A Pilot Randomized Controlled Trial Testing the Acceptability and Feasibility of a Pediatric Interactive Relational Agent (PIRA) vs. Standard Preoperative Education

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A. Specific Aims/Objectives

The purpose of this study is to determine the feasibility and acceptability of enhanced preoperative education using a Pediatric Interactive Relational Agent (PIRA), designed for children ages 4 through 10 years and their families, compared to the standard preoperative education currently provided. Specifically, the study aims are to evaluate the following: 1. Parental/Child PIRA access and utilization, 2. Parental satisfaction and encountered issues with the PIRA, and 3. Differences in parental preoperative anxiety, child preoperative anxiety, and child experience with emergence from anesthesia between the PIRA and control group.

B. Background and Significance

Surgery and anesthesia can be extremely stressful experiences for the pediatric population. Children, in particular, may respond negatively to the impact of the experience. Kain (1999) and Kotiniemi et al. (1997) found that more than 60% of children experienced anxiety during preoperative waiting, increasing the risk of numerous psychological stressors such as postoperative delirium and agitation. Additionally, they found sleep and eating disorders, separation anxiety, temper tantrums, and aggressive behaviors lasting up to 2 weeks, 6 months, and 1 year in 50%, 20%, and 7% of pediatric patients, respectively (Yuki & Daaboul, 2011). The negative impact of stress in children can result in short and long-term sequelae (examples as mentioned above), a regression of the child's emotional and behavioral development, delay of hospital discharge, and decreased overall parental satisfaction. Likewise, Stargatt et al. (2006)

and Bevan et al. (1990) demonstrated that parental anxieties can have a negative influence over the child's postoperative behavioral outcomes.

Anecdotally, parents frequently report a lack of understanding or a plan for how to address the idea of surgery and anesthesia to their child. This has been especially problematic in school-age children, who may lack the ability to anticipate and comprehend the necessary issues, solutions, and consequences. Evidence supports the benefits of enhanced preoperative education for pediatric patients and families. This, coupled with the lack of developed interactive agents preparing the pediatric patient and family for the perioperative anesthesia experience, demonstrated a need for the creation of such tools. This PIRA was developed by perioperative clinical experts, including perioperative Registered Nurses (RNs), Certified Registered Nurse Anesthetists (CRNAs), Physician Anesthesiologists, and Child Life Specialists (CLS) all with greater than two years' clinical experience, in addition to nonmedical parents. Piloting this intervention in a randomized controlled trial (RCT) to determine its impact on pediatric and parental anxiety, satisfaction, likelihood to recommend to others, and emergence from anesthesia, is critical for successful implementation and potential future iterations.

Given the large anesthetic volume at Boston Children's Hospital (BCH), this PIRA intervention has the ability to positively impact tens of thousands of patients and families to adjunct the preoperative process to reduce anxiety, provide knowledge in regards to the perioperative anesthesia experience (preoperative, intraoperative and postoperative), enhance communication between the child and parent (encourage questions, explanations as it relates to the perioperative experience), prevent post-operative maladaptive behavior (POMB), and increase parental satisfaction with the perioperative experience. Testing these potential benefits while adjusting the PIRA based on user feedback is essential for maximizing the impact and

dissemination of the tool. Moving forward, expanding the PIRA to include additional languages, a wider developmental age range, different anesthetic options other than general anesthesia, and including anesthetic locations outside of the operating room—such as radiology, procedural rooms, wound care, gastroenterology, or the emergency department—will further enhance these benefits and include more families.

C. Preliminary Studies

Perioperative programs designed to decrease patient and parental anxieties and set expectations are paramount to positive medical and psychosocial interactions, satisfaction, and outcomes. Numerous perioperative program publications and randomized controlled trials (RCTs) show interactive preoperative information reduces parental and patient anxiety (Batuman et al., 2016; Bartik & Toruner, 2017; Cassidy et al. 1999; Chartrand et al., 2016; Felder-Puig et al., 2003; Fortier et al., 2015; Hilly et al., 2015; Kain et al., 1996; Kain et al., 1995; Kain et al., 2007; Kassai et al., 2016; Liguori et al., 2016; Maclaren & Kain, 2007; McEwen et al., 2007; O'Conner-Von, 2008; Perry et al., 2012; Vaezzadeh et al., 2011; Wakimizu, 2015; Wantanakorn et al., 2018). Others have demonstrated that education and information programs decrease emotional trauma and regressive behaviors such as bedwetting, night terrors, and medical anxiety (Bartik & Toruner, 2017; Batuman et al., 2016; Hilly et al., 2015; Kain et al., 2007). RCTs have even found lower pain scores and opioid requirements in pediatric patients who participated in a preoperative information program (Chartrand et al., 2016; Kain et al., 2007). Furthermore, a systematic review of RCTs using media-based interventions for preoperative education found a parental desire for more education. This systematic review reported a statistically significant reduction in anxiety and an increase in knowledge after the interventions (Lee et al., 2003).

In adults, educational interactive videos, also called conversational or relational agents (Trinh et al., 2017), which include user participation and feedback have shown a significant reduction in preoperative anxiety (Ryu et al., 2018; Tou et al., 2012; Hoybye et al., 2016), increased satisfaction (Narimatsu et al., 2011), increased knowledge, and a shorter anesthetic interview, potentially indicating a greater understanding of the anesthetic plan, process, and risks (Kakinuma et al., 2011). In pediatrics, there are no such tested educational interactive relational agents, avatars, or animated videos for surgery or anesthesia.

Using an e-Delphi method to determine important topics to include in such a relational agent, in conjunction with a multidisciplinary team to develop age appropriate dialogue and content, a Pediatric Interactive Relational Agent (PIRA) was created. This PIRA, developed at BCH and programmed with a team at Northeastern University, is the first known relational agent specifically targeting pediatric patients ages 4 through 10 years old and their families, to educate them about anesthesia and the perioperative process prior to their surgical date.

D. Design and Methods

(1) Study Design

This study is a pilot 1:1 randomized trial with one control group and one intervention group. Children age 4 through 10 years and their parents will be randomized to receive the PIRA versus the standard education prior to Otorhinolaryngology (ORL) or Urology surgery. For the purpose of this protocol, “parents” refers to the biological or legally adopted parents or legal guardians. Using surveys, assessments, and data we collect from the medical record and PIRA, we will look at PIRA access and utilization, parental satisfaction and encountered issues with

PIRA, and differences in parental and child preoperative anxiety as well as child emergence agitation between the intervention and control groups.

(2) Patient Selection and Inclusion/Exclusion Criteria

We plan to enroll parents and their children, ages 4 through 10 years old, who are undergoing general anesthesia and elective, outpatient ORL or Urology surgery at BCH Waltham. Children will be American Society of Anesthesiology (ASA) physical status I or II. Parents must be at least 18 years of age or older. Since the study PIRA is currently only available in the English language, both parents and their children must be fluent in English in order to understand and interact with the PIRA.

Parents without reliable internet access to the Google Chrome browser through a tablet or computer, parents of children with diagnosed developmental delays, parents who have children who have had previous surgical history under general anesthesia, and parents of children involved in other anesthesia-related studies at BCH will be excluded for this study. A prior surgery or procedure performed under local anesthesia or without anesthesia (e.g. newborn circumcision, frenulotomy, or newborn Achilles tenotomy), would not exclude the participant. These exclusion criteria will be assessed during the consent phone call.

(3) Description of Study Treatments or Exposures/Predictors

Families that agree to participate in the study will be assigned a number (either one or two) from a random number generator. This will determine whether they are assigned to the PIRA (intervention) group or to the standard education (control) group.

Participants (children and their parents) will not be blinded to the study group (they will know if they received the PIRA). On the day of surgery, the research team member observing enrolled children for signs of anxiety in the preoperative area and the PACU nurse observing the children as they awaken from anesthesia post-operatively will be blinded to group assignment; they will not know, nor will they ask families, about their preoperative education experience.

***Intervention Group*:** If assigned to the intervention group, families will receive access to the PIRA for a minimum of two days in addition to the standard of care pre-op education provided for all families (described below for the control group). The child's first name and age will be entered into the PIRA's enrollment page so that the tool can address the child by name and educate them in an age-appropriate manner. After an account has been created, an email containing instructions on the purpose of PIRA and how to use the program (Appendix A) will be sent to the email address provided by the family from a research team member at a BCH. Included in this email will be a hyperlink to access the PIRA, as well as a unique username and password for families to log in. Once enrolled, the PIRA will be accessible to the family as often and for as long as desired up to 10 days prior to the scheduled surgery. Parents will receive a reminder email a few days prior to their child's surgical date prompting them to log-in and complete the PIRA with their child at least once before the procedure. The parents will be encouraged to reach out to the Principal Investigator at any time if they have difficulty accessing the PIRA or if questions arise regarding the educational content within the program.

C*ontrol group*: Participants assigned to the control group will receive the standard of care preoperative education at BCH Waltham. These participants will not receive any

additional preoperative educational materials or resources other than what is currently provided by their care team. This usually includes a routine phone call, text, or email from a pre-operative staff member within a few days of the child's scheduled procedure to provide basic information about fasting, when to arrive at the hospital, and anything additional that needs to be done prior to the procedure (e.g. COVID-19 testing), when applicable. Any specific information about the anesthetic will be deferred to the anesthesia team for the surgical day, per usual.

In both the intervention and control groups, if parents specifically request additional information to prepare for surgery, pre-op staff may send them the "Social Story" developed by the Autism Spectrum Center, Child Life Services, and Waltham Surgical Services. This document provides an age-appropriate step-by-step guide as to what to do and what to expect on the day of surgery.

On the day of surgery, all parents participating in the study, regardless of group assignment, will receive surveys to complete in the pre-operative holding area via REDCap®. The surveys will be given to the parent who consented to the study. If both parents are present, and both consented to the study, they will both receive surveys to complete. A research staff member trained for reliability and blinded to the study arm will assess the child for signs of anxiety in the pre-op holding area.

For both groups, once the surgical procedure is complete, and the child has gone to the PACU, Emergence Agitation/Delirium will be assessed per standard of care at Waltham by the bedside PACU nurse using the Pediatric Agitation Emergence Delirium Scale (PAED). The

research team will collect this PAED information retrospectively from the child's electronic medical record.

(4) Definition of Primary and Secondary Outcomes/Endpoints:

See Table 1 for Summary of Outcomes/Measures

Patient Demographics

Parental age, gender, ethnicity, and highest education level achieved will be collected as part of the REDCap® preoperative survey to better understand the pilot group and educational needs (Appendix B).

Primary Outcomes

Parental Utilization:

- *When provided with the opportunity to obtain more information as it relates to the perioperative experience, do parents and their children use the tool?*
- *How many times did they access the tool and for how long?*
- *Were there any barriers to accessing the PIRA tool?*

If there were problems surrounding the accessibility, content, language, or any other system issues, this will affect utilization and the PIRAs future potential impact. Regardless of the medium, materials, or content provided, no preoperative educational program can be successful and sustainable unless readily adopted and utilized by parents and children. As such, a primary outcome will evaluate whether families actually viewed the materials, with whom, and how much time they spent with the PIRA.

***Parental Perceived Impact and Impressions*:**

- *Did parents find the tool subjectively helpful?*
- *What improvements or changes in content or language would they consider?*
- *Would parents recommend the PIRA to future families?*

Identifying parental perceived benefits or drawbacks to the PIRA may elucidate the familial interactions and how they feel about their educational experience in a different way than anxiety or other objective data. Similarly, given the novel nature of the PIRA, it is important to identify any educational gaps and potential for future topics and educational needs. If parents believe the PIRA improved their preoperative experience, it could be useful for future families.

Secondary Outcomes

Child Anxiety in Preoperative Waiting:

As discussed, more than 60% of pediatric patients have been found to suffer from anxiety in the preoperative period. The effects of anxiety may have behavioral sequelae, or Postoperative Maladaptive Behaviors (POMB), which can last up to a year or longer. Therefore, reducing anxiety levels should be a priority of any educational tool for pediatrics. Numerous randomized control trials have demonstrated decreased child anxiety in preoperative waiting for those patients who participated in preoperative educational programs including videos, tours, apps, games, and books. *Is there a similar difference in the control and intervention groups' preoperative anxiety with this PIRA intervention?*

Parental Anxiety in Preoperative Waiting:

In several cited studies, parental anxiety directly correlates with the pediatric patient's anxiety. Thus limiting or reducing parental anxiety is an important part of a preoperative education intervention. *Does improved communication and education decrease parental anxiety?* An intervention which serves to improve communication between the parent/child as well as the parent/anesthesia provider AND reduce parental anxiety would perhaps provide significant benefits.

Emergence from Anesthesia: Presence or absence of emergence agitation/delirium (ED):

Depending on the study, ED has an incidence between 10-80%, with most studies showing 30-50% of children having ED after a general anesthetic (Przybylo et al., 2003; Ringblom et al., 2018). ED can be extremely distressing for parents, delay discharge from post-anesthesia care unit (PACU), can result in injury to the patient or staff (due to uncontrolled flailing, kicking, punching), and can also potentially result in the unintentional dislodgement of intravenous catheters or other tubes (e.g. nasogastric, gastrostomy, chest, endotracheal tubes). Data have shown a reduction in ED incidence with the use of preoperative education programs (Kain et al., 2004). *Is there any effect on the incidence of ED for children who have more interactive preoperative education, such as PIRA, compared to standard information?*

(5) Data Collection Methods, Assessments, Interventions and Schedule

On the day of the surgical procedure, participating parents in both the PIRA and the control groups will receive the same in-person surveys in the preoperative holding area. Surveys will be administered via REDCap® and completed on iPads which have been given to the

parents by a member of the research team (Appendix B). In both groups, the parent(s) who consented to the study and there on the day of surgery will be given the surveys.

The surveys will have no identifying questions and will be automatically uploaded to REDCap®. They will be accessible only to members of the research team. Children will not be asked to complete any surveys but will be observed in the pre-op holding area by a member of the research team and in the PACU by a PACU nurse, as per standard of care at BCH Waltham. Both will have been trained for reliability in conducting the study-specific assessment tools.

Pediatric Anesthesia Emergence Delirium (PAED) scores will be collected retrospectively from the child's electronic medical record. All data collected will be de-identified and presented or published in aggregate. The research team will provide a finished copy of the manuscript upon request.

Primary Outcomes Data

Parental Utilization:

The amount of time spent using the PIRA and the number of times the PIRA was accessed will be able to be collected via the program itself, stored on a secure Northeastern University Server, and will be accessible only to the study team. Each click of the mouse a user makes in the system will be timestamped and saved on the database. This information will be de-identified. Additionally, the parental survey administered by the research team member in the preoperative holding area will obtain self-reported data on PIRA access and time spent using the tool (Appendix B).

Parental perceived impact and impressions:

This outcome will be assessed in the same survey (Appendix B) as Parental Utilization. The survey will have no identifying questions and will be automatically uploaded to REDCap®, accessible only to members of the research team. Any data will be de-identified and presented in aggregate.

Secondary Outcomes Data

Child Anxiety in Preoperative Waiting:

Child anxiety will be assessed using the modified Yale Preoperative Anxiety Scale (mYPAS), an observational state anxiety measure for children containing 27 items in five categories (activity, emotional expressivity, state of arousal, vocalization, and use of parents). See Figure 1. The mYPAS has been validated for measuring childrens' anxiety (Kain et al., 1995; Kain et al., 1997). Members of the research team who will administer the mYPAS for this study will be trained for reliability. mYPAS scores range from 22.5 to 100, with higher scores indicating more anxiety.

Parental Anxiety in Preoperative Waiting:

Parental anxiety will be assessed using the State-Trait Anxiety Inventory (STAI). See Figure 2. This self-report anxiety instrument contains two separate 20-item subscales that measure trait (baseline) and state (situational) anxiety (Spielberger, 1973; Spielberger, 1983; Spielberger, 1989) This survey will take place in the preoperative holding area and will be administered in conjunction with the previous utilization/recommendation survey (Appendix B). The STAI is scored from 20-80, with higher scores indicating more anxiety.

Emergence from Anesthesia: Presence or absence of emergence agitation/delirium (ED):

To determine any effect this PIRA may have on ED, the PACU RN assigned to care for the given patient will assess emergence upon patient arrival to PACU using the PAED scale. See Figure 3 for PAED Scale. The PAED is a routine assessment conducted by PACU RNs at Waltham for all post-operative pediatric patients upon emergence from anesthesia. A member of the research team will retrospectively extract the PAED score from the patient's chart. The PAED scale measures five behaviors, each rated on a five-point scale of zero to four. The scores are summed for total scale score up to a maximum value of 20 (Sikich & Lerman, 2004). An assessment of the internal consistency and reliability of the PAED scale validated it for assessing ED in children recovering from general anesthesia (Ringblom et al., 2018). A PAED ≥10 yields 64 percent sensitivity and 86 percent specificity (Sickich & Lerman, 2004), and a score of >12 yields 100 percent sensitivity and 94.5 percent specificity for the diagnosis of ED (Bajwa et al., 2010). For use in this study, ED will be considered present with a score ≥ 12.

(6) Study Timeline

This study will take approximately one year to complete after IRB approval.

E. Adverse Event Criteria and Reporting Procedures

This is a minimal risk study. Any adverse effects associated with this study will be reported to the BCH IRB by the Principle Investigator (PI). If participants experience any adverse event related to this study and need follow-up for any concerns, they may be referred to the Patient Relations Department or Social Work Department at BCH as indicated.

F. Data Management Methods

All collected survey data as well as pre-op and PACU observation data will be de-identified and presented in aggregate, stored in REDCap® and kept in password-protected folders on BCH computers, accessible only by the research team members. The data collected directly from the PIRA program itself will be stored on a secure Northeastern University Server, and will be accessible only to the study team. Upon completion of data collection, the PIRA data will be transmitted back to BCH electronically and stored on the BCH server. All research team members will have completed CITI training.

G. Quality Control Method

Qualitative, free-text data will be analyzed by two or more members of the research team to ensure validity and concurrence of identified themes.

H. Data Analysis Plan

A Student's t-test will be used to compare the mean anxiety scores, mYPAS, between the groups. Free text entries from parents will be clarified, consolidated, and summarized by the research team for themes. Quantitative data from the parental preoperative survey will be summarized for mean, median, mode, and standard deviation and presented both numerically and graphically using Microsoft Excel.

I. Statistical Power and Sample Considerations

This pilot protocol is powered to see an effect on pediatric anxiety, as measured by the mYPAS. A sample size of 30 per group will provide 80% power to detect a difference of 6 in mean mYPAS scores between the two groups (assuming a standard deviation for the mYPAS of 8 based on published data in preoperative holding) (Kain et al., 1997), based on Student's t-test and assuming a two-tailed alpha level of 0.05. With a range of 22.5-100, prior studies (Kain et al., 1997) have used a reference score of 37 as consideration for high anxiety cases, with the

prevalence of such high-anxiety cases at 24%. Based on anticipated attrition of 20% due to failure to interact with the PIRA, potential for surgical or anesthesia cancellations before or on the day of surgery, or withdrawal from the study, a total of 76 patients (38 in each group) will be recruited.

J. Study Organization

This study will be directed by Linda Bulich, MD and Mark Blazey, DNP, CRNA with the support of other research team members at Boston Children's Hospital Waltham. The entire research team will be responsible for overseeing patient screening, recruitment and consent. Members of the research team will also be responsible for data collection, data analysis, as well as identifying and reporting adverse events.

Study team members at Northeastern University (Teresa O'Leary, BA, PhD Student and Timothy Bickmore, BSE, MS, PhD, Associate Dean of Research) were responsible for programming the PIRA and will be monitoring the tool for any technical issues and updating as needed.

Table 1. Outcomes

Outcome	**Measurement**	**Scoring**	**Timing**
Participant Demographics	Age of parent, Gender of parent who completed PIRA, Ethnicity	See Appendix B	Preoperative Waiting, self-reported.
Parental Utilization of PIRA (Primary)	Parental Survey	See Appendix B	Preoperative Waiting, self-reported.

Recommendation to Future Families (Primary)	Parental Survey	See Appendix B Sliding Scale (0 = Definitely NOT Recommended - 10 = Definitely Recommend)	Preoperative Waiting, self-reported.
Potential Gaps or Recommendations for Future Iterations (Primary)	Parental Survey, free text entry	See Appendix B Summarized for themes	Preoperative Waiting, self-reported.
Parental Anxiety (Secondary)	STAI	See Appendix B and Figure 2. Range 20-80, higher = greater anxiety	Preoperative Waiting, self-reported
Child Anxiety (Secondary)	mYPAS (Observational)	See Figure 1. Range 22.5-100	Preoperative Waiting, observed by a Research Assistant (RA)
Emergence from Anesthesia (ED) (Secondary)	PAED Scale (Observational)	See Figure 3. Range 0-20; Threshold for ED $\geq$12	PACU, observed by a Registered Nurse (RN) as per BCH standard of care.

Appendix A. Email Instructions for use of the Interactive Anesthesia Education Program

To the Parent/Guardian of _____:

Thank you for your participation in this study. Please refer to the below instructions for using the PIRA program.

Access to the education program is by a computer or tablet device through the hyperlink included below on the Google Chrome browser ONLY. Please note, a mobile device and other internet browsers will not work with this online tool.

Along with the hyperlink, we have also provided you with a unique username and password. Once you click on the hyperlink, you will be prompted to enter this information to access the program.

Link:

Username:

Password:

When you are ready to review the education materials, click, "start at the beginning" You or your child will be required to periodically answer questions or respond by clicking the mouse to move it forward. Either you or your child can click, but please make sure that both you and your child are able to see and hear the teaching the entire time.

If you need to stop for a prolonged period of time for whatever reason, you can start at the beginning again to ensure no content is missed. Refreshing the page will reset the program. It will not save where you left off.

You will receive one email reminder a few days prior to your child's surgical date reminding you to complete the PIRA at least once with your child. If you have any problems accessing the education program, or any issues during its use, please contact the study PI, Linda Bulich, at 617-355-7737 or linda.bulich@childrens.harvard.edu.

Thank you,

Linda Bulich, MD

Appendix B. Parental PIRA Survey

Please complete the survey, below. Your responses to the following questions will better help us to understand how to improve our preoperative education and communication for parents and their children. As a study participant, you were randomly assigned to either receive an online interactive tool focused on educating children, named PIRA, or you received our standard preoperative information. If any of the below questions make you uncomfortable, please leave them blank.

Demographics:

Q1. Your current age (in years):

Q2. Gender:

Q3. Ethnicity:

Q4. Highest level of education achieved:

Pre-Operative Education Experience:

Q1. What of the following statements describes your experience with the anesthesia education agent, Ira? (Select all that apply)

- ❑ I did not receive the link to Ira
- ❑ I received the link to Ira, but did not watch it
- ❑ I received the link to Ira, but a different care provider or family member watched Ira.
- ❑ I watched Ira WITHOUT my child
- ❑ I watched Ira WITH my child
- ❑ I had a hard time using Ira
- ❑ My child liked using or watching Ira
- ❑ My child seemed LESS stressed about surgery or anesthesia because they watched Ira
- ❑ My child seemed MORE stressed about surgery or anesthesia because they watched Ira
- ❑ I understood anesthesia better after watching Ira
- ❑ Ira helped me talk to my child about anesthesia and surgery
- ❑ Ira helped answer questions about anesthesia
- ❑ I felt less stressed about surgery or anesthesia because I watched Ira
- ❑ Ira made my surgery experience BETTER
- ❑ Ira made my surgery experience WORSE

- ❑ Ira was difficult to use or understand

Q2. In total, about how long did you spend with the interactive education agent, Ira?

- ❑ Less than 5 minutes
- ❑ 5-30 minutes
- ❑ 30-60 minutes
- ❑ More than 60 minutes
- ❑ I did not view the agent

Q3. How likely are you to recommend the interactive education agent, Ira, to future families? (Skip if you did not receive or view Ira)

This is a sliding scale

0 = Not at all Likely to Recommend----------100 = Extremely likely to recommend

Q4. Write any topics that were missing, unclear, or absent from the interactive education agent, Ira. (Skip if you did not receive or view Ira)

**Free Text Response_____

Q5. Write any suggestions for future improvements to the interactive education agent, Ira. This may include any difficulties in accessing or using it. (Skip if you did not receive Ira)

**Free Text Response_____

Q6. Self-evaluation questionnaire. Rate the following statements how they apply to you from 1 = Not at all to 4 = Very Much So

	1 = Not at all	2 = Some what	3 = Moderately so	4 = Very much so
I feel calm				
I feel secure				
I am tense				
I feel strained				

I feel at ease

I feel upset

I am presently worrying over possible misfortunes

I feel satisfied

I feel frightened

I feel comfortable

I feel self-confident

I feel nervous

I am jittery

I feel indecisive

I am relaxed

I feel content

I am worried

I feel confused

I feel steady	
I feel pleasant	

Figure 1. Modified Yale Preoperative Anxiety Scale (mYPAS) for Child Anxiety

Domain: Activity
1. Looking around, curious, playing with toys, reading (or other age-appropriate behavior); moves around holding area/treatment room to get toys or go to parent; may move toward OR equipment
2. Not exploring or playing, may look down, may 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
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 or will not separate from parent

Domain: Vocalizations
1. Reading (nonvocalizing 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)

Domain: 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, extremely upset, may have wide eyes

Domain: State of Apparent Arousal
1. Alert, looks around occasionally, notices/watches anesthesiologist (could be relaxed)
2. Withdrawn child sitting still and quiet, may be sucking on thumb or face turned in to 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

Figure 2. Parental State-Trait Anxiety Inventory (STAI) for Parental Anxiety

Self-evaluation questionnaire	STAI Form Y-1			
	1	2	3	4
1. I feel calm	□	□	□	□
2. I feel secure	□	□	□	□
3. I am tense	□	□	□	□
4. I feel strained	□	□	□	□
5. I feel at ease	□	□	□	□
6. I feel upset	□	□	□	□
7. I am presently worrying over possible misfortunes	□	□	□	□
8. I feel satisfied	□	□	□	□
9. I feel frightened	□	□	□	□
10. I feel comfortable	□	□	□	□
11. I feel self-confident	□	□	□	□
12. I feel nervous	□	□	□	□
13. I am jittery	□	□	□	□
14. I feel indecisive	□	□	□	□
15. I am relaxed	□	□	□	□
16. I feel content	□	□	□	□
17. I am worried	□	□	□	□
18. I feel confused	□	□	□	□
19. I feel steady	□	□	□	□
20. I feel pleasant	□	□	□	□

1: Not at all, 2: Somewhat, 3: Moderately so, 4: Very much so

Figure 3. PACU Pediatric Anesthesia Emergence Delirium (PAED) for Anesthesia Emergence Delirium

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

K. References

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