Pediatric Procedural Sedation: guidelines and compliance

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Sedation and analgesia: purpose

- allows patients to tolerate unpleasant procedures by relieving anxiety, discomfort, or pain
- in children and uncooperative adults, may expedite conduct of procedures requiring immobility
Sedation and analgesia: quality assurance issues

- defined competencies in airway mgmt
- disease states that may impact risk
- familiarity with pharmacology
  - sedation / reversal / rescue
- procedural monitoring and equipment
- sentinel events & tracking outcomes

equal standard of care throughout hospital
# Risks of Sedation

<table>
<thead>
<tr>
<th>Oversedation</th>
<th>Undersedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>hypoventilation</td>
<td>pain</td>
</tr>
<tr>
<td>airway obstruction</td>
<td>psychological distress</td>
</tr>
<tr>
<td>aspiration</td>
<td>hypertension</td>
</tr>
<tr>
<td>hemodynamic depression</td>
<td>tachycardia</td>
</tr>
<tr>
<td>excessive movement</td>
<td>excessive movement</td>
</tr>
</tbody>
</table>
The “problem”

- explosion of non or “minimally” invasive procedures outside the OR
- need for comfortable and reasonably still patients (often) without anesthesiologist
- historically → sedation algorithms w/out
  - extensive understanding of drugs
  - consistent procedural guidelines
  - appropriate credentialing
Midazolam–fentanyl IV sedation: case report of respiratory arrest
Yaster M. *Pediatrics* 86:463,1990

- 14 m 13 kg astrocytoma for BMA
  - midazolam 1.5 mg IV
  - fentanyl 0.025 mg IV x 3 (movement)
- cyanosis and respiratory insufficiency
  - no pulse oximetry
  - no supplemental oxygen available
  - no recording vital signs prior to arrest
Pediatric anesthesiologists were by necessity at the forefront of early safety guidelines and quality assurance initiatives

- although not specifically a pediatric issue, children received sedation more frequently, for both practical and humane reasons
- early pharmacology was either relatively new and unfamiliar (fentanyl, midazolam) or unreliable (chloral hydrate)
- the anesthesia model of comprehensive care was unfamiliar to the practitioners suddenly “responsible” for sedation
95 incidents reviewed – 60 death or CNS injury
  o 80% primary event respiratory
multi-drugs and routes noted (> 50% at least 2)
  o worsened outcome with 3 or more drugs
10 children (9 deaths) in car seats or at home
2 children died prior to arrival at facility
non-hospital: CNS injury/death 92.8% vs. 37.2%
  o inadequate monitoring and/or resuscitation
Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures

COD. American Academy of Pediatrics; 1992

- patient selection and evaluation
- patient preparation (NPO status)
- clinical skills practitioner
- monitoring (pulse oximetry essential)
- documentation (informed consent)
- emergency plans (equipment)
- recovery and discharge criteria
Sedation disasters: risk factors

- poor patient selection or evaluation
- drug error leading to overdose
  - drug–drug interaction
  - drug "stacking" (cumulation)
- lack of peri-procedural monitoring
- poor emergency skills/equipment
- premature discharge
Joint Commission Guidelines

- institutional standards → responsibility of the Department of Anesthesia
- surveys, site visits for accreditation
- standards published in Comprehensive Accreditation Manual for Hospitals

www.JCAHO.org
The anesthesia care model is mandated by the JCAHO

"patients with the same health status receive comparable level of quality of surgical and anesthesia care throughout the hospital"

Mosby Year Book, Inc.; St. Louis, 1995
The standards for anesthesia care apply when patients, in any setting, receive, for operative or other procedures, by any route, the administration of moderate, deep sedation or anesthesia.” *

<table>
<thead>
<tr>
<th>level of sedation</th>
<th>level of consciousness</th>
<th>responsiveness</th>
<th>airway reflexes</th>
</tr>
</thead>
<tbody>
<tr>
<td>minimal (anxiolysis)</td>
<td>awake</td>
<td>normal</td>
<td>intact</td>
</tr>
<tr>
<td>moderate (formerly “conscious”)</td>
<td>slightly drowsy, may drift off to sleep</td>
<td>to verbal commands or light tactile</td>
<td>intact</td>
</tr>
<tr>
<td>deep sedation</td>
<td>frequently drowsy or asleep</td>
<td>repeated or painful stimulation</td>
<td>may be lost</td>
</tr>
<tr>
<td>anesthesia</td>
<td>asleep</td>
<td>none</td>
<td>lost</td>
</tr>
</tbody>
</table>
oxymoronic “conscious” sedation properly referred to as “moderate” sedation
- cardio–respiratory stability is implied
- respiratory insufficiency might occur in deep sedation / general anesthesia
- cardiovascular status maintained in deep sedation but may need support in GA
- excluded: ICU ventilator pts, pain mgmt,
“continuum” of levels stressed

deeper than intended level may be related to patient factors and agents used

monitoring vigilance, recognition and ability to rescue are stressed

Practitioners intending..given level of sedation..should be able rescue..level..deeper than intended
### Passero Scale for Sedation is standard documentation utilized

<table>
<thead>
<tr>
<th>S</th>
<th>sleep, easy to arouse</th>
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<tbody>
<tr>
<td>1</td>
<td>awake and alert</td>
</tr>
<tr>
<td>2</td>
<td>slightly drowsy, easily aroused</td>
</tr>
<tr>
<td>3</td>
<td>frequently drowsy, arousable, drifts off to sleep during conversation</td>
</tr>
<tr>
<td>4</td>
<td>somnolent, minimal or no response to physical stimulation</td>
</tr>
</tbody>
</table>
Pre-procedure patient evaluation

- preoperative evaluation (w/in 30 days)
  - H & P, indicated labs, *pre-op dx*
- informed consent for procedure
  - risks, benefits, potential complications
  - alternative options considered
  - discussed with patient *and family*
- consent for anesthesia documented
<table>
<thead>
<tr>
<th>Food Group</th>
<th>Fasting Period</th>
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</thead>
<tbody>
<tr>
<td>SOLIDS &amp; MILK PRODUCTS</td>
<td>6-8 hours</td>
</tr>
<tr>
<td>BREAST MILK</td>
<td>4 hours</td>
</tr>
<tr>
<td>CLEAR FLUIDS</td>
<td>2 hours</td>
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</table>
Pre–anesthesia assessment (i)

- appropriate medical evaluation (include data)
  - outcome of prior "anesthetics"
  - assignment of ASA status

<table>
<thead>
<tr>
<th>ASA</th>
<th>Description</th>
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<tbody>
<tr>
<td>I</td>
<td>normally healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>mild systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>severe systemic disease</td>
</tr>
<tr>
<td>IV</td>
<td>life-threatening disease</td>
</tr>
<tr>
<td>V</td>
<td>moribund patient</td>
</tr>
<tr>
<td>E</td>
<td>denotes emergency</td>
</tr>
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</table>
Pre–anesthesia assessment (ii): airway assessment

is there an increased risk for:

- procedural airway obstruction
- difficult mask ventilation
- difficult endotracheal intubation
- procedural hypoxemia
Airway Assessment: history

RED FLAGS

- obstructive sleep apnea (OSA)
- stridor
- snoring
- poorly controlled GERD
- anterior mediastinal mass
- difficult endotracheal intubation
Airway Assessment: mallampati classification

- head neutral
- wide as possible mouth opening
- stick tongue out
- classify based on oropharyngeal structures seen
Airway Assessment: Physical
RED FLAGS

- high mallampati score (grade 4)
- large tongue (TRI 21, mucopolysaccharidoses)
- mid-face hypoplasia (Crouzon, Treacher-Collins)
- recessed mandible (Pierre-robin sequence)
- cervical ROM issues (Klippel-Feil)
- target issues (laryngeal mass, foreign body)
planned choice of anesthetic
  - procedure specific (urgency, duration, pain)
  - patient specific (age, ASA status, NPO)
  - environment specific (? proximity to help)

PC.13.20,EP10 "patient is an appropriate candidate for the planned anesthesia"
documented in patient medical record after pre–anesthesia assessment and before administration of anesthesia
Pre—anesthesia assessment (iii): RED FLAGS for “routine” sedation

- full stomach (ingestion or underlying condition)
- impaired respiratory status (RAD, colds etc.)
- altered CNS status
- obstructive sleep apnea
- anticipated difficult airway
- prior issues with anesthesia/sedation
- virtually any ASA 3 (or ↑) patient
Immediate pre-anesthesia assessment

The patient is reevaluated immediately before anesthesia induction

- final review patient chart / plan
- interval changes?
- NPO status confirmed
- verify ID, procedure and site ("time-out")
- appropriate patient monitoring
- equipment check for care & rescue
Appropriate equipment

- airway equipment (positive pressure O₂)
- appropriate CV meds ± defibrillator
- monitoring before, during and after
- suction apparatus available and ready
- IV access in situ or readily available
  - IV recommended ≥ deep sedation
- opioid and benzodiazepine antagonists
Monitoring standards

- solely devoted qualified personnel
- LOC (Passero) / pain scores
- oxygenation – pulse oximetry
- ventilation – end-tidal CO₂
- circulation (BP, pulse, ECG if indicated)
- *appropriate* recording parameters at a minimum of 30 minutes after last dose
RIH has a 3-paged record with required JCAHO components includes pre-procedure assessment (pg 1), procedural monitoring and medication log (2) and post-procedure monitoring and discharge criteria (3)
Recovery care

- Aldrete Scoring Criteria encouraged
- appropriate monitoring continued
- emergency equipment/personnel
- compliance with discharge criteria is documented in the medical record
Discharge criteria (i):
**must be documented**

- return baseline mental status
- stable VS within acceptable limits
- reasonable hydration status
- at least 2 hours after reversal agents
- responsible adult to accompany home
- written instructions – diet, meds, activity
- emergency phone number provided
Discharge criteria (ii): recent JCAHO modifications

- if Passero sedation score of 4, physician responsible for sedation MUST personally attend to the discharge
- responsible adult for transport home documented *regardless* of mode of transportation (e.g. taxi, bus etc.)
Practical aspects of sedation

- who does it? (credentialing)
- sedation plans and pharmacology
- procedural & provider outcomes
  - compliance with guidelines
  - quality of studies
  - anxiolysis and reduction PTSD
  - sentinel events and selected APO’s
 Credentialing guidelines

- moderate sedation – education and ongoing departmental QA / credentialing
  - based on outcomes, volume or both
  - on-line course with assessment
- IV deep sedation – expertise with agents, equipment, monitoring and rescue
  - e.g. ICU or ER attendings
- not applicable to emergency airway mgmt
Pharmacology of sedation


- No regimen can provide 100% efficacy with
  - total safety
  - ease of administration
  - predictable and easily reversible effects
  - lack of side effects
  - no residual CNS or CV depression
Sedation: general pharmacologic considerations

- patient selection – identify high risk
- drug unpredictability (interpt variability)
  - titration smaller doses; avoid fixed recipe
  - If multiple drugs, give separately
  - the continuum of sedation – *ability to rescue*
- institutional guidelines drug availability
- drug combination: sum greater than parts
  - opioids especially associated w/respiratory ↓
Sedation pharmacology: making a rational choice

- is the procedure painful?
- is total immobility required?
- is it urgent?
- can or should NPO guidelines be met?
- who is available as a provider?
if total immobility required (MRI) then plan must call for deep sedation
most common choice is propofol
dexmedetomidine has less respiratory depression but may ↓ heart rate
Propofol and the non-anesthesiologist: institutional guidelines may dictate its use

- potent sedative
- rapid metabolism
- anti-emetic properties
- CNS excitability
- hypotension
- respiratory depression
- bacterial growth
Dexmedetomidine in the radiology suite

- FDA approved 2008 sedation outside the ICU, although off-label in children
- Very specific $\alpha_2$ agonist with sedative and mild analgesic properties; virtually no respiratory ↓
- CT scan → 62 pts w/out adverse event *
- MRI → dex/midazolam vs. propofol→both worked, dex w/slightly longer recovery ** BUT
- ↓ hypotension and desaturation than propofol ***

* Mason. Anesth Anal 2006;103:57
*** Korogulu. Anesth Analg 2006;103:63
Sedation pharmacology: the painful procedure (i) NON-URGENT

- Analgesia either through meds or regional/local
  - If no local, meets criteria for “general anesthesia”
- Total immobility may not be required
- Non-anesthetic coping techniques may be useful
  - Especially indicated for recurring painful procedures, such as bone marrow/LP in leukemics
- NPO guidelines should be met
reasonable expectations for the patient/parent

assume “full–stomach” even past the time period for usual emptying (pain, stress, meds)

consider moderate sedation vs. general anesthesia with an ETT (usually in the OR)

- anecdotally, a possibly disturbing trend towards ketamine “dissociative (general) anesthesia”
Sedation pharmacology: rational drug choices for painful procedures

- propofol a popular choice but requires ↑ dose
  - combining w/low-dose fentanyl usually preferred
- remifentanil infusion (0.1–0.2 mcg/kg/min)
- dexmedetomidine infusion
- ketamine (1–2 mg/kg IV or 3–4 mg/kg IM)
  - post-sedation nausea, emergence reactions
  - often supplemented low-dose propofol, midazolam
Trends & challenges in sedation by non-anesthesiologists

- ↑ demand practitioners and “services”
- agents like propofol blur distinction between sedation and anesthesia
- resurgence in ketamine with revised “guidelines” for use, including NPO
- need for large cooperative data bases to detect safe from unsafe practices
Outcomes in pediatric sedation: Pediatric Sedation Consortium

- Collaborative database 37 institutions
- 2006*: 30K sedation encounters w/ no deaths, 1 cardiac arrest, 1 aspiration
  - 0.5% required urgent airway intervention
- 2009**: 49K propofol sedations w/ no deaths, 2 cardiac arrests, 4 aspirations
  - 1.5% required urgent airway intervention

** Cravero Anesth Analg 108:795;2009
Sedation and analgesia by non-anesthesiologists: QI activity

- compliance institutional guidelines
- credentialing with lists available
- service specific procedure forms
- computerized tracking of procedures
- computerized tracking of medications
- two-tiered review of outcomes
Thanks for your attention and have a good day