatric patients requiring moderate sedation for painless and/or painful procedures with the use of topical or local anesthetic. – Consensus recommendation
- IM/IV Ketamine, IV Etomidate or IN/IV Dexmedetomidine (with addition of topical or local anesthetic) should be considered for use for pediatric patients requiring moderate sedation for painful procedures. – Consensus recommendation

Pharmacological Interventions for Minimal, Moderate, and Deep Sedation

- Propofol is safe and effective for deep sedation. – Strong recommendation, moderate quality evidence (20)
- Etomidate is safe and effective for moderate sedation. – Strong recommendation, low quality evidence (21-23)
- Ketamine is safe and effective for moderate sedation. – Strong recommendation, moderate quality evidence (24-26)
- Ketamine is associated with increased airway/respiratory adverse events, emesis, and recovery agitation when administered in high IV dose (initial dose of ≥2.5 mg/kg or total dose ≥5 mg/kg), in children <2 years or ≥13 years of age, or when co-administered with anticholinergics or benzodiazepines. – Strong recommendation, moderate quality evidence (24-25)
- Intravenous dexmedetomidine is safe and effective for moderate sedation during non-invasive/painless procedures. – Strong recommendation, low quality evidence (27-29)
- Intranasal dexmedetomidine is safe and effective to provide minimal sedation during non-invasive/painless procedures or painful procedures with the use of a topical anesthetic. – Strong recommendation, low quality evidence (30-49)
- Chloral hydrate is safe and effective for moderate sedation during non-invasive/painless (e.g., ECHO) procedures. – Strong recommendation, low quality evidence (50-60)
- Intranasal midazolam is safe and effective to provide minimal sedation during non-invasive/painless procedures (e.g., ECHO). – Strong recommendation, low quality evidence (34,58,61-70)
- Intravenous pentobarbital is safe and effective for moderate sedation during non-invasive/painless procedures. – Strong recommendation, moderate quality evidence (71-75)
- Nitrous oxide dosed at 50% continuous flow is safe and effective when used as the sole agent for minimal sedation in children greater than 1 year of age. – Strong recommendation, low quality evidence (76-91)
- Nitrous oxide dosed at 50% continuous flow is safer and more effective than 70% nitrous oxide for minimal sedation in children greater than 1 year of age. – Strong recommendation, low quality evidence (92-94)

Pharmacological Procedural Pain Management

- Instill 2% lidocaine gel into the urethra before urinary catheterization for children >2 years old. – Strong recommendation, moderate quality evidence (95-98)
- IV morphine is effective for pain reduction for extremity fracture reduction. – Strong recommendation, low quality evidence (99-101)
- Intranasal fentanyl is safe and effective to reduce moderate to severe pain. – Strong recommendation, moderate quality evidence (102-108)

Pharmacological Interventions for Discomfort

- Ondansetron (Zofran) should be considered to prevent and decrease medication (ketamine) related vomiting in children ≥5 years old. – Strong recommendation, low quality evidence (109)

Fasting Requirements

- Evaluation of oral intake for children 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 urgent procedures is 3 hours for milk, breast milk, infant formula, and solids. – Strong recommendation, low quality evidence (110-115)
- Children 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 (5,110,112,114,116-117)
- 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 (118-122)

Monitoring

- Capnography effectively evaluates ventilation during procedures requiring moderate and deep sedation. – Strong recommendation, low quality evidence (5,123-127)

Discharge

- Discharge is safe thirty minutes after the administration of the final dose of sedation if no adverse events occurred. – Strong recommendation, low quality evidence (128)

Trained Personnel

- Providers with emergency medicine training may safely administer medications for minimal, moderate, and deep sedation. – Strong recommendation, low quality evidence [129-132]
- 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 children greater than 1 year of age. – Strong recommendation, low quality evidence. [133-135]

Evidence Against

Non-Pharmacological Treatment of Pain, Anxiety and/or Discomfort

- Music should not be used as first line pain relief. – Weak recommendation, low quality evidence [136]

Evidence Lacking/Inconclusive

Positioning for Comfort

- Children should be allowed to sit up when possible to decrease anxiety and increase cooperation. – Strong recommendation, low quality evidence [137-140]

Pharmacological Interventions for Minimal, Moderate, and Deep Sedation

- Intranasal fentanyl, as a single agent, is safe and effective for sedation. – Weak recommendation, low quality evidence [102,106,107]
- Oral pentobarbital is safe and effective to provide moderate sedation during non-invasive/painless procedures. – Weak recommendation, low quality evidence [72,141,142]
- Oral pentobarbital and oral chloral hydrate are safe and effective for sedation in neonates and infants. – Weak recommendation, low quality evidence [72,141,143,144]

Pharmacological Procedural Pain Management

- Morphine and/or LMX cream should be used for chest tube removal. – Strong recommendation, low quality evidence [145-147]
- Subcutaneous lidocaine should be used before drain removal. – Strong recommendation, very low quality evidence [148]
- Oral morphine and/or fentanyl is effective for pain relief for burn dressing changes. – Strong recommendation, low quality evidence [102,149-152]
- Oral sucrose should be used for insertion of urinary catheters in infants younger than 90 days. – Strong recommendation, low quality evidence [153]
- 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 [154-159]
- Intranasal ketamine is safe and effective in reducing pain and preprocedure anxiety. – Weak recommendation, low quality evidence [160-163]

*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 parent and child 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. Categories of Sedation). [6-7,164] 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. [165,166] When performing procedures, providers with emergency medicine and/or advance life support training may safely administer medications for minimal and moderate sedation. [129-132] 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.

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 and patient (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 signing the TCH sedation informed consent form.

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 children 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 children's brain development. Healthcare providers should speak with parents/guardians about the risks, benefits and timing of procedures requiring sedation and anesthesia. [167]

Non-pharmacological Interventions

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

Parent Teaching [5,9,14,16-19,138-140]

- 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.
- 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 of their supportive role and typical responses of children undergoing the procedure.
- Encourage and facilitate parent involvement in the support of their child.
- 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 [9,13,16-17]

- Assess child's present understanding.
- Consider the child's developmental age and coping style when deciding how much time in advance to prepare patient.
- Keep information short and concrete in addition to utilizing visual aids to describe procedure.
- Emphasize sensory aspects of procedure- what child will feel, see, hear, smell and touch.
- Emphasize what child can do during procedure (e.g., lie still, count out loud, squeeze a hand, hug a doll).
- Give the child choices where choices are allowed.
- Be honest with child 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).
- Provide a positive ending, praising efforts of cooperation and coping.
- Many procedures can be performed without sedation when the child/family is prepared using the guiding principles outlined on in Tables 8 and 9.
- CBI is effective in helping children through procedures.
- Allow children to sit up when possible since it is less threatening than forcing the child to lie down in a supine position.

Room Preparation [5-6,168]

- 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 children 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 parent for less invasive procedures AND/OR for older children (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.
- Children 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 O_2 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 [CO_2] 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 6 (Medications for Procedural Sedation).
- Pain management is essential. Refer to the TCH Formulary for Newborn Center and Pediatric Pain Management Guidelines.
- Initiate Procedural Pain Protocol (e.g., PIV, venipuncture, port-a-cath, IM, arterial, AV Graft/AV Fistula access). See Table 4.

Table 4. Procedures Utilizing Topical Analgesics

Site Preparation	Procedure
Topical anesthetic preparation per the Procedural Pain Protocol	Portacath access Peripheral IV Venipuncture IM injection Arterial puncture AV graft/AV fistula access
Lidocaine 4% topical cream to site before biopsy	Skin biopsy

Analgesia for Specific Procedures

- Instill 2% lidocaine topical into the urethra before urinary catheterization for children >2 years old. [95-98]
- Use IV morphine for pain reduction for extremity fractures. [99-101]
- 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. See Table 4.

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 [3-6,123-127,169]

- A minimum of two health care providers must be present throughout the procedure- 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 (refer to Table 5) and a baseline physiological assessment for all patients including: [3-6,118-122,164]
    - Heart rate
    - Blood pressure
    - Respiratory rate
    - Skin color
    - O_2 saturation

Minimal sedation: [3-6,169]

- Obtain IV access if necessary
- Monitor patient continuously on pulse oximetry during the procedure.
- Document the following items:
    - HR, pulse oximetry O_2 saturations and level of sedation at least every 15 minutes
    - HR, RR, BP, and pulse oximetry O_2 saturation pre- and post-procedure.

Moderate sedation: [3-6,123-127,169]

- 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 O_2 saturation
    - Capnography to measure $ETCO_2$ 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 stethescopes, 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

Deep Sedation: [3-6,123-127,169]

- 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 O_2 saturation
    - Capnography to measure $ETCO_2$ 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 stethescopes, 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 [3,128,169]

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[109]

Discharge readiness after sedation will be measured by utilizing the Modified Aldrete Scoring System[170]

Table 5. 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[3,168,171]

- 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.
- Chloral Hydrate at any dose up to the maximum recommended dose per the TCH formulary is considered moderate sedation.

Measures

Outcome

- Depth of sedation (i.e., minimal, moderate, deep)
- # of children receiving mild/moderate/deep sedation
- # of cases per unit (EC, Acute Care)
- # 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
- # of procedures delayed due to NPO status
- # of Child Life consults
- 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

Table 6. 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]			
Sedative (hypnotics)						
Chloral hydrate (Oral) O: 15-60 min Dur: 60-120 min	N/A	**Neonates:** 25-50 mg/kg/dose; **MAX** cum dose 50 mg/kg **Children:** 50 - 100 mg/kg/dose **MAX** cum. dose: 1 gram or 100 mg/kg, whichever is less. If first dose is <100 mg/kg AND <1 gram, a second dose may be repeated in 30 minutes if adequate sedation is not achieved after the first dose	Contact Anesthesiologist[3]	Gastric mucosal irritation, N/V, H/A	Effects unreliable in age > 3 yrs. Contraindicated in severe cardiac disease, renal/hepatic failure.	**$**
Dexmedetomidine (IV) O: 5-10 min Dur: 60-120 min	N/A	**Children and Adults: Bolus (Give over 10 min):** 2-3 mcg/kg once **Infusion:** 1-2 mcg/kg/h **MAX** dose: 2 mcg/kg/h	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 CVICU, PICU, DI, EC and Mobile Sedation Unit	**$$**
Dexmedetomidine (IN)^ O: 15-25 min Dur:~ 85 min	**Children ≥6 months of age:** 1 - 2 mcg/kg/dose once **MAX** 200 mcg (100 mcg per nare)	**Children ≥6 months of age:** 3 - 4 mcg/kg/dose **MAX** 200 mcg (100 mcg per nare); an additional dose of 1 mcg/kg may be administered in 30 minutes if necessary; **MAX** cumulative dose 4 mcg/kg	N/A	↓HR, ↓BP	Relative contraindication with heart block, severe renal or hepatic impairment, or concomitant use of beta blockers. Use restricted to CVICU, PICU, DI, , EC, Mobile Sedation Unit and Ambulatory Sedating Units	**$$**
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.	**$$**
Etomidate (IV) O: < 1 min Dur: 5-15 min	N/A	**Children > 10 yrs and Adults:**0.1-0.3 mg/kg/dose Repeat doses may be needed	Contact Anesthesiologist[3]	Respiratory depression, myoclonus, N/V, adrenal suppression	Avoid use if suspect patient is septic. Administration by physician only	**$$**
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 and Adults:** 0.05 mg/kg/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.	**$**
Midazolam (IV) O: 2-3 min Dur: 60 min	**Neonates:** 0.05 mg/kg/dose **Infants, Children and Adults:** 0.05-0.1 mg/kg/dose **MAX** single dose: 5 mg	**Infants, Children and Adults:** 0.05-0.1 mg/kg/dose, dose may be repeated once in 2-3 minutes if needed. **MAX** cum. dose: 10 mg	Contact Anesthesiologist[3]	Respiratory depression, blurred vision, H/A, N/V	Reduce dose when used in combination w/ opioids. May produce paradoxical excitement.	**$**
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]			
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_2O	**Children > 1 year:** 51-70% N_2O; 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	**$$**
PENTObarbital (IV) O: 1-5 min Dur: 15-45 min	N/A	**Infants ≥ 6 months and Children:** 1-3 mg/kg/dose **MAX** cum. dose: 6 mg/kg or 200 mg, whichever is less	Contact Anesthesiologist[3]	↓HR, ↓BP, thrombophlebitis, laryngospasm, respiratory depression	May produce paradoxical excitement. Avoid in patients w/ porphyria.	**$$$$**

PENTObarbital (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:** 50-200 mcg/kg/min **MAX:** 200 mcg/kg/min	↓BP, respiratory depression, injection site pain	Avoid in patients w/ egg or soy allergies. Highly lipophilic. 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 Adults:** 0.5-1 mcg/kg/dose or 25-50 mcg/dose, may repeat in 5 min if needed **MAX** cum. dose: 100 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 **MAX** Infants: 2 mg/dose; Children 1-6 years: 4 mg/dose; Children ≥7 years and adolescents: 6 mg/dose	Respiratory depression, apnea, ↓BP, ↓HR, seizures, delirium	Reduce dose when used in combination w/ benzodiazepines. **Use lowest dose in opioid naïve patients.**	**$**
Dissociative – Moderate Sedation Monitoring Needed				
Drug (Route) Onset [O] (min) Duration [Dur] (min)	***Dosing***	**Common Adverse Reactions**	**Comments**	**Cost†**
Ketamine (IV) O: 1 min Dur: 5-10 min	**Children:** 1-2 mg/kg/dose administered over 60 seconds, an additional dose of 0.5-1 mg/kg/dose may be administered if necessary **Adults:** 1 mg/kg/dose administered over 60 seconds, an additional dose of 0.5-1 mg/kg/dose may be administered if necessary	Arrhythmia, ↓HR, ↑/↓BP, ↑ICP, N/V, pain at injection site, airway obstruction, laryngospasm, respiratory depression	Contraindicated in children < 3 months or known/suspected psychosis	**$**
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	**$**
Ketamine (IN)^ O: 10-15 min Dur: up to 60 min	**Children ≥ 2 yrs and Adults:** 0.5-0.8 mg/kg/dose; May give second dose in 10-15 min if needed: 0.5 mg/kg/dose once **MAX** cum. dose:100 mg (50 mg per nare)	Dizziness, feeling of unreality, nausea/vomiting, changes in hearing, mood change, bad taste		**$**

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:** Initial dose: 0.1 mg/kg. If needed, repeat every 2-3 min **> 5 years or ≥ 20 kg:** Initial dose: 2 mg. If needed, repeat every 2-3 min	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.
Individuals credentialed to provide Moderate Sedation MUST have: BLS, PALS, or ACLS certification AND successful completion of TCH Sedation Course and Examination. Individuals who have primary appointments to Anesthesiology, Critical Care, and Neonatology are exempt.

1. **Individuals credentialed to provide Deep Sedation MUST have secondary appointment under Pediatric Anesthesiology in accordance with policy MS 100-06.**
2. **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 Scheduler at 832-826-4161 to determine the availability of an Anesthesiologist. If an Anesthesiologist is not available, the procedure should be aborted and rescheduled with general anesthesia.**

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

Table 7. Developmental Understanding of Pain

PREOPERATIONAL THOUGHT (2-7 YR)
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
CONCRETE OPERATIONAL THOUGHT (7-12 YR)
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
FORMAL OPERATIONAL THOUGHT(≥ 12 YR)
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

Table 8. Developmentally Appropriate Non-Pharmacologic Techniques

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 9. Description of Specific Cognitive-Behavioral Interventions (CBI)

Distraction

- 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.

Relaxation

With an infant or young child:

- 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."

With a slightly older child:

- 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.

Guided Imagery

- 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.

Thought Stopping

- 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.

Behavioral Contracting

Informal—May be used with children as young as 4 or 5 years of age:

- 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.

Formal—Use written contract, which includes:

- 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)

Children presenting to the Emergency Center requiring an Emergent or Urgent Procedure

Children presenting to the Emergency Center may require procedures that need to be performed as soon as possible. Table 10 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.

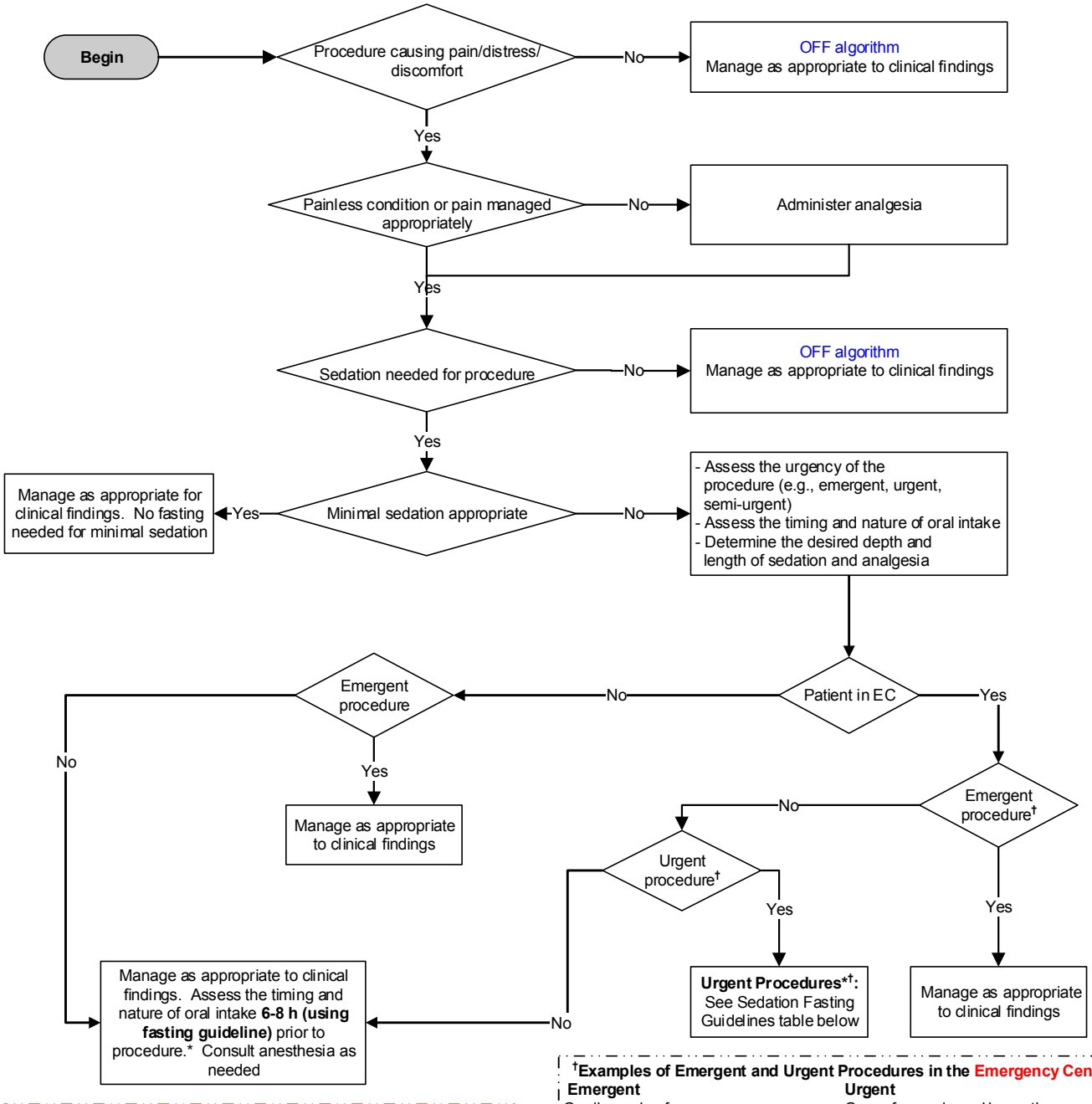
All other procedure-related practice recommendations included in the clinical guideline should be followed as clinically indicated regardless of the degree of procedural urgency.

Table 10. Degree of Procedural Urgency in Texas Children's Hospital® Emergency Center^ (172)

<table>
<tr><th>Urgency and Fasting Parameters</th><th>Types of Procedures</th></tr>
<tr><td>Emergent
(No fasting)</td><td>- 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</td></tr>
<tr><td>Urgent
Moderate and Deep Sedation^ Fasting Guidelines for an Urgent Procedure (171)<table><tr><th>Ingested Food</th><th>Minimum Fasting Period (in hours)</th></tr><tr><td>Clear liquids</td><td>0</td></tr><tr><td>Breast Milk, Infant Formula, Non-Human milk</td><td>3</td></tr><tr><td>Light or Heavy Meal</td><td>3</td></tr></table></td><td>- 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</td></tr>
<tr><td>Semi-Urgent, Non-urgent and Elective
Moderate and Deep Sedation^ Fasting Guidelines for Children Requiring a Semi-Urgent/Non-Urgent/Elective Procedure (2,117)<table><tr><th>Ingested Material</th><th>Minimum Fasting Period (in hours)</th></tr><tr><td>Clear liquids</td><td>2</td></tr><tr><td>Breast milk</td><td>4</td></tr><tr><td>Infant formula</td><td>6</td></tr><tr><td>Non-human milk</td><td>6</td></tr><tr><td>Light meal (plain toast/clear liquids)</td><td>6</td></tr><tr><td>Heavy meal (fatty/fried foods)</td><td>8</td></tr></table></td><td>Semi-urgent
- Foreign body removal
- In-grown toenail
- Sexual assault examination
- Computed Tomography (CT) for new onset seizures
Non-urgent or Elective
- Non-vegetable foreign body
- Chronic embedded soft tissue foreign body</td></tr>
</table>

^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 Children Requiring a Procedure



Moderate and Deep Sedation Fasting Guidelines*

Ingested Food	Minimum Fasting Period	
	Non-Urgent/Semi-Urgent Urgent Procedures Outside the EC	*Urgent Procedure in the EC*
Clear liquids	2 hours	0 hours
Breast milk	4 hours	3 hours
Infant formula	6 hours	3 hours
Non-human milk	6 hours	3 hours
Light snack (plain toast/clear)	6 hours	3 hours
Heavy snack (fried/fatty foods)	8 hours	3 hours

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

†Examples of Emergent and Urgent Procedures in the Emergency Center:

Emergent	Urgent
Cardioversion for life-threatening dysrhythmia	Care of wounds and lacerations
Reduction of markedly angulated fracture/dislocation with soft tissue/vascular compromise	Repair of animal and human bites
Chest tube placement for tension pneumothorax	Abscess I & D
Intractable pain or suffering	Fracture reduction
Testicular torsion	Joint dislocation
Paraphimosis reduction	Lumbar puncture
Reduction of incarcerated hernia	Chest tube placement
Neuroimaging for trauma/ cord compression/	Thoracocentesis
Sudden blindness/suspected stroke	Arthrocentesis
Intubation	Neck imaging
	Oropharyngeal foreign body removal
	Laceration repair for vascular control

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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
3. Literature Review of Relevant Evidence
   - Searched: PubMed, Cochrane, CINAHL
4. Critically Analyze the Evidence
   - Nine systematic reviews, two meta-analyses, fifty-three randomized controlled trials (RCTs), and seventy-one 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 must 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 family, to make the ultimate judgment regarding care.

Version History

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Originally completed	May 2010
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