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

equal standard of care throughout hospital

- 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

Risks of Sedation

OVERSEDATION	UNDERSEDATION
hypoventilation	pain
airway obstruction	psychological distress
aspiration	hypertension
hemodynamic depression	tachycardia
excessive movement	excessive movement

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

Adverse sedation events in pediatrics: critical analysis contributory factors

Cote CJ et al. *Pediatrics* 105:805;2000

- 95 incidents reviewed – 60 death or CNS injury
  - 80% primary event respiratory
- multi-drugs and routes noted (> 50% at least 2)
  - 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%
  - 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

JCAHO standards mandate comprehensive care

"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." *

* represents a 2002 update of AAP guidelines and adopted by JCAHO in 2003

JCAHO levels of sedation (2003 revision)

level of sedation	level of consciousness	responsiveness	airway reflexes
minimal (anxiolysis)	awake	normal	intact
moderate (formerly “conscious”)	slightly drowsy, may drift off to sleep	to verbal commands or light tactile	intact
deep sedation	frequently drowsy or asleep	repeated or painful stimulation	may be lost
anesthesia	asleep	none	lost

Procedural levels of sedation (i)

- 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,

Procedural levels of sedation (ii)

- "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

S	sleep, easy to arouse
1	awake and alert
2	slightly drowsy, easily aroused
3	frequently drowsy, arousable, drifts off to sleep during conversation
4	somnolent, minimal or no response to physical stimulation

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

RIH pre-anesthesia fasting guidelines

SOLIDS & MILK PRODUCTS	6-8 hours
BREAST MILK	4 hours
CLEAR FLUIDS	2 hours

Pre-anesthesia assessment (i)

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

ASA I	**normally healthy patient**
ASA II	**mild systemic disease**
ASA III	**severe systemic disease**
ASA IV	**life-threatening disease**
ASA V	**moribund patient**
E	**denotes emergency**

Pre-anesthesia assessment (ii): airway assessment

is there an increased risk for:

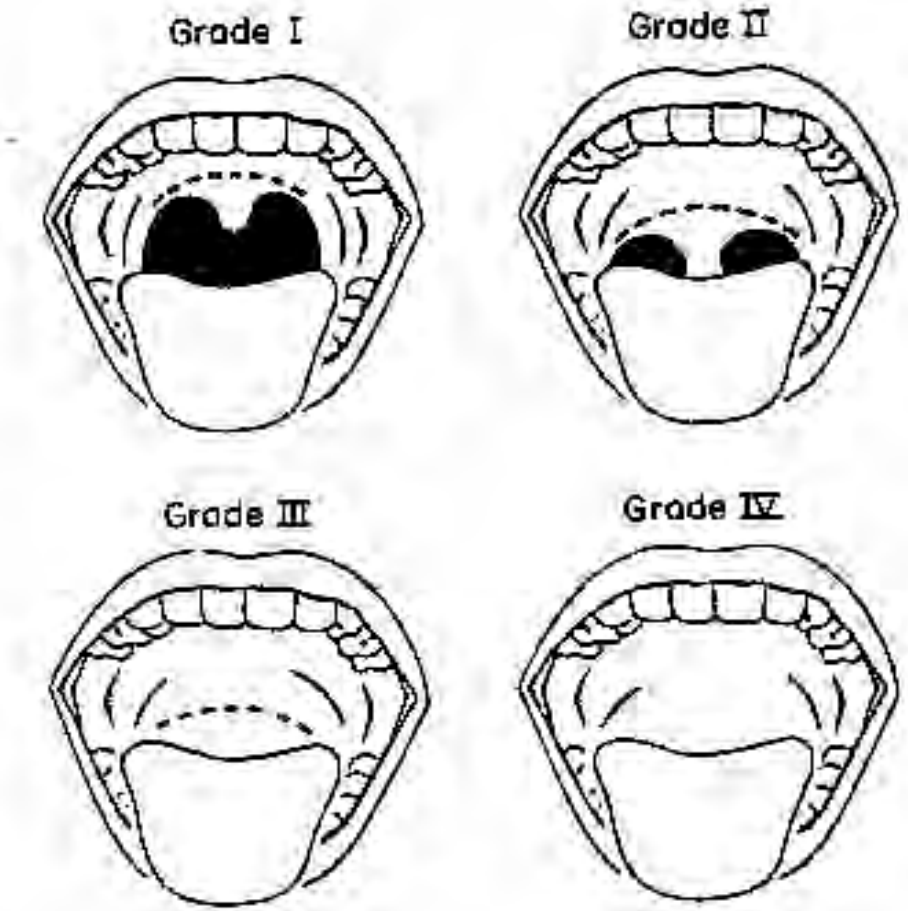
- procedural airway obstruction
- difficult mask ventilation
- difficult endotracheal intubation
- procedural hypoxemia

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)

Pre-anesthesia assessment (ii)

- 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

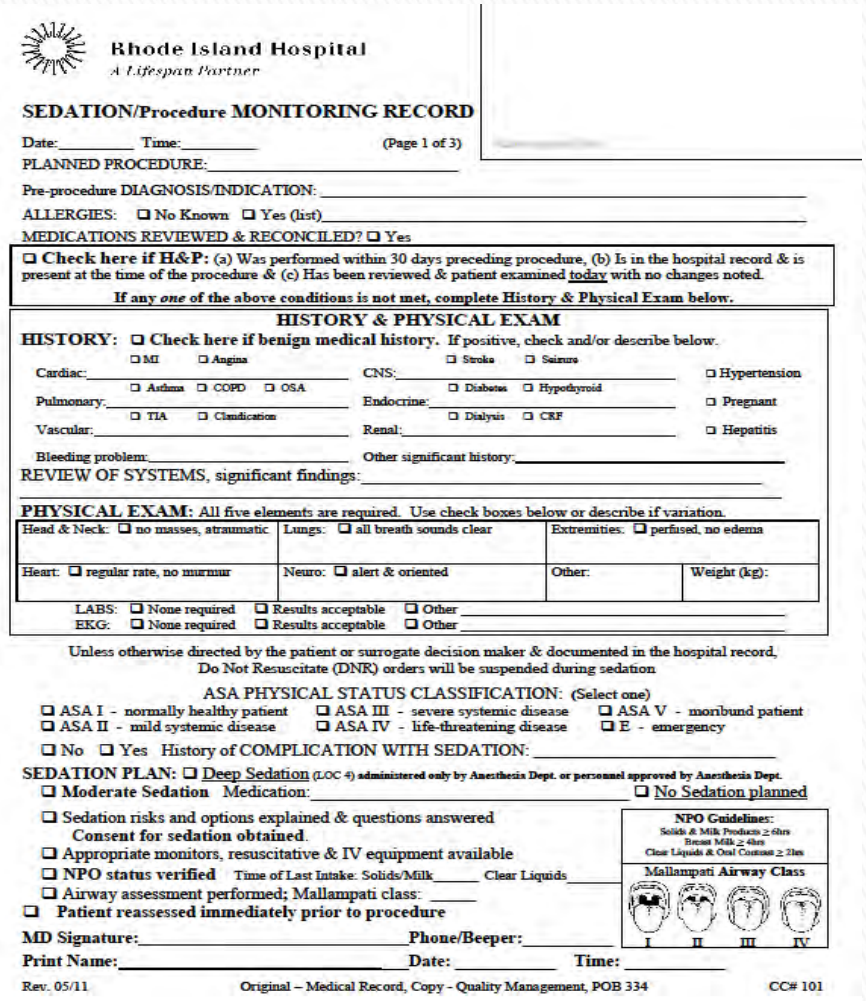
- airway equipment (positive pressure O_2)
- appropriate CV meds ± defibrillator
- monitoring before, during and after
- suction apparatus available and ready
- IV access in situ or readily available
  - IV recommended ≥ deep sedation
- opioid and benzodiazepine antagonists

Monitoring standards

- solely devoted qualified personnel
- LOC (Passero) / pain scores
- oxygenation – pulse oximetry
- ventilation – end-tidal CO_2
- circulation (BP, pulse, ECG if indicated)
- *appropriate* recording parameters at a minimum of 30 minutes after last dose

Required documentation

- 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)



Rhode Island Hospital
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SEDATION/Procedure MONITORING RECORD

Date:_____ Time:_____ (Page 1 of 3)

PLANNED PROCEDURE:_____

Pre-procedure DIAGNOSIS/INDICATION:_____

ALLERGIES: ❑ No Known ❑ Yes (list)_____

MEDICATIONS REVIEWED & RECONCILED? ❑ Yes

❑ **Check here if H&P:** (a) Was performed within 30 days preceding procedure, (b) Is in the hospital record & is present at the time of the procedure & (c) Has been reviewed & patient examined today with no changes noted.

If any *one* of the above conditions is not met, complete History & Physical Exam below.

HISTORY & PHYSICAL EXAM

HISTORY: ❑ **Check here if benign medical history.** If positive, check and/or describe below.

Cardiac: ❑ MI ❑ Angina
CNS: ❑ Stroke ❑ Seizure ❑ Hypertension
Pulmonary: ❑ Asthma ❑ COPD ❑ OSA
Endocrine: ❑ Diabetes ❑ Hypothyroid ❑ Pregnant
Vascular: ❑ TIA ❑ Claudication
Renal: ❑ Dialysis ❑ CRF ❑ Hepatitis
Bleeding problem:
Other significant history:

REVIEW OF SYSTEMS, significant findings:_____

PHYSICAL EXAM: All five elements are required. Use check boxes below or describe if variation.

Head & Neck: ❑ no masses, atraumatic	Lungs: ❑ all breath sounds clear	Extremities: ❑ perfused, no edema	
Heart: ❑ regular rate, no murmur	Neuro: ❑ alert & oriented	Other:	Weight (kg):

LABS: ❑ None required ❑ Results acceptable ❑ Other _____
EKG: ❑ None required ❑ Results acceptable ❑ Other _____

Unless otherwise directed by the patient or surrogate decision maker & documented in the hospital record, Do Not Resuscitate (DNR) orders will be suspended during sedation

ASA PHYSICAL STATUS CLASSIFICATION: (Select one)

❑ ASA I - normally healthy patient ❑ ASA II - mild systemic disease ❑ ASA III - severe systemic disease ❑ ASA IV - life-threatening disease ❑ ASA V - moribund patient ❑ E - emergency

❑ No ❑ Yes History of COMPLICATION WITH SEDATION:_____

SEDATION PLAN: ❑ Deep Sedation (LOC 4) **administered only by Anesthesia Dept. or personnel approved by Anesthesia Dept.**
❑ **Moderate Sedation** Medication:_____ ❑ No Sedation planned

❑ Sedation risks and options explained & questions answered
Consent for sedation obtained.
❑ Appropriate monitors, resuscitative & IV equipment available
❑ **NPO status verified** Time of Last Intake: Solids/Milk_____ Clear Liquids_____
❑ Airway assessment performed; Mallampati class: _____
❑ **Patient reassessed immediately prior to procedure**

NPO Guidelines:
Solids & Milk Products ≥ 6hrs
Breast Milk ≥ 4hrs
Clear Liquids & Oral Contrast ≥ 2hrs

Mallampati **Airway Class**

I II III IV

MD Signature:_____ **Phone/Beeper:**_____
Print Name:_____ **Date:** _____ **Time:** _____

Rev. 05/11 Original – Medical Record, Copy - Quality Management, POB 334 CC# 101

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

"Beware of simple solutions to difficult problems" D Fisher.Radiology,1990

- *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?

Sedation pharmacology:
the painless procedure

- 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 α-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
** Heard. *Anesth Analg* 2008;107:1832
*** 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

Sedation pharmacology:
the painful procedure (ii) URGENT

- 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
- remifentanyl 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. *Pediatrics* 118:1087;2006

** 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