Study Protocol

Comparison of Midazolam (Versed) and Distraction on Anxiety, Emergence Delirium, Sedation/Agitation, and Vomiting in Pre-operative Patients ages 3 to 5

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Purpose, Specific Aims, and Research Questions

The primary purpose of this study is to compare diversion as a non-pharmacological method of reducing pre-operative anxiety in children ages 3-5 years old. A secondary purpose is to compare the incidence of emergence delirium, sedation/agitation, and vomiting between groups who used diversion as opposed to midazolam (Versed) to manage preoperative anxiety.

Specific aim

For this study, the diversion activity will include an interactive tablet-like electronic distraction device (ITEDD). The specific aim of this study is to compare the effect of the ITEDD versus oral midazolam (Versed) on pre-operative anxiety, post-operative emergence delirium (ED), sedation/agitation, and vomiting between groups of children ages 3-5.

Research Questions

1. **Research Question**: Is there a difference in anxiety in children aged 3-5 who received ITEDD vs. patients who received oral midazolam (Versed)?
2. **Research Question**: Is there a difference in the incidence of emergence delirium in children aged 3-5 year of age who received ITEDD vs. those who received oral midazolam (Versed)?
3. **Research Question:** Is there a difference in sedation/agitation level pre- and post-operatively in children aged 3-5 years who received ITEDD vs. those who received oral midazolam (Versed)?
4. **Research Question:** Is there a difference in the incidence of post-operative vomiting in children 3-5 years who received ITEDD vs. those who received oral midazolam (Versed)?

Background/Review of Literature/Significance

As research has shown, pre-operative anxiety in children can have a lasting impact on a child and the current methods of controlling pre-operative anxiety in children is limited by the side effects of the medications used to treat pre-operative anxiety. It is important for nurses to investigate the effectiveness of non-pharmacologic interventions that can help to manage pre-operative anxiety and yet are not associated with adverse effects. In preparation for this study the literature was reviewed as it related to optimizing immediate post-operative outcomes in pediatric patients ages 3 to5 years old. The prevalence of pre-operative anxiety is high in children and is associated with crying, separation anxiety, and temper tantrums in as many as 88% of children following surgery" (Kain et al., 1996). Many children will develop anxiety associated with unknown procedures, unfamiliar surroundings, and parental separation (Kain et al., 2004). The standard treatment for preventing this anxiety pre-operatively is to medicate children with oral midazolam (Versed). However, midazolam (Versed) is not without side effects, and is specifically linked to emergence delirium, sedation/agitation, and vomiting post-operatively (Taketomo, 2012).

In the literature several studies were found that examined strategies to reduce anxiety in pediatric surgery patients. Kain et al. (1999) found that midazolam (Versed) was more effective than no pre-medication for managing anxiety in children, but side effects of midazolam (Versed) were

not examined. Thus the routine administration of pre-operative sedation midazolam (Versed) has proven to be beneficial to increase pediatric cooperation and reduce negative behavior (Kain 1996). However, the use of midazolam (Versed) as a pre-operative sedation can have harmful side-effects. These side effects can include respiratory depression, apnea, CNS depression, hypotension, nausea/vomiting, emergence delirium, and paradoxical reactions including increased aggression and agitation (Taketomo, 2012).

Since side effects can limit the usefulness of midazolam (Versed) for managing pre-operative anxiety in children, we looked in the literature for evidence of non-pharmacologic interventions. In a systematic review reported by Yip et al (2010) the authors found several non-pharmacologic interventions that were as effective as midazolam (Versed) for managing anxiety in children. Among those non-pharmacologic interventions that showed promise was the use of distraction with interactive devices.

When examining the literature associated with the use of interactive devices for managing pre-operative anxiety in children, only three studies were found. Lee and others (2013) in a three-group randomized controlled trial of children ages 1 to 10 found low doses of midazolam (Versed) in combination with diversion using a smart phone were more effective in reducing anxiety than either midazolam (Versed) or diversion alone. However, the incidence of side effects between groups was not examined. One major limitation in this study was the wide age range and the relatively small sample size. Thus, it is not known if the diversion activity is as useful in younger children as it is in older children. Likewise, in a study reported by Patel and others (2006), a diversion activity using a handheld tablet-like device resulted in less anxiety than the midazolam (Versed) group. However, they also did not compare the incidence of emergence delirium, sedation/agitation, or vomiting post-operatively and their sample was too small to examine individual age groups. Since the mean age of their sample was >8 years, it is not known if this intervention would be useful for younger children.

Finally, Seiden and others (2014) in a two-group randomized controlled trial also found that children who used a tablet-like diversion device had less anxiety ($p < .001$) compared to those who received oral midazolam (Versed) but only after removing those less than two years of age from their sample. This study also found that the diversion group had less emergence delirium and a shorter time to discharge as compared to the midazolam (Versed) group. In addition, midazolam (Versed) and anesthesia side effects such as sedation/agitation, and vomiting were not compared in this study.

While several researchers have now reported that the use of a diversion device is as effective (or more effective) than oral midazolam (Versed) for managing pre-operative anxiety in children, these studies consisted of older children and it is still not known if children 3-5 years of age would have the same outcomes as older children. It is also not known if a diversion activity compared to midazolam (Versed) will result in less sedation/agitation or less post-operative vomiting than is seen with midazolam (Versed). Thus the purpose of this study is to improve upon the previous studies to see if use of an interactive tablet-like diversion device (ITEDD) is useful for managing pre-operative anxiety in children 3-5 years of age; and to see if it results in fewer adverse effects such as emergence delirium, sedation/agitation, or vomiting.

Variables

Anxiety: Every year nearly 5 million children in the United States undergo elective surgery and nearly 50% of them exhibit some degree of pre-operative anxiety (Kain et al 2006). Anxiety is defined as a painful or apprehensive uneasiness of mind usually over an impending or anticipated ill (Merriam Webster Inc., 2015). Pre-operative anxiety in children is associated with an increase in post-operative pain, an increase consumption of analgesics, and sleep disturbances (Kain et al., 2006).

Emergence Delirium (ED) is defined as a "mental disturbance during the recovery from general anesthesia consisting of hallucinations, delusions, and confusion manifested by moaning, restlessness, involuntary physical activity, and thrashing about in bed" (Sikich et al., 2004). While children are experiencing ED they are at risk for harming themselves and their caregivers. The incidence of ED in pediatric patients is estimated at anywhere from 18 to 80% (Sikich et al., 2004). Furthermore, children having ENT procedures ages 2- to 5 years old are at an even higher risk. One of the side effects of midazolam (Versed) is paradoxical reaction with "behavioral changes and agitation" (Seiden et al., 2014). Paradoxical reaction occurs in 2% of cases (Taketomo, 2012).

Sedation/Agitation: Pediatric patients that exhibit signs and symptoms of anxiety are routinely given oral midazolam (Versed) preoperatively (Lee et al., 2013). However, midazolam (Versed) is not without side effects and these include excessive sedation, depressed respiratory status, altered mental status, paradoxical reactions, and possible anaphylaxis (Taketomo, 2012).

Vomiting: Post-operative vomiting is a common side effect of sedation medication and anesthesia. Administration of midazolam (Versed) is a contributing factor to increased incidence of vomiting (Taketomo, 2012). Nearly all patients receiving general anesthesia are given anti-emetics in an attempt to avoid the unpleasant side effect. However, they are only partially effective and have their own side-effects. Ondansetron is a commonly prescribed anti-emetic after surgery and the side effects of this drug include tachycardia, lightheadedness, rash, hypokalemia, constipation, transient elevations in liver enzymes, weakness, blurred vision, bronchospasm, and hypersensitivity reactions (Taketomo, 2012).

Theory

According to Erik Erickson, children ages 3 to5 years old (early childhood), are within the psychosocial stage of initiative versus guilt (Santrock, 2003). Within this framework, children take initiative within the world around them creating a sense of accomplishment and mastery. Children in this stage of development benefit from asserting control, by exploring the world around them, and by accomplishing tasks on their own. We propose that children having the autonomy to choose games on the ITEDD will experience either the same or decreased anxiety and less emergence delirium, sedation/agitation, and vomiting, when compared to children who are medicated with midazolam (Versed).

Methodology

Design

A 2-group randomized control trial will be used to answer the research questions.

Recruitment Procedure

A representative from the research team will contact the family after the preoperative office visit to review inclusion/exclusion criteria and determine eligibility for study. If the patient is determined to be a candidate for the study, the researcher will explain the study to the parents. Written informed consent from the parent and assent from the minor child will be obtained prior to surgery.

Sampling and Group Assignment

Stratified random assignment will be used to maximize the likelihood that the groups will be similar at baseline and will not differ on two important variables (age and interaction with Child Life Services). Since it is anticipated that a 3- and 5-year-old may respond differently to the interventions it is important that the groups have a similar number of children of each age to prevent our findings from being affected by any one age. This will be controlled both statistically and by design using stratified random assignment. Interaction with a Child Life Specialist will vary. Child Life Specialists (CLS) are trained to help children and their families cope with surgery, illness, and hospitalizations. The CLS will assess the need for child life services using communication with nursing staff, observations of patient/family, child and family relationships, chart reviews and availability (this is a usual and customary care procedure). The CLS will evaluate and prioritize which patients in the area will receive child life service interaction that day. Thus, not all patients in our study will receive this interaction. Since not all children in our study will receive child life services and it is suspected that differences in outcomes may be related to this interaction, we will control for this variation both statistically and by design. Thus, group assignment will be stratified to control for age and child life services interaction.

Stratified Random Assignment Procedure

On the day of surgery, the investigator will choose one of two envelopes based on child life services: one envelope states “will receive child life services” or “will **not** receive child life services.” Inside the chosen envelope will be the three additional envelopes indicating the age of the patient. The investigator will select the envelope with the appropriate age. This envelope will be presented to the patient’s parent who will then blindly select the card from the last envelope indicating either Group A or Group B (see Figure 1).

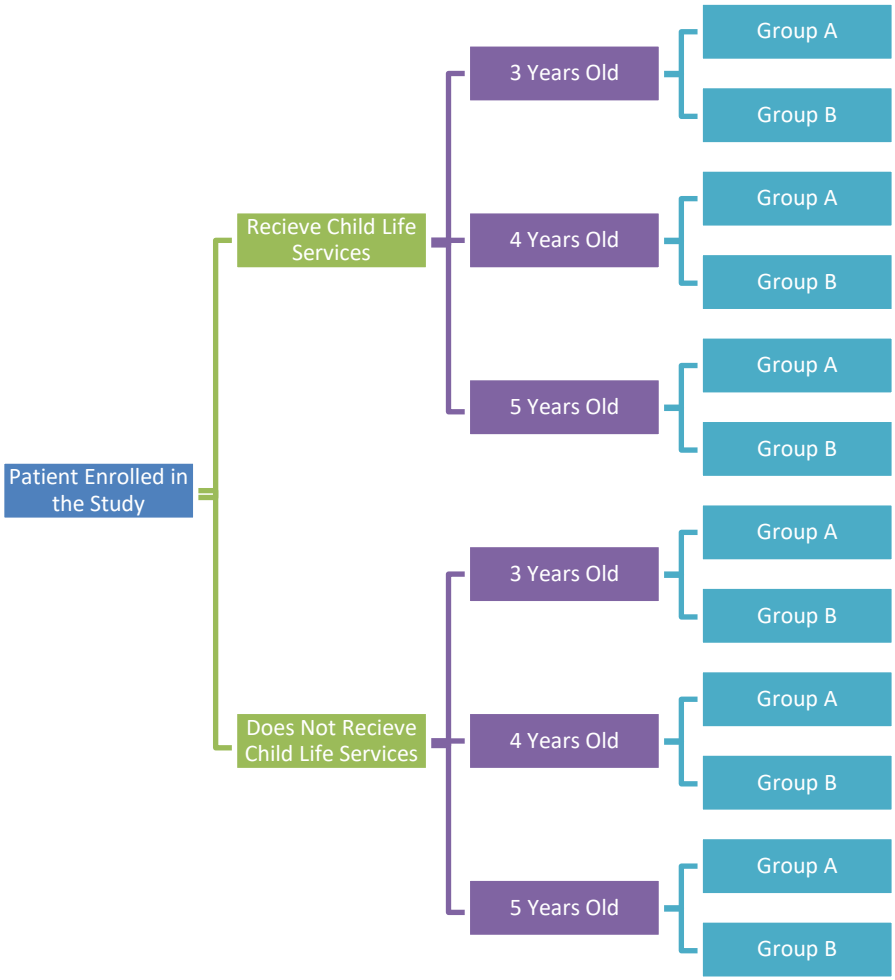

Figure 1

Two variations based on Child Life Services:

1. Patient enrolled in study will receive Child Life services.
2. Patient enrolled in study will **not** receive Child Life services

Sample and sample size

The study group will consist of 130 pre-school aged children 3-5 years who will be undergoing elective ENT, Ophthalmology, Urological, General Surgery, Neurology, and Plastic Surgery including tonsillectomy, adenoidectomy, T&A, placement or removal of ear tubes (unilateral and bilateral), strabismus, nasal lacrimal duct probing, inguinal hernia repair, hydrocele, orchiopexy, circumcision, meatotomy, chordee repair, umbilical hernia repair, nevus removal, removal of benign mass, Botox injections, lesion/cyst removal, soft tissue biopsy, excision finger syndactyly, and otoplasty under general anesthesia. Sample size was determined assuming a 2-point difference, an alpha of .05, a power of .80, and a moderate effect size. It was estimated that this study would require a sample of 65 patients per group (James Bena MS, biostatistician).

Inclusion criteria

Children selected for the study will be classified as ASA Class I and II. This is the American Society of Anesthesiologist's grading system used to assess the degree of a patient's "sickness" or "physical state" prior to selecting the anesthetic or prior to performing surgery.

Included will be patients meeting Class I criteria. These include those who normal healthy patients with no organic, physiologic, or psychiatric disturbances.

Also included will be patients meeting ASA Class II criteria are those who have only mild systemic disease no functional limitation, well-controlled disease of one body system, diabetes without systemic effects, or mild obesity.

The patients selected for this study will be those who meet the ASA Class I and II criteria and are scheduled for elective surgeries including tonsillectomy, adenoidectomy, combination tonsil and adenoidectomy (T&A), placement or removal of ear tubes, strabismus, nasal lacrimal duct probing, inguinal hernia repair, hydrocele, orchiopexy, circumcision, meatotomy, chordee repair, umbilical hernia repair, nevus removal, removal of benign mass, Botox injections, lesion/cyst removal, soft tissue biopsy, excision finger syndactyly, and otoplasty under general anesthetic, with mask induction of anesthesia.

Exclusion criteria

Children younger than 3 or older than 6, or children having any procedure other than tonsillectomy, adenoidectomy, T&A, placement or removal of ear tubes, strabismus, nasal lacrimal duct probing, inguinal hernia repair, hydrocele, orchiopexy, circumcision, meatotomy, chordee repair, umbilical hernia repair, nevus removal, removal of benign mass, Botox injections, lesion/cyst removal, soft tissue biopsy, excision finger syndactyly, and otoplasty will be excluded from this study.

Likewise, children who do not meet the criteria for ASA Class I or II will be excluded from this study.

Children will be excluded if Anesthesia determines that it would be in the best interest of the patient to be pre-medicated with midazolam (Versed) prior to surgery.

Also excluded will be children with cognitive and/or developmental delays, children going directly to the ICU from the operating room and children with an allergy to midazolam.

Procedures

Control group: Once written informed consent has been obtained from the parent, the parent will be asked to select an envelope from the package of envelopes for that child's strata (age and Child life interaction). The researcher will open the envelope in front of the parent and explain the group assignment to both the child and the parent: "Your child has been assigned to the control group. Children in this group receive the usual and customary pre-operative care which consists of premedication for anxiety. As part of the study the child will be assessed for anxiety and sedation/agitation pre-operatively. Post-operatively we will assess emergence delirium, sedation/agitation, and vomiting."

Experimental group: Once written informed consent has been obtained from the parent, the parent will be asked to select an envelope from the package of envelopes for that child's strata (age and Child Life interaction). The researcher will open the envelope in front of the parent and explain the group assignment to both the child and the parent: "Your child has been assigned to the distraction group. Children in this group will receive usual and customary preoperative care but will be asked to play with an ITEDD pre-operatively. Your child will be assessed for anxiety and sedation/agitation preoperatively. Post-operatively we will assess emergence delirium, sedation/agitation, and vomiting."

Children in the experimental group that are *not* interested in playing with the interactive tablet-like distraction device will be removed from the study. Children will then receive the usual and customary pre-operative care which consists of premedication (midazolam/Versed) for anxiety.

Routine standard of care:

Patients will check in at P20 Surgical registration desk and then be assigned a pre-operative room in M20. Nursing staff will complete assessment questions in EPIC and orient patients and families to the pre-operative environment.

Control Group (Group A):

Patients in the control group will receive routine standard of care during the study. Study participants assigned to control group will receive the usual oral midazolam per Anesthesia. Patients will remain in M20 for 15 to 20 minutes to allow for the onset of action of midazolam (Versed) and will then be escorted to the operating room with parental accompaniment.

Experimental Group (Group B):

Patients in the experimental group (group B) will receive routine standard of care during the study. Study participants in group B will be given an ITEDD and will choose developmentally appropriate games (see appendices) and activities on the ITEDD. Patients will then be escorted to the operating room while continuing to use the ITEDD with parental accompaniment.

The child will be allowed to independently choose which games he or she would like to play and will have the ability to change to another game at any point. This will allow the child to exert control over real world scenarios (such as playing hair salon) and play games that include tasks that they can successfully master on their own (such as puzzles and letter recognition). The child will have unlimited play prior to going to the Operating Room (OR) as well as during induction in the OR.

The following games were chosen to be downloaded on the ITEDD using knowledge of developmental milestones for children from ages 3-5 years as well as games that would challenge the skills of the child to maintain distraction. Child Life Services served as a consultant on game and activity selections appropriate to this age group.

Game	Recommended Age Ranges	Description
Elmo Loves ABCs	3-6 years	Letter recognition & tracing along with videos & songs
Dora's ABCs Vol1: Letters and Sounds	3-6 years	Learning letter sounds and practicing tracing upper & lowercase letters
Preschool Monkey Lunchbox	3-6 years	Randomized activities such as matching, letter recognition, differences, counting, & puzzles
Art of Glow	3-6 years 3-4 years with assistance	Drawing with various shapes
Cut the Rope HD	5-6 years 5 years with assistance	Using a finger to cut the rope to drop a piece of candy into a monster's mouth using physics
Where's My Water?	4-6 years 4-5 years with assistance	Clearing obstacles out of the way to create a path to get water to the shower for an alligator
Cake Doodle	3-6 years 3 years with assistance	Choosing and mixing ingredients in order to bake a cake & then decorate the cake
Toca Hair Salon	3-6 years	Wash, cut, and style hair on various characters
Toonia Colorbook	3-6 years	Variety of coloring pages
Shiny Party	3-5 years	Interactive story as well as a game mode with shape recognition, matching, & puzzles
Sonic Dash	5-6 years 5 years with assistance	Hedgehog endlessly running to collect rings and dodge obstacles
Lego Juniors Create and Cruise	3-6 years 3 years with assistance	Drive or fly a vehicle that you build from Legos
Match Blitz	4-6 years	A multiplayer matching game when the first person to 10 matches wins
Disney Junior Appisodes—Mickey Mouse Road Rally	3-6 years	Interactive Mickey Mouse episode
You Tube Kids	4-6 years 4-5 years with assistance	A portal to search, listen to, & watch TV shows, music, and educational videos geared toward children

Setting

The study will take place on the M20 nursing unit and pediatric operating rooms.

Data Collection

Basic demographic information will be collected at the time of random assignment and will include age, race, gender, and scheduled procedure. No Protected Health Information (PHI) is needed for this study. All findings will be reported in the aggregate and every effort will be made to ensure privacy and confidentiality of all patient data. Subjects will only be identified by a study number and all data will be kept secured in a locked file in a locked office accessible only to the study staff.

Outcome Measures

Outcomes to be measured include:

1. Pre-induction anxiety as measured by the m-YPAS scale (see appendix 1) after having received either pre-operative:
    a. Medication with PO midazolam and parental presence during induction.
    b. ITEDD and parental presence during induction.
2. Sedation/Agitation score via the RASS (see appendix 2).
3. Incidence of post-operative emergence delirium (ED) as measured by the PAED scale.
4. Incidence of post-operative vomiting. If POV occurred was pharmacological intervention required.

	Induction OR	Admit to PACU	Wake-up from anesthesia
Anxiety	m-YPAS		
Emergence Delirium			PAED
Sedation/Agitation	RASS	RASS	
Vomiting		POV	POV

Instruments/Tools/Measurement Methods:

Anxiety will be assessed using modified Yale Preoperative Anxiety Scale (m-YPAS) to measure anxiety in children during induction of anesthesia. The m-YPAS has been found to be a useful and valid tool for measuring anxiety in pediatric patients ages 2-6 (Kain et al. 1997). The m-YPAS has 22 numerically weighted items separated into five categories, scores range from 22 (no anxiety) to 100 (high level of anxiety).

Sedation/agitation will be assessed using the Richmond Agitation Sedation Score (RASS). This tool will be administered in pre-operative holding area, at induction, and on admission to the PACU postoperatively. The RASS is a 10-item tool completed by the nurse and based on nursing observations of behavior. Scores on the RASS can range from -5 (unarousable) to +4 (highly agitated and combative). The RASS tool has demonstrated excellent validity, reliability and is used at the Cleveland Clinic to evaluate patients in the recovery room (Ely et al., 2003).

The Pediatric Anesthesia Emergence Delirium Scale (PAED) will be used to assess patients for presence of emergence delirium in the PACU. The PAED is an observational tool used by the nurse/evaluator. Previous studies suggest this is a valid measure of ED in pediatric patients

(Sikich et al., 2004). The PAED tool contains 5 items on the patients' behavior. The first 3 questions are reverse scored (4 = not at all; 3=just a little; 2=quite a bit; and 1=very much) and the last 2 questions are scored as follows (0=not at all; 1=just a little; 2=quite a bit; 3=very much; and 4=extremely). Scores on the PAED scale can range from 0 to 20. The authors of the PAED scale reported scores of >10 correspond to a "sensitivity of 0.64 and a 1-specificity of 0.14". Inter-observer reliability of the PAED was noted at 0.84 and deemed an acceptable instrument of emergence delirium (Sikich et al., 2004). Bajwa (2010) reported sensitivity of 100% and specificity of 94.5% for a score of >12 for the PAED when used by an experienced observer; thus, for purposes of this study scores >12 will be considered evidence of ED.

Vomiting will be assessed as a positive occurrence when child is actively vomiting and will be recorded on the data collection instrument as present or absent during the PACU stay.

The investigators will be responsible for monitoring data collection and storing data collection forms in a locked cabinet in the PIs locked office.

Appendix 1

The m-YPAS

Activity	**1. Looking around, curious, playing with toys, reading (or other age appropriate behavior); moves around holding area/treatment room to get toys or to go to parent; may move toward operating room**
	2. Not exploring or playing; may look down, fidget with hands, or suck thumb (blanket); may sit close to parent while waiting or play has a definite manic quality.
	3. Moving from toy to parent in unfocused manner; non-activity-derived movements; frenetic/frenzied movement or play; squirming, moving on table; may push mask away or cling to parent.
	4. Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys, will not separate from parent, desperate clinging.
Vocalizations	**1. Reading (non-vocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to talk in social situations or too engrossed in play to respond**
	2. Responding to adults but whispers, "baby talk," only head nodding
	3. Quiet, no sounds or responses to adults
	4. Whimpering, moaning, groaning, silently crying
	5. Crying or may be screaming "no"
	6. Crying, screaming loudly, sustained (audible through mask)
Emotional Expressivity	**1. Manifestly happy, smiling, or concentrating on play**
	2. Neutral, no visible expression on face
	3. Worried (sad) to frightened, sad, worried, or tearful eyes
	4. Distressed, crying, extreme upset, may have wide eyes
State of Apparent Arousal	**1. Alert, looks around occasionally, notices or watches what anesthesiologist does (could be relaxed)**
	2. Withdrawn, sitting still and quiet, may be sucking thumb or have face turned into adult.
	3. Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense
	4. Panicked whimpering may be crying or pushing others away, turns away.
Use of Parents	**1. Busy playing, sitting idle, or engaged in age appropriate behavior and doesn't need parent; may interact with parent if parent initiates the interaction.**
	2. Reaches out to parent (approaches parent and speaks to otherwise silent patient), seeks and accepts comfort, may lean against parent
	3. Looks to parent quietly, apparently watches actions, doesn't seek contact or comfort, accepts it if offered or clings to parent
	4. Keeps parent at distance or may actively withdraw from parent, may push parent away or desperately clinging to parent and not let parent go

Appendix 2

The Pediatric Anesthesia Emergence Delirium Scale

The child makes eye contact with the caregiver.	**4 Not at all** **3 Just a little** **2 Quite a bit** **1 Very Much** **0 Extremely**
The child's actions are purposeful.	**4 Not at all** **3 Just a little** **2 Quite a bit** **1 Very Much** **0 Extremely**
The child is aware of his/her surroundings.	**4 Not at all** **3 Just a little** **2 Quite a bit** **1 Very Much** **0 Extremely**
The child is restless	**0 Not at all** **1 Just a little** **2 Quite a bit** **3 Very much** **4 Extremely**
The child is inconsolable.	**0 Not at all** **1 Just a little** **2 Quite a bit** **3 Very much** **4 Extremely**

Appendix 3

Richmond Agitation Sedation Scale (RASS) *

Score Term Description

+4 Combative Overtly combative, violent, immediate danger to staff
+3 Very agitated Pulls or removes tube(s) or catheter(s); aggressive
+2 Agitated Frequent non-purposeful movement, fights ventilator
+1 Restless Anxious but movements not aggressive vigorous
0 Alert and calm
-1 Drowsy Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* **(>10 seconds)**
-2 Light sedation Briefly awakens with eye contact to *voice* **(<10 seconds)**
-3 Moderate sedation Movement or eye opening to *voice* **(but no eye contact)**
-4 Deep sedation No response to voice, but movement or eye opening to *physical* stimulation
-5 Unarousable No response to *voice or physical* stimulation

Procedure for RASS Assessment

1. Observe patient
    a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
    b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
    c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
    d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.
    e. Patient has any movement to physical stimulation. **(score –4)**
    f. Patient has no response to any stimulation. **(score –5)**