Development of a Decision Aid for Preoperative Anxiety: A Quality Improvement Project

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Abstract

This paper describes the process of developing a patient decision-aid (PDA) prototype for preoperative anxiety at Doernbecher's Children's Hospital (DCH). There are many evidence-based interventions to manage pediatric preoperative anxiety, but there remains no uniform strategy to address this concern. PDAs are tools that promote shared-decision making (SDM) and reduce decisional conflict. This quality improvement (QI) project aimed to develop a PDA, guided by the iterative process proposed by Coulter's Model, a recommended methodological framework by the International Patient Decision Aids Standards Collaborative (IPDAS). An expert panel was assembled and the Delphi Method informed the systemic process for attaining consensus on priority items to be included in the decision aid through controlled feedback stages. Our finalized PDA prototype provides information on preoperative anxiety, pharmacological and non-pharmacological options, risks, and benefits. Our team created the first parental decision aid for preoperative anxiety at DCH, and this PDA was deemed useful and acceptable by perioperative clinicians. As a result of this project, future revisions and improvements to the PDA may lead to a uniform process to facilitate SDM to support a successful child/parent separation prior to surgery at DCH.

Keywords: Coulter's Model, Delphi Method, International Patient Decision Aids Standards Collaborative (IPDAS), Patient Decision Aids (PDA), pediatric preoperative anxiety, Shared Decision Making (SDM)

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Introduction

Problem Description

One of the most distressing aspects for children during the perioperative period is separation from their parents (Kain et al., 2006; Moura et al., 2016). Pediatric preoperative anxiety is associated with many risks, including poor behavioral adherence during anesthetic induction and adverse postoperative outcomes (Gauchan, 2019; Kain et al., 2006; Sola et al., 2017). Multiple pharmacologic and non-pharmacological strategies are available to attenuate preoperative anxiety in children and facilitate a smooth separation, with the most effective separation intervention individualized to the child (Moura et al., 2016; Sola et al., 2017). Shared decision-making (SDM) significantly improves parental comprehension, reduces decisional conflict, and permits perioperative staff to individualize separation strategies for each child (Wyatt et al., 2015). Currently, there is no consistent process to facilitate SDM to support a successful child/parent separation prior to surgery at Doernbecher Children's Hospital (DCH). During the preoperative period, a varying degree of information is provided to parents by staff during an often stressful and time-limited period, resulting in parental decisional conflict and uncertainty. This quality improvement (QI) project systematically and iteratively developed a parental decision aid to help the decision team navigate a stressful period and support a successful separation strategy at DCH.

Available Knowledge

Preoperative anxiety, characterized by feelings of tension, apprehension, and nervousness is a common phenomenon affecting an estimated 40-60% of children that undergo surgery (Gulur et al., 2019). The most stressful times during the perioperative experience are separation from parents and induction of anesthesia (Gulur et al., 2019). A stressful perioperative experience creates a three times

higher likelihood for children to exhibit negative physiologic and psychologic behaviors, leading to potentially higher costs for health services, maladaptive behaviors after surgery, and inability to cope with future medical encounters (Ahmed et al., 2011; Kain et al., 2006; Moura et al., 2016). Factors associated with higher preoperative anxiety include children between the ages of 1 and 5 years old, those with negative emotionality, increased intensity of reactions, and inhibited temperament (shyness/withdrawal), a history of previous negative medical encounters, and/or children with anxious parents (Ahmed et al., 2011; Gulur et al., 2019; Moura et al., 2016). In addition, the perioperative period can be particularly stressful for children with psychological, developmental, or behavioral disorders (Dave, 2019; Elliot et al., 2018). Therefore, the perioperative team should identify children at the greatest risk for preoperative anxiety and work with families to develop an individualized plan to facilitate an anxiety-free experience.

Both pharmacological and behavioral interventions attenuate anxiety and distress in children during the perioperative period (See Appendix C). The primary goals of these interventions are to facilitate a relatively anxiety-free separation of children from their parents, a smooth induction of anesthesia, and a less anxious and more compliant postoperative recovery (Gulur et al., 2019). Despite sedative premedication being one of the most commonly used interventions to prevent and treat preoperative anxiety, there remains no widely accepted premedication regimen (Qiao et al., 2017; Sola et al., 2017). Premedication with oral midazolam is most frequently used in pediatric patients and has widely demonstrated efficacy in reducing separation and induction anxiety (Gauchan et al., 2019; Pasin et al., 2015; Wang et al., 2020). Intranasal midazolam is a noninvasive route of administration, with safe and often higher bioavailable premedication levels than the oral route (Khoshrang et al., 2021). Dexmedetomidine, in both oral and intranasal formulations, is increasingly used for premedication due to its favorable profile of sedative, analgesia, and anxiolytic effects without the risk of respiratory depression (Gauchan et al., 2019; Ibrahim, 2014; Jun, 2017; Lewis & Bailey, 2020; Mondardini, 2019;

Pasin et al., 2015; Wang et al., 2020). Although both dexmedetomidine and midazolam are equally effective in reducing parental separation anxiety and producing successful mask acceptance rates during induction, dexmedetomidine is more effective in facilitating a smooth postoperative recovery (Gauchan et al., 2019; Pasin et al., 2015; Wang et al., 2020). Ketamine, frequently administered orally, intranasally, and intramuscularly, is another preoperative medication that, when used alone, has potential undesirable postoperative side effects, including salivation, delirium, and anxiety (Dave, 2019; Ibrahim, 2014; Kamel & Amin, 2020; Khoshrang, 2021). However, in combination with other premedications (dexmedetomidine or midazolam), ketamine exhibits complementary pharmacological effects resulting in fewer perioperative adverse events, improved cooperation, less preoperative anxiety, and a superior option for quiet separation and smooth induction of anesthesia in special populations (Qiao et al., 2017). Sedative premedications are effective for treating preoperative anxiety, but they should not be used routinely in all children undergoing surgery. Instead, pharmacological interventions are recommended for children at significant risk for developing preoperative anxiety with variables such as age, duration of surgery, and potential recovery delays also in mind**.** However, if premedication would benefit the child, it is important to not withhold it (Gulur et al., 2019).

Non-pharmacological strategies to manage preoperative anxiety for children undergoing anesthesia and surgery are widely advocated (Gulur et al., 2019). The most successful behavioral interventions include role-play prior to surgery, audiovisual presentations related to preanesthetic information, and targeted Child Life sessions tailored to patient's developmental needs (Batuman et al., 2016; Hatipoglu et al., 2018; West et al., 2020). Other effective behavioral methods available to address separation anxiety include play therapy, OR tours, distraction in the form of interactive games and tablet computer devices, transportation to the operating room via toy car or wagon, relaxation-guided, and imagery and music therapy (Kim et al., 2019; Liu et al., 2018; Park et al., 2020; Perry et al., 2012; Sola et al., 2017; Stewart et al., 2019; Vagnoli et al., 2019; Van Der Heijden et al., 2015). Most importantly, non-

pharmacologic preoperative preparation in children must be age-appropriate (Perry et al., 2012). Children react to the stress of surgery and anesthesia in an age-dependent manner, with younger children (< 3 years) not benefitting from teaching interventions as coping mechanisms have not yet developed, while older children (7-12 years) require more explanation and participation (Dave, 2019). Ultimately, children who received behavioral interventions with or without premedication had significantly less preoperative anxiety, emergence delirium and required less analgesia in the recovery room than those who received only premedication (Gulur et al., 2019; Meletti et al., 2019).

Though numerous interventions are available to manage pre-operative separation anxiety, there remains no uniform strategy to address this concern. Additionally, the decision to determine an appropriate intervention is time-limited and often stressful for families, creating decisional conflict. Shared decision-making (SDM) is an essential component of evidence-based medicine that promotes collaboration between patients, family members, and healthcare providers and guides patient health decisions while considering their individual needs, values, and preferences (Elwyn et al., 2006). SDM increases parental knowledge and decreases parental decisional conflict, though its application remains limited in pediatric health care settings (Wyatt et al., 2015). Factors like children's evolving developmental context, multiple stakeholders (child, family members, healthcare providers) with varying preferences and values, parents acting as surrogate decision-makers, and complex legislation and policy regarding pediatric health decisions complicate successful pediatric SDM. Barriers to SDM in pediatrics include poor quality and insufficiently tailored information, conflicting power relations between parties involved, insufficient time, and parent/child emotional conflict. Whereas, facilitators of SDM include low stake decisions, good quality information tailored to literacy and developmental needs of families involved, trust and respect towards healthcare providers, and strong SDM tools/resources (Boland et al., 2019). Developing a tool to facilitate optimal decision making with an overall goal to decrease pediatric preoperative anxiety will be beneficial to promote SDM in the perioperative setting.

SDM is a vital element of patient care and is often implemented through the use of patient decision aids (PDAs), which are tools designed to facilitate SDM (Wyatt et al., 2015). PDAs provide health information regarding options and outcomes to assist patients in making informed, value-based decisions alongside the care team (Elwyn et al., 2006). Decision aids describe the decision to be taken, the options available, and the outcomes of these options (benefits, harms, uncertainties) based on current evidence available (BMJ, 2013). PDAs have the potential to improve health outcomes by presenting complex medical information in a simple and readable format that allows patients and clinicians to collaborate more effectively, improving communication and increasing patient involvement and understanding (Ankolekar et al., 2018; BMJ, 2013). In order to promote SDM in the perioperative environment, a PDA that clearly and effectively outlines available interventions to address and allay pediatric preoperative anxiety is essential.

Rationale

This project aimed to develop a PDA guided by the methodological framework in Coulter's Model development process (see Appendix D). This comprehensive model includes and expands upon the theoretical framework recommended by The International Patient Decision Aid Standards Collaboration (IPDAS). The overarching purpose of IPDAS and Coulter's methodological criteria is to enhance the quality and effectiveness of SDM through collaboration on the systematic development and implementation of decision aids (Coulter et al., 2012; IPDAS, 2021). The model emphasizes the iterative development of a PDA prototype by a multidisciplinary steering group to establish consensus following critical appraisal of comprehensive evidence. The documentation of a systematic and transparent process for PDA development provides reassurance of the PDA's validity and reliability (Coulter et al., 2012; IPDAS, 2021). Implementation of the model development process informed our systematic approach for developing a high-quality and relevant parental decision aid for child/parent preoperative separation.

Specific Aims

The overall goal of this quality improvement (QI) project was to systematically and iteratively develop a parental decision aid to help the decision team navigate a stressful period and support a successful child/parent separation strategy at DCH. Primary aims used to achieve this goal included utilizing a modified Delphi technique to assemble a team of stakeholders to serve as an expert panel by March 21, 2022, determining items to include in the decision aid by July 1, 2022, and developing the decision aid with expert consensus by September 19, 2022.

Methods

Context

DCH is an 80-bed pediatric academic teaching hospital in Portland, Oregon, affiliated with Oregon Health & Science University (OHSU). DCH employs around 45 OR Registered Nurses (RNs), 12 Certified Surgical Technologists (CSTs), 29 anesthesia providers, and 42 surgical attendings, with nine operating rooms and over 6,000 surgical cases per year. In anticipation of a child's procedure, a preoperative nurse contacts the parents days before surgery to discuss the check-in process, fasting requirements, and covid-19 testing requirements. If the child has a history that suggests potential difficulties associated with separation, such as past trauma, developmental disabilities, autism, or a previous negative healthcare experience, a child life specialist (CLS) referral is triggered. CLS contacts the parents a day before the procedure to formulate a strategy and discuss methods for separation. In the absence of a CLS referral, a CLS is available as needed in the preoperative area. On the day of surgery, the patient and one designated caregiver arrive 1-1.5 hours before the surgery start time. Due to infection control measures, only one parent is allowed in the waiting and preoperative area. Barriers to successful separation at DCH can be identified at the system and child/parent levels. System characteristics include inconsistent communication between care teams and providers, time constraints, and limitations on the number of caregivers in the perioperative area. Child/parent characteristics

include children aged two to eight, family tension, and interpersonal dynamics, including avoidant and aggressive parental attachment, clingy temperament in children, and special populations with sensory deficits. Specific strategies at DCH to address separation include engaging the child in the induction process (mask flavors, stickers), distraction (games, videos, toys), and premedication with oral or nasal medication prior to separation. Currently, there is no consistent process to facilitate SDM to support a successful child/parent separation prior to surgery at DCH.

Interventions

Our QI project utilized the methodological framework in the Delphi Method to guide expert panel selection and iterative stages of feedback to gain expert consensus. The Delphi Method is a well-validated systematic process for attaining consensus through controlled feedback from an expert panel, often used in healthcare to develop guidelines, protocols, and guidance tools when there is limited or conflicting evidence available (Taylor, 2020).

Our first intervention included assembling an expert panel. Suitable expert panelists must be skilled and competent within the specialized area of knowledge related to the target problem and selected upon the investigators' judgment (Hsu & Sandford, 2007). The key stakeholder groups relevant to our target problem include preoperative nursing staff, CLS, and anesthesia providers. Inclusion criteria for the expert panel included an awareness of SDM and strategies to facilitate a smooth preoperative child/parent separation. We aimed to achieve an expert panel of 10-20 members. While there is no consensus in literature for the optimal number of panelists in the Delphi Method, Hsu & Sandford (2007) report that the majority of Delphi studies use between 15-20 respondents with 10-15 respondents effective when the background expertise of the respondents are homogenous. With assistance from DCH perioperative leadership, primary investigators selected the panelists who met the inclusion criteria in the key stakeholder group at DCH and invited them by email to participate in the project.

Next, there were three phases of structured communication with the expert panel to achieve panel consensus. According to Taylor (2020), the majority of research using the Delphi method utilize Likert scales to evaluate panelists' responses with consensus defined as a 70% agreement rated seven or more on a 9-point Likert evaluation scale. Each expert stakeholder in our QI project rated the importance of priority items on a 1 to 9 scale as (1= not at all, 9= extremely). A rule of disagreement was considered 30% of responses to the item within the lowest tertile (1-3) and a rule of consensus as 70% or more in the highest (7-9). Open-ended comments were reviewed to help interpret scores and clarify numbers within the 4-6 threshold.

During phase one, we applied background information and clinical evidence from our literature review to engage our expert panel to determine items to include in the decision aid. An anonymous, online Qualtrics survey (see Appendix E) was distributed to our expert panel to identify priority items for inclusion in the decision aid. The survey design included a Likert scale of potential items to include in the PDA, with the option to add free-text comments. During phase two, items with an inconclusive consensus during phase one were reevaluated and additional (new) items were surveyed with Likert scales utilizing identical criteria to establish a rule of disagreement or consensus. Items that reached a high consensus or disagreement during phase one were not included in this survey. Design and formatting options were presented to panelists during phase two to elicit consensus on the visual representation of the PDA. The prototype PDA was developed based on data obtained from phase one and two surveys. The PDA was designed with specific strategies to reduce cognitive demand by incorporating recommendations by IPDAS to address health literacy and comprehension. The decision aid aimed to incorporate a basic design with visual reinforcement of key concepts and language at or below the eighth-grade reading level reinforced by the Simple Measure of Gobbledygook (SMOG) index (Muscat et al., 2021). Finally, we evaluated the decision aid's usability among our expert panel (Survey

3). Using the data from this evaluation phase, we addressed any potential design, comprehension, or content issues and created a finalized prototype PDA.

Measures

Evaluated measures correspond with the project's interventions (see Table 1). The selected outcome measures addressed the specific aims to assemble a team of stakeholders to serve as an expert panel and determine items to include in the decision aid through expert consensus over two Delphi phases.

Table 1 Interventions and Evaluated Measures

Intervention	Measure
Aim 1: Build Expert Panel	• Stakeholder # = # of invited panelists/# of actual panelist • Panelist member specialty
Aim 2: Delphi Phase 1	• Response rate of stakeholder= # of surveyed panelists/# of responses by surveyed panelists • Consensus agreement of items to include • Items requiring revisit d/t lack of consensus • Themes of free-text responses
Aim 3: Delphi Phase 2	• Response rate of stakeholder= # of surveyed panelists/# of responses by surveyed panelists • Consensus agreement on items to include in PDA and design of PDA • Themes of free-text responses
Aim 4: Small Scale Usability Test	• Survey on comprehensibility, usability, and clarification of content and design

Analysis

The expert panel composition was reported as percentages of invited versus actual panelists and panelist area of specialty. Survey response data from both Delphi-rounds and the usability assessment was compiled and analyzed with Qualtrics software. Quantitative survey analyses from Likert-scale responses included distribution of items that reached agreement/disagreement consensus during Phase

1 and Phase 2, including range, mean and standard deviation of each item. Yes/no and multiple-choice consensus items from the usability survey were represented by distribution of ratings. Qualitative analysis categorized thematic responses from free-text comments and post-survey meeting notes.

Ethical Considerations

Ethical considerations include the safe handling of data and maintaining the anonymity of survey respondents. We secured data via OHSU encryption, password protection, and two-factor authentication. The authors report no conflict of interest involved in the undertaking of this QI project. This project was reviewed by the OHSU Institutional Review Board (IRB) and considered IRB-exempt (IRB ID: STUDY00024163.

Results

We conducted literature reviews of methods for alleviating pediatric perioperative anxiety, shared decision-making, PDAs, and a consensus framework for the Delphi Method. The databases used include PubMed (Medline), CINAHL, Ovid Medline, and Google Scholar. The search strategy was limited to studies published within the last ten years that were available in the English language. The search terms used in these databases include: "pediatric preoperative anxiety," "pediatric perioperative anxiety," "preoperative anxiety in children," "behavioral interventions," "non-pharmacological interventions," "non-pharmacological management," "pharmacological interventions," "pharmacological options," "preoperative medication in children," "preoperative pediatric medication," "pediatric premedication," "preoperative pediatric anxiolysis," "perioperative pediatric anxiolysis" "preoperative pediatric preparation," "child life specialist," "child life preparation," "shared-decision making," "shared decision making pediatrics," "patient decision aid," "Delphi Method," "Delphi Consensus Method," and "modified Delphi Method." The literature reviews on alleviating preoperative anxiety in the pediatric population and SDM informed the structured communication with our expert panel, which subsequently informed our PDA's systematic and iterative development. The literature pertaining to the Delphi

method informed our selection and composition of the expert panel and the iterative consensus process.

The Delphi Method: Building the Expert Panel

With assistance from DCH perioperative leadership, we first identified a key stakeholder group at DCH relevant to our target problem and invited them by email to participate in the project. We provided all panelists with the context of the target problem and our project's planned interventions. Of the twelve invitations extended, twelve stakeholders agreed to participate in determining priority items to include in the decision aid through expert consensus over two Delphi Phases. Baseline demographic data collected from the panelists included the panel members' specialty, years in direct patient care, and years in the pediatric perioperative environment. The expert panel included 5 anesthesia providers (41.7%), 5 perioperative nurses (41.7%), 1 child life specialist (8%), and 1 specialty practice leader (8%). The majority (66%) of the panel had >10 years of experience in direct patient care and 50% of the panel had 5-10 years of experience in the pediatric perioperative environment. See Table 1, Appendix I for additional baseline demographic details.

The Delphi Method: Phases 1 and 2

Both Delphi phases included an anonymous Qualtrics survey (Appendix I, Table 2 and 3) distributed to panelists via email (May and June 2022, respectively), allowing for two weeks of response time with two subsequent email reminders prior to the closing of each survey. See Appendix J for a detailed timeline of survey distribution. Each survey contained potential items to be included in the PDA and sections for panel members to enter free text comments.

The first Delphi phase survey yielded a 100% response rate. Of the priority items surveyed, 81.25% (26/32) of the items reached a strong consensus of ≥70% agreement in the upper-tertile of the Likert Scale, indicating these 26 items should be included in the final PDA. The majority of items with a strong consensus consisted of pharmacological evidence-based strategies to address preoperative

pediatric anxiety. The only pharmacological strategy that reached an indeterminate consensus (<70% consensus in the upper-tertile of the Likert Scale) was a statement regarding the use of opioids during the preoperative period. The remaining four items with an indeterminate consensus concerned non-pharmacological strategies (use of music therapy and toy/wagon transport devices) and risk communication (risk of emergence delirium, delayed discharge). These items were re-surveyed in the second phase to reach a final decision. Only one item reached a weak consensus, ≥70% agreement in the lower tertial of the Likert Scale, regarding the percentage of pediatric patients receiving pre-medication to reduce preoperative anxiety. This item was edited based on current evidence-based data and later added to the final PDA as part of baseline background information on the subject. Free text comments related to intravenous (IV) placement in the perioperative area informed multiple surveyable items in survey 2.

The second Delphi phase survey addressed three sections: (1) Items from the first survey that had an indeterminate consensus, (2) Ten new items relating to IV placement and the use of Ketamine and Dexmedetomidine as pharmacological strategies for managing preoperative anxiety, and (3) Eight questions on the design and layout of the PDA (see Appendix I, Table 3). The second Delphi phase survey yielded a 67% response rate. Of the priority items surveyed and re-tested, 11 of the 15 items (73.3%) reached a strong consensus of ≥70% agreement. The four items that did not reach consensus in the second survey pertained to the premedication profiles of Ketamine, Dexmedetomidine, and opioids. Ultimately, detailed information regarding these premedications were excluded from the final PDA, determined to contain confusing or not strongly accepted information by the majority of the expert panel. However, the consensus from the first survey indicated a strong agreement that simple information regarding the options of Acetaminophen, Ketamine, and Dexmedetomidine should be on the final PDA, and therefore it was included. All eight items regarding the design and layout of the PDA reached a consensus: six items in the yes and no format reached a strong consensus, and the remaining

three items in the multiple-choice format reached a weak rule of consensus defined by ≥30% agreement (see Appendix I, Table 3, Section 3). These multiple-choice items concerned the PDA's format, font, and color template.

PDA Prototype Development

In July 2022, a PDA prototype was developed. Information included in the prototype PDA reached strong consensus agreement, defined as ≥70% agreement in the upper tertile of the Likert Scale (7-9; moderately agree to agree strongly) from Delphi Phase 1 and 2 surveys. Statements not reaching consensus were excluded from the protype PDA. The design of the PDA utilized IPADAS standards in an inclusive format with visual graphics and tables to represent information and, when possible, validated by the SMOG (Simple Measure of Gobbledygook) readability index with the omission of medical jargon.

Evaluation Phase: Finalized PDA and Usability

Following the development of the prototype, a survey was sent to panel members to elicit feedback and usability of the PDA. This survey consisted of seven questions that prompted direct feedback regarding the content, organization, presentation, and usability of the prototype PDA in “yes, no, and maybe format,” with options for free text comments after each question. In addition, this survey contained an open-ended final question that encouraged expert panel members to provide additional feedback on items that should be modified in the final PDA (see Appendix I, Table 4). The prototype PDA survey yielded an 83% response rate. Of the items surveyed, 85.7% (6/7) of the items reached a strong consensus of ≥75% agreement. These items included consensus that the PDA uses current evidence-based practice (100% agreement), contains essential (80% agreement) and unbiased (90% agreement) information, is well organized (80% agreement), is useful for clinical practice (80% agreement) and will help families feel empowered about the decision-making process (90% agreement). The only item without a strong consensus pertained to the conciseness and clarity of the PDA. Free text comments relating to this item included: “It is quite busy”; “Very busy and initially overwhelming to look at”; “Too

much"; and a comment stating the display needs to be more user-friendly. As a result of these and additional free text responses, the following changes were made to the prototype PDA:

1. Addition of language clarifying final decisions are to be made at the discretion of anesthesia
2. Removal of an age requirement for IV placement at OHSU per organization policy
3. Clarification of non-pharmacological section headers
4. Correction of details regarding CLS involvement in pediatric preoperative patient care
5. Adaptation of overall PDA for readability and comprehension per SMOG standards (8th grade reading level)
6. Adjustment and simplification of the overall PDA layout

The data obtained from this evaluation phase informed the necessary edits to design, comprehension, and content issues before a rollout of a larger-scale PDA feasibility study in the future. In addition to addressing necessary improvements from the feedback above, adjustments and simplifications of the overall layout of the PDA were performed based on direct feedback to improve the practical application to construct a finalized PDA.

Discussion

Summary

This QI project aimed to systematically and iteratively develop a parental decision aid to help the decision team navigate a stressful period and support a successful child/parent separation strategy at DCH. The decision aid facilitated elements of SDM by using evidence-based information to clearly and effectively outline available interventions to address and allay pediatric preoperative anxiety. We adapted Coulter's Model, a recommended methodological framework by IPDAS, to guide the iterative process of developing the PDA. The Delphi Method was applied for expert panel selection and the systemic process for attaining consensus through controlled stages of feedback from the expert panel.

Primary findings of the project include:

1. Delphi Phase 1 Survey: Of survey items, 81% reached strong consensus and immediate inclusion in the final PDA. While 18.75% gained weak or indeterminate consensus and required re-testing in Delphi Phase 2 survey.
2. Delphi Phase 2 Survey: Of the re-tested items on themes and comments shared in the phase 1 survey, 73% reached a strong consensus. The three items on which consensus was not achieved were excluded from the final prototype. Of the new items addressing the design and layout of the prototype PDA, 100% reached a consensus and informed the aesthetic creation of the final PDA
3. Usability Assessment: Of the usability survey items, 85.7% reached a strong consensus for the PDA's content, organization, presentation, and efficiency in the clinical setting.
4. Final PDA: The data obtained from this usability assessment informed final edits to the prototype PDA's design, comprehension, and content. The final PDA included the following elements: the definition, impact, and overall risks of pediatric preoperative anxiety and evidence-based options for pharmacological and non-pharmacological management of this phenomenon.

Interpretation

Guided by IPDAS criteria, our team created a PDA using the methodological framework found in Coulter's Model for developing high-quality PDAs. Coulter's Model identifies the following critical features in developing a decision aid: scoping and design, development of a prototype, iterative initial testing, field testing in real-world settings, and production of a final version for dissemination (Witteman et al., 2021). For this QI project, we conducted the primary phases of Coulter's Model to design a prototype PDA confirmed through a usability assessment and primed for future "alpha" and "beta" field-testing to finalize the model development process (see Appendix D) (Witteman et al., 2021). In the most

recent update by IPDAS informing their standards for the systematic development process for PDAs, many of the eight published decision aids identified as potential exemplars for other developers included an adapted version of Coulter's Model in their process (Witteman et al., 2021). This latest IPDAS publication commending Coulter's Model for PDA creation further strengthens our rationale for using this framework as the theoretical underpinning of our QI project.

The Delphi method was used to achieve our aims of assembling an expert panel and achieving panel consensus through a systematic, structured process. The Delphi Method has been widely used to develop multiple healthcare guidance tools, such as a pediatric prehospital destination decision tool (Anders et al., 2021) and a patient decision aid for implantable cardioverter defibrillator candidates (Carroll et al., 2013). By definition, the Delphi method consists of panel selection, the development of content surveys, and iterative stages to gain consensus on predetermined data (Taylor, 2019). Our QI project followed this design closely, from creating an expert panel to distributing three separate Delphi phases of content surveys. The composition of our panelists aligned with current Delphi accepted standards: 12 members with specialized knowledge related to the target problem of pediatric preoperative anxiety (Taylor, 2019). Our content surveys were based on current evidence, and the project's iterative stages successfully reduced the range of responses described in the Delphi method to gain consensus (Taylor, 2019). Throughout the Delphi phases, the majority of panelists' survey results and comments correlated closely with the evidence pertaining to pharmacologic and non-pharmacologic strategies to facilitate parent/child separation. However, indeterminate responses were found for some pharmacologic (ketamine, dexmedetomidine, opioids) and non-pharmacologic interventions (music therapy, use of wagon/toy as a transport device). This result could be because these pharmacological agents are rarely used at DCH in the perioperative pediatric setting and not because panelists disagreed with the literature. The lack of consensus regarding non-pharmacological interventions may be explained by the large body of non-pharmacologic options and evidence available to address pediatric

preoperative anxiety. In addition, the literature presented to the panelists regarding non-pharmacological options contained interventions regardless of their availability and accessibility specific to DCH. Interestingly, the non-pharmacologic items that did not reach consensus in survey 1 reached a strong consensus in survey 2, perhaps due to the inclusion of a literature table in survey 2 providing the evidence for the information distributed in these surveys or perhaps due to the lower participation in survey 2.

Arguably the most significant change made to the PDA from survey results was in response to the Delphi Survey 3, which solicited feedback for the prototype PDA and included a usability assessment. This survey yielded a theme of the prototype PDA being too complex, overwhelming, and "too busy" in design and layout. The survey results revealed that we did not meet our goal of incorporating language at or below the eighth-grade reading level, reinforced by the SMOG index. The constructive criticism on usability and readability informed significant edits to the prototype PDA, including simplified language, content, and overall design, aiming to increase usability, comprehensibility, and acceptability in future field testing. The SMOG index decreased following our significant edits to language, although we still scored above our desired goal of an eighth-grade reading level. In a topic as complex as pediatric preoperative anxiety that includes what can be abstruse definitions, considerations, and interventions that require the use of scientific and difficult-to-understand language, we ran into conflict deciding between including applicable evidence-based content or creating a universally usable and friendly tool. Ultimately, select medical terminology was retained in the final protype PDA to ensure accuracy of options, benefits and risks.

The main elements of a successful PDA include decisions to be taken, options available, and the outcomes of these options – including benefits, harms, and uncertainties (BMJ, 2013). We defined the decision to be made (allaying pediatric preoperative anxiety), clearly communicated evidence-based information about options available (pharmacologic and non-pharmacologic interventions), and

presented the risks and benefits of those options. Our decision aid incorporates a simple, basic design using visual reinforcements of vital concepts and information to encourage a clear communication of evidence-based information to the decision team.

Strengths & Limitations

Guided by IPDAS criteria and Coulter's Model for developing high-quality PDAs, our team created the first parental decision aid for pediatric preoperative anxiety at DCH. Our PDA is relevant to our target population, is evidence-based and useable. The Delphi technique provided a process to obtain anonymous and controlled feedback from experts free from dominant influence, bias, and pressure. The electronic distribution of surveys allowed experts to participate and engage with the process in their own time and space until a consensus was reached. However, despite the strengths of utilizing an anonymous online Delphi technique, the lack of face-to-face interaction means there is no opportunity for participants to elaborate on their views. To overcome this, we included free-text comments for each Likert-scale item within our survey. Next, due to the manner in which the expert panel members were invited to participate, selection bias may be a restriction in this study. As a result, the representativeness and reproducibility with another set of stakeholders may differ. The information included in the PDA is tailored to DCH by containing information influenced by stakeholders' knowledge, the standard of practice, interaction with a distinct patient population, and interventions relevant to the location at DCH. Therefore, in its current form, this PDA may not be valid for implementation outside the DCH facility.

Delphi Phase 2 and 3 survey response rates were lower than the Delphi Phase 1 survey. Inadequate response rates may be related to provider fatigue (participants asked similar questions multiple times), the detailed and rigorous development process, or survey distribution timing, which primarily occurred during the summer months. A lower response rate, unavoidably, created the

potential for skewed survey results if only nursing staff or anesthesia providers responded or vice versa, which cannot be excluded or confirmed due to anonymous survey responses.

The main challenge in developing our PDA arose from presenting information in a way that is easy to understand by the general population on the complex topic of pediatric preoperative anxiety. Despite significant edits to language and improvement in our readability index score, our finalized PDA still fell short of our desired level of comprehension. Moreover, the usability assessment of the PDA was small, and additional larger-scale testing in both patients and health professionals at DCH is warranted to ensure the PDA's usability, acceptability, and comprehensibility. We hope that with future revisions and improvements, the decision aid will address the needs of low-health literacy and socially-disadvantaged groups before dissemination as part of the daily perioperative practice at DCH.

Conclusions

As a result of this QI project, there is now a process to facilitate SDM to support a successful child/parent separation prior to surgery at DCH. Our team created the first parental decision aid for preoperative anxiety at DCH, and this PDA was deemed useful by perioperative clinicians. Suggested next steps are the continuation of Coulter's Model through iterative "alpha" testing of the prototype PDA for usability/comprehensibility by patients and usability/acceptability by health professionals at DCH, with revision and improvement of the decision aid as needed. Ultimately, after "beta" real-world field testing, a final version of the pediatric preoperative anxiety PDA may be disseminated and utilized as a part of the daily perioperative practice at DCH. The PDA may benefit pediatric perioperative environments similar to DCH in helping the decision team navigate a stressful period and support a successful separation strategy.

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Appendices

Appendix A

Project Timeline For Developing a Child/Parent Decision Aid for Preoperative Anxiety
Year: 2022

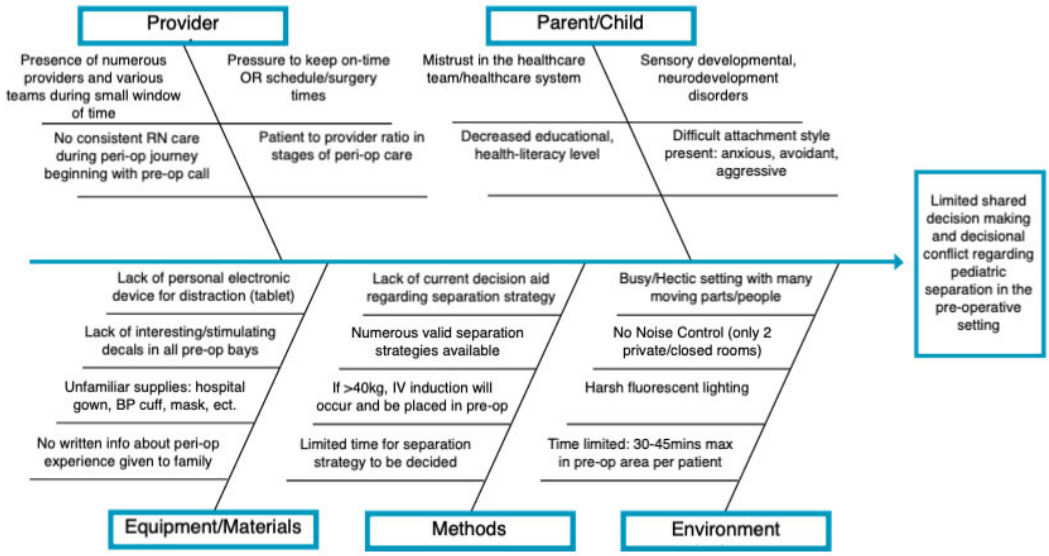
	Feb	March	April	May	June	July	Aug	Sept	Oct- Dec
Finalize initial survey, introduction, knowledge, and methods	X by 28th								
Complete IRB determination		X by 7th							
Assemble an expert panel		X by 21st							
Delphi Phase 1				X by 16th					
Delphi Phase 2						X by 1st			
PDA draft survey								X by Sept 14th	
Final data analysis								X by Sept 19th	
Write sections 13-17 of final paper									X by Oct 10th
Prepare for project dissemination									X by Nov 4th

Appendix B

Template: Cause and Effect Diagram

Team: Bloodgood, Pavlenko **Project:** Implementing a Separation PDA in Pediatric Pre-op

1) Input the effect you'd like to influence.
2) Input categories of causes for the effect (or keep the classic five).
3) Input causes within each category.



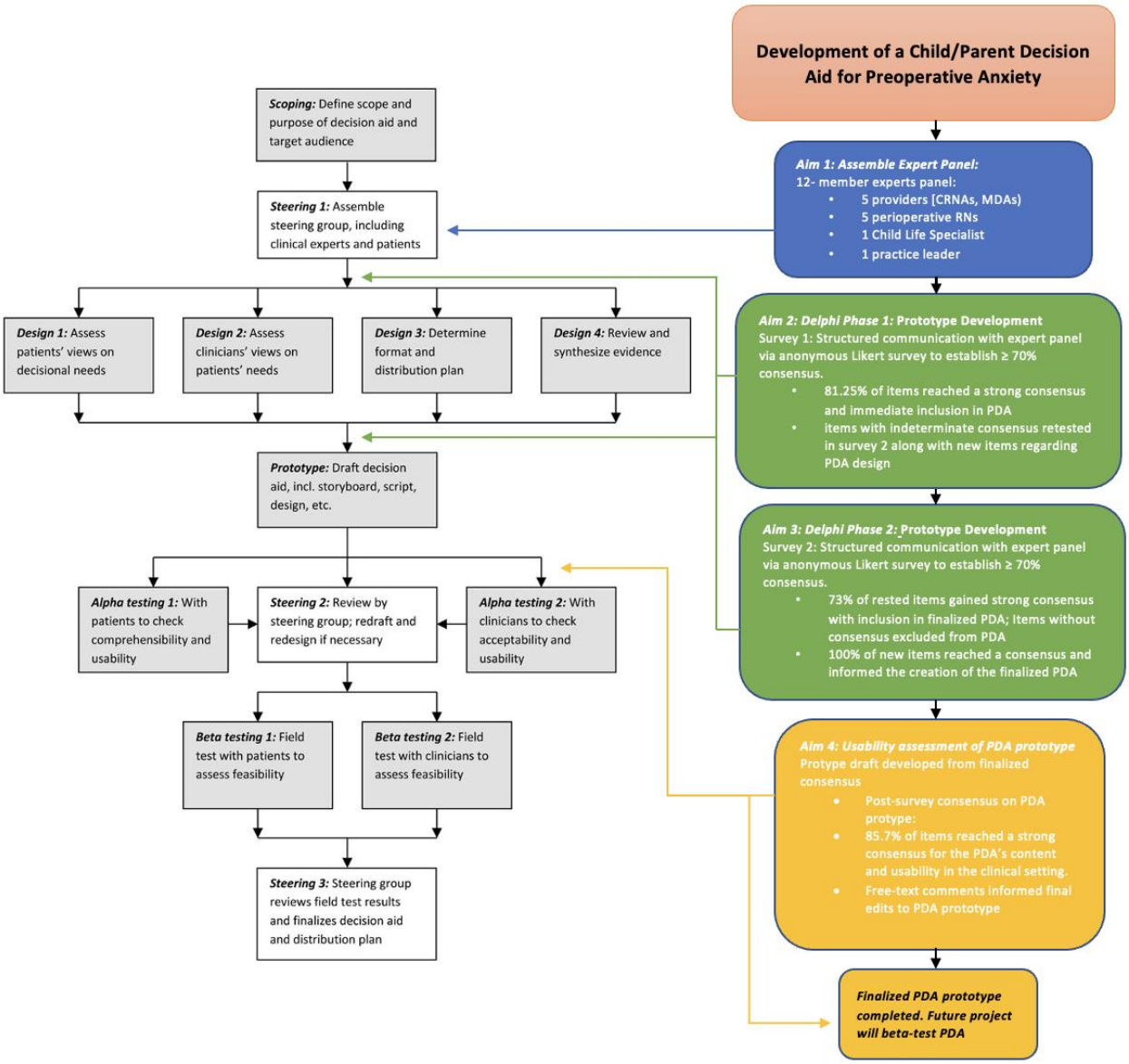
Appendix C

Pharmacological Strategies	
Intervention	**Study**
PO Dexmedetomidine (4mcg/kg)	Gauchan, 2019; Pasin, 2015
IN Dexmedetomidine (2-3mcg/kg)	Ibrahim, 2014; Jun, 2017; Lewis, 2020; Mondardini, 2019; Pasin, 2015; Wang, L, 2020
PO Midazolam (0.5mg/kg)	Gauchan, 2019; Pasin, 2015; Sola, 2017; Wang, L, 2020
IN Midazolam (0.2-0.5mg/kg)	Khoshrang, 2021; Pasin, 2015
PO Ketamine (10mg/kg)	Kamel, 2020
IN Ketamine (5-7mg/kg)	Ibrahim, 2014; Khoshrang, 2021
IM Ketamine (4-6mg/kg)	Dave, 2019
PO Ketamine (3mg/kg) + IN Dexmedetomidine (2.5mcg/kg)	Qiao, 2017

Behavioral Strategies	
Intervention	**Study**
Transportation to OR (toy car, wagon)	Liu, 2018; Park, 2020
Pre-operative interventional teaching strategies	Batuman, 2016; Hatipoglu, 2018; Meletti, 2019; Perry, 2012; West, 2020
Video/Tablet-based or VR Interactive Distraction	Kim, 2019; Sola, 2017; Stewart, 2019
Music	Van Der Hejiden, 2015
Relaxation-guided Imagery/Hypnosis	Vagnoli, 2019

Appendix D

Model Development Process for Decision Aids (Adapted from Coulter et al., 2012)



Appendix E

Development of a Decision Aid for Pediatric Preoperative Anxiety: Clinician Survey

Demographics

- Please indicate your specialty:
    a) Anesthesia provider
    b) Perioperative RN
    c) Child-Life Specialist
    d) Other: _____

- Please indicate years involved in direct patient care:
    a) <1 year
    b) 1-3 years
    c) 5-10 years
    d) >10 years

- Please indicate years involved in the pediatric perioperative environment:
    a) <1 year
    b) 1-3 years
    c) 5-10 years
    d) >10 years

Instructions

You have been asked to participate in the following survey regarding developing a decision aid on pediatric preoperative anxiety for use in the perioperative setting at Doernbecher Children's Hospital. This decision aid will be used to help parents/families navigate the options to manage a child's preoperative anxiety.

The survey is organized in the following sections:

- Strategies to address preoperative anxiety
    - Pharmacological strategies
    - Behavioral strategies
- Factors associated with preoperative anxiety interventions
- Risks associated with preoperative anxiety interventions

Please rate the statements in each section on a scale from 1 to 9. A rating of 1 being you "strongly disagree" and that the statement should NOT be included in the decision aid. A rating of 9 being you "strongly agree" and that the statement SHOULD be included in the decision aid. After each section, you will be given the opportunity to add any free text comments that you feel are necessary.

Introduction

Preoperative anxiety, characterized by feelings of tension, apprehension, and nervousness, is a common phenomenon affecting an estimated 40-60% of children that undergo surgery. The most stressful times

for a child tend to be separation from parents and induction of anesthesia. Strategies to reduce anxiety and distress in children during the perioperative period include pharmacologic (medication) and non-pharmacologic options. The primary goals of these options are to facilitate a relatively anxiety-free separation of children from their parents, a smooth induction of anesthesia, and postoperative recovery. There is not a "one size fits all" option. The best approach is individualized to the unique needs of your child.

Please provide any additional comments in free text below that you feel have not been included in this introductory section:

_____
_____
_____

Strategies

Pharmacological Strategies

Not all children require medications to reduce preoperative anxiety. About 50% of children in the United States receive medication to reduce preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Midazolam (also known as Versed) belongs to a classification of medications known as benzodiazepines. Benzodiazepines are widely used to relieve stress and anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Midazolam administered orally is the most commonly used medication to relieve preoperative anxiety in children.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Midazolam, if not accepted orally by the child, can be administered intranasally as a premedication.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Alternatives to Midazolam are available, though are less commonly used. These alternatives are useful for particular circumstances such as midazolam allergy and/or inability to tolerate oral or intranasal medications.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

An alternative to midazolam as premedication is dexmedetomidine. This decision aid should include information on dexmedetomidine.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Another alternative to midazolam as premedication is ketamine. This decision aid should include information on ketamine.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Acetaminophen (Tylenol), is another common medication given preoperatively. This decision aid should include information on acetaminophen.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Opioids, like fentanyl, are other medications that can be given preoperatively to provide pain control and sedation. This decision aid should include information on opioids.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Medications to reduce a child's anxiety are typically administered 10-30 minutes prior to surgery.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

All medications are dosed appropriately, based on the pediatric patient's weight.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Please provide any additional comments or pharmacological interventions in free text below that you feel have not been included in this section:

_____
_____
_____

Behavioral Strategies

Targeted child-life sessions tailored to a child's developmental needs is a very successful non-pharmacological strategy to address preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Play therapy prior to parental separation is useful to decrease preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Distraction in the form of tablet computer devices that have games or videos are a successful way to decrease preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Transporting a child in a toy car or wagon can help decrease preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Music therapy is a successful and realistic way to decrease preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Immersion into the perioperative experience in the form of OR tours, introduction to supplies including masks, IV supplies, and role-playing peri-operative processes can help decrease preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Please provide any additional comments or non-pharmacological interventions in free text below that you feel have not been included in this section:

_____

_____

_____

Factors

Children between the ages of 1-5 years old have the highest risk of experiencing increase preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Children with particular personality traits that include negative emotionality, increased intensity of reactions, and inhibited temperament (shyness/withdrawal) have a higher risk of experiencing increased preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Children with experience of previous numerous or negative medical encounters have a higher likelihood of experiencing increased preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Children with psychological, developmental or behavioral disorders have a greater risk for preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Children with parents who have a high level of anxiety during the perioperative period have a higher likelihood of experiencing increased preoperative anxiety.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Please provide any additional comments or factors affecting preoperative anxiety recognition and management in free text below that you feel have not been included in this section:

_____
_____
_____

Risks

Midazolam, when administered in appropriate weight-based doses for preoperative anxiety control, causes minimal drowsiness, breathing, and heart problems.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Midazolam, when administered orally leaves a bitter taste in the mouth, and when given nasally can produce irritation, discomfort, and burning.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

There is a risk of paradoxical reaction with administration of midazolam, where some children become agitated rather than mildly sedated.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

The occurrence of allergic reactions to midazolam are very rare (less than 0.02%). Clinical signs of an allergic reaction to midazolam include a skin rash, swelling around the mouth/face, difficulty breathing, wheezing, increased/decreased heart rates, and low blood pressure.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Increased preoperative anxiety leads to maladaptive negative physical and psychological behaviors that continue to affect the child post-operatively.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Unmanaged preoperative anxiety can increase the likelihood for future inability to cope with additional medical encounters.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Unmanaged preoperative anxiety can lead to poor post-operative pain control.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Untreated preoperative anxiety can lead to increased risk of emergence delirium.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Pharmacological treatment of preoperative anxiety may increase the risk of delayed PACU discharge.

Strongly Disagree	Disagree	Moderately Disagree	Mildly Disagree	Undecided	Mildly Agree	Moderately Agree	Agree	Strongly Agree
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Please provide any additional comments or risks associated with the treatment/management or lack thereof of preoperative anxiety in free text below that you feel have not been included in this section:

_____
_____
_____

Thank you for your time and participation in our survey.

Appendix F

IRB Application

Request for Determination Form

Research Integrity Office
Mail Code L106-RI
Portland, Oregon 97239-3098
Phone: 503.494.7887
Fax: 503.346.6808

Version 1.1
Updated 5.28.2019

PI Name	**Julie Soelberg, PhD, CRNA**	eIRB	**STUDY00024163**
Project Title	**Development of a Decision Aid for Pediatric Preoperative Anxiety: A Quality Improvement Project**		

INSTRUCTIONS

Use this form when:

- *You are not sure if your project requires IRB oversight, or*
- *You would like a formal determination from the IRB as to whether the project requires IRB oversight, or*
- *You are conducting research with samples or data that are not individually identifiable to the research team, but the project involves genetic research.*

Complete the entire form unless your response to a particular question instructs you to skip ahead.

Upload the form to the eIRB in place of, or in addition to, a protocol.

If your project meets the definition of Research (Section 1), includes Human Subjects (Section 2), and OHSU is Engaged in the research (Section 3), you should submit a new study with a full protocol instead of submitting this form.

Section One – Research

Research is a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

☐ This project is research. → **Skip to Section Two**.

☒ I don't think this project is research, or I am not sure. → **Answer the questions below:**

1.1. Is this a case study of a single patient or a case series of three or fewer patients? If so, describe.
Note: Inclusion of more than three patients is generally considered research.
No.

1.1.1. If yes, will it involve testing of biological specimens for non-clinical purposes? If so, describe.

1.2. Is this a quality improvement/quality assurance, program evaluation, or public health project? If so, explain. (*These types of activities may not meet the definition of research. See the Quality*

Improvement or Research? Quick Guide on the IRB Policies and Forms web page for more information.)
Yes. This is a quality improvement project that aims to develop a decision aid for use in the preoperative area at Doernbecher Children's Hospital (DCH). The presurgical period often causes anxiety in children and multiple options exist at DCH to reduce a child's preoperative anxiety. This project will help the decision team by presenting the available options in the format of a decision aid. Through surveys and meetings, a team of OHSU perioperative clinicians will iteratively develop the decision aid. Participation will be voluntary.

1.3. Will individuals, groups, or institutions/organizations be randomized or otherwise designated to receive different interventions that will be compared? If so, explain. *Note: Randomization or comparison against a control tends to indicate a systematic investigation, which may be research.*
No.

1.4. What are you hoping to learn from this project? Will the knowledge you gain be generalizable to other contexts or situations?
The intent of this project is to create a functional and acceptable decision aid that presents the options available at DCH to address pediatric pre-operative anxiety. This project is specific to DCH and therefore not generalizable to other contexts or situations beyond the scope of this hospital.

1.5. What will you do with the results? *Note: Whether you intend to publish does not itself determine whether your project is research.*
The results of this project will be used to develop a decision aid for the preoperative area at Doernbecher Children's Hospital. Results of the project will not be published. Results will be presented to DCH perioperative personnel and OHSU School of Nursing personnel via oral and/or poster presentations.

Section Two – Human Subjects

A **human subject** is a **living individual** about whom an investigator conducting research obtains:
- Data through **intervention** or **interaction** with the individual, or
- **Identifiable private information** (*information is identifiable if the identities of the subjects are **readily ascertainable** to the investigator, either directly or indirectly through a coding system*)

☐ This project involves human subjects. → **Skip to Section Three.**

☒ This project is not research. → **Skip to Section Five.**

☐ This project is or may be research, but I don't think it involves human subjects, or I am not sure. → **Answer the questions below:**

2.1. Are all of the subjects in the research known to be deceased? *Note: Decedents are not considered human subjects.*

2.2. Describe the data and/or specimens to be used for the project.

2.3. Are all of the data and/or specimens pre-existing or going to be collected for some purpose other than this project?

If yes:

2.3.1. What is the original source of the data and/or specimens? How will they be provided to the investigators?

2.3.2. Are all of the data and/or specimens de-identified such that none of the investigators working on the project could readily ascertain the identities of the subjects, either directly or indirectly through a coding system? Explain. *Note: If investigators have a way of identifying individual subjects, the project likely involves human subjects.*

If no:

2.3.3. How will the investigators (at OHSU or another institution) collect the data and/or specimens? *Note: If investigators will intervene (including both physical procedures and manipulations of the subject or subject's environment) or interact (including all forms of communication or interpersonal contact) with individuals in order to collect information about them, this project likely involves human subjects.*

Section Three – Engagement in Research

OHSU is **engaged** in a research project if **OHSU employees, students, or other agents** do any of the following:

- **Intervene or interact** with human subjects for the research,
- Obtain **individually identifiable private information** about human subjects for the research, or
- Obtain the **informed consent** of individuals for participation in the research.

There are exceptions for certain recruitment activities and for performance of some protocol-required procedures as a commercial service or on an emergency or temporary basis.

☐ This project is research and OHSU is engaged in the research project. → **Skip to Section Four. If the project also involves human subjects, STOP and complete a new study submission.**

☐ This project is not research, or it is research that does not involve human subjects. → **Skip to Section Four.**

☐ This project is or may be human research, but I don't think OHSU is engaged in the project, or I am not sure. → **Answer the questions below:**

3.1. Describe OHSU's and any other institutions' roles in the research, including which investigators will interact with human subjects, obtain subjects' identifiable private information, or obtain informed consent for the research. *Note: If OHSU investigators will do any of these things, OHSU is probably engaged in the research.*

3.2. Will OHSU employees, students, or agents obtain ***only de-identified data or specimens*** (that is, the data/specimens are completely anonymous or the data/specimens are coded and OHSU investigators will not have access to the key to the code)? *If so, OHSU is probably not engaged in the research.*

3.3. Will OHSU employees, students, or agents ***only release pre-existing data or specimens*** to investigators at another institution (that is, OHSU investigators will have no part in testing of specimens or data analysis)? *If so, OHSU is probably not engaged in the research.*

Section Four – Oregon Genetic Privacy Law

Genetic Research is research using human DNA samples, genetic testing, or genetic information. **Genetic information** is information about an individual or the individual's blood relatives obtained from a genetic test. For more details, see our Genetic Research web page.

☐ This project does not involve genetic research. → **Skip to Section Five.**

☐ This project involves genetic research. → **Answer the questions below:**

4.1. The specimens/data are (check one):

☐ Anonymous (meaning the identity of the individuals or their blood relatives cannot be determined by anyone, including through a code or other means of linking the information to a specific individual)
☐ Coded (meaning that some link exists that would allow re-identification of the data/specimens, even if the OHSU investigators will not have access to it)

NOTE: If the specimens or data are individually identifiable, you are likely conducting human research. ***STOP and complete a new study submission.***

4.2. For coded data/specimens, describe the method of coding and steps you will take to ensure data security. (See HRP-461 WORKSHEET – Oregon Genetic Research – Anon-Coded on the IRB Policies and Forms web page for specific criteria regarding coded genetic research.)

4.3. In Oregon, the individuals who originally provided the data/specimens must have consented to genetic research, or you must verify that the individuals have not "opted out" of genetic research at OHSU (see our Genetic Research web page for more information). Indicate how your project complies with this requirement (check one):

☐ Subjects consented for this project specifically
☐ Subjects consented for future genetic research generally
☐ Subjects did not consent, but we will exclude any subjects who opted out of coded/anonymous genetic research – Describe your plan to verify opt-out status:

☐ None of the specimens/data are from subjects in Oregon
☐ Other – Describe:

Section Five – HIPAA

Protected Health Information (PHI) = health information + one or more of the 18 identifiers. See our HIPAA and Research web page for more details.

Even if your project is not human research or OHSU is not engaged in the research, you may have requirements under HIPAA if you are using, obtaining, or releasing/disclosing PHI.

All HIPAA forms linked below are available on the IRB Policies and Forms web page. Upload them on the ***Recruitment, Consent and Authorization*** page of the IRQ.

☒ This project does not collect any health information. → **Stop here, no HIPAA requirements.**

☐ This project collects health information, but does not involve access to or recording of any of the 18 individual identifiers, and therefore does not involve PHI. → **Stop here, no HIPAA requirements.**

☐ Investigators on this project will only have access to data/specimens already at OHSU and that meet the definition of a Limited Data Set *(no direct identifiers such as name, MRN, initials, or street address, but may include dates and geographic subdivisions smaller than a state*), and the Limited Data Set will NOT be sent outside OHSU. → **Stop here, no additional HIPAA requirements.**

☐ PHI will be accessed, used, and/or sent outside OHSU, but not for research purposes (examples: case reports, QA projects, public health reporting). → **Stop here, comply with OHSU HIPAA policies for non-research activities.**

Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (contains any of the 18 individual identifiers, photos or illustrations that contain identifiable features such as pictures of a patient's face or tattoos), must first obtain each patient's

authorization. In the case of deceased individuals, consent might be obtained from the next of kin.
Authorization to Use and Disclose Protected Health Information Form

☐ PHI will be accessed only for purposes preparatory to research, such as preparing a protocol or compiling a recruitment list, and the PHI will not be released outside OHSU. → Prep to Research **form required.**

☐ This project is research and will collect and use PHI, but all subjects are known to be deceased. → Decedents Representation **form required.**

☐ This project is research and will collect PHI, but only for the purpose of preparing a Limited Data Set to send outside OHSU. → Data Use Agreement **required.**

☐ This project is research and OHSU will receive a Limited Data Set from another institution for this project. → **Data Use Agreement may be required by the other institution. If so, submit DUA for review and signature to the office that handled the contract for the project (if there was one, or to OPAM if there was no contract). DUAs for OPAM should be directed to Contract-triage@ohsu.edu.**

☐ This project is research, PHI will be accessed, used, and/or sent outside OHSU for purposes of this study, and none of the above options apply. → **You most likely need a Waiver or Alteration of Authorization. Any disclosures outside OHSU must be tracked in the Accounting of Disclosures System.**

☐ Other – Explain:

Appendix G

IRB Determination

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

March 7, 2022

Dear Investigator:

On 3/7/2022, the IRB reviewed the following submission:

Title of Study:	Development of a Decision Aid for Pediatric Preoperative Anxiety: A Quality Improvement Project
Investigator:	Julie Soelberg
IRB ID:	STUDY00024163
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office

Appendix H

Letter of Support from Implementation Site

Letter of Support from Clinical Agency

Date: *[04/05/2022]*

Dear *[Student Name]*,

This letter confirms that I, *[Jenifer Green, SPL]*, allow Katherine Bloodgood and Julia Pavlenko (OHSU Doctor of Nursing Practice Student) access to complete their DNP Final Project at our clinical site. The project will take place from approximately March 31, 2022 to August 31, 2022.

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s)**: Doernbecher Children's Hospital, 700 S.W. Campus Drive, Portland, Oregon 97239
- **Project Plan:**
  - Identified Clinical Problem The presurgical period often causes anxiety in children and multiple options exist at DCH to reduce a child's preoperative anxiety.
  - Rationale: This project seeks to develop a decision support aid guided by the methodological framework in Coulter's Model development process to inform a systematic approach for developing a high-quality parental decision aid for child/parent preoperative separation. Coulter's Model development process is an extension of the evidence-informed framework established by The International Patient Decision Aid Standards (IPDAS) Collaboration.
  - Specific Aims: The overall goal of this quality improvement (QI) project is to systematically and iteratively develop a parental decision aid to help the decision team navigate a stressful period and support a successful child/parent separation strategy at DCH. Primary aims to achieve this goal will include assembling a team of stakeholders to serve as an expert panel by April11, 2022, determining items to include in the decision aid by May 30, 2022, and developing the decision aid with expert consensus by June 27, 2022.
  - Methods/Interventions/Measures: An expert panel of 10-15 members will be composed of DCH perioperative staff. An anonymous, online Qualtrics survey will be distributed to our expert panel to identify priority items for inclusion in the decision aid. The survey design will include a Likert scale of potential items to include in the PDA, with the option to add free-text comments. A second survey will reevaluate items with an inconclusive consensus by identical methods. Design and formatting options will be presented to panelists during phase two to elicit consensus on the visual representation of the PDA.
  - Data Management: Data from survey respondents will be securely handled with maintenance of anonymity via OHSU encryption, password protection, and two-factor authentication.
  - Site(s) Support: \

During the project implementation and evaluation, Katherine Bloodgood and Julia Pavlenko will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Katherine Bloodgood SRNA, Julia Pavlenko SRNA, and DNP Chairperson Julie Soelberg Ph.D., CRNA.

Best Regards,

DNP Project Preceptor (Name, Job Title, Email, Phone):_____

Signa

Da

Appendix I

Table 1
Demographic Characteristics Table
Clinical Demographic Characteristics of Participants

Baseline characteristic (By Question Number [Q])	N = 12	
	n	%
Q1: Specialty		
Anesthesia Providers	5	41.67
Perioperative Nurse	5	41.67
Child Life Specialist	1	8.33
Specialty Practice Leader	1	8.33
Q2: Years in Direct Patient Care		
< 5 years	0	0
5-10 years	4	33.33
>10 years	8	66.67
Q3: Years in Pediatric Perioperative Environment		
<1 year	1	8.33
1-4 years	2	16.67
5-10 years	6	50
>10 years	3	25

Table 2
Results of Delphi Survey 1
Results From Development of a Decision aid for Preoperative Anxiety Survey 1

Survey 1 Items (By Question Number [Q] and Consensus)	Range	Mean	SD	Distribution of ratings %		
				1-3	4-6	7-9
Section 1: Behavioral and Pharmacological Strategies						
Strong Consensus						
Q5. Midazolam (also known as Versed) belongs to a classification of medications known as benzodiazepines. Benzodiazepines are widely used to relieve stress and anxiety.	2-9	7.67	1.80	.083	.0	.917
Q6. Midazolam administered orally is the most commonly used medication to relieve preoperative anxiety in children.	3-9	7.92	1.61	.083	0	.917

Q7. Midazolam, if not accepted orally by the child, can be administered intranasally as a premedication	4-9	8.33	1.37	0	.083	.917
Q8. In some circumstances, an IV can be inserted and Midazolam may be given through the IV	8-9	8.64	0.48	0	0	1.0
Q9. Alternatives to Midazolam are available, though are less commonly used. These alternatives are useful for particular	5-9	8.08	1.11	0	.083	.917
Q10. An alternative to midazolam as premedication is dexmedetomidine. This decision aid should include information on dexmedetomidine	5-9	7.83	1.21	0	.167	.833
Q11. Another alternative to midazolam as premedication is ketamine. This decision aid should include information on ketamine	3-9	7.33	1.70	.083	.083	.833
Q12. Acetaminophen (Tylenol), is another common medication given preoperatively. This decision aid should include information on acetaminophen	4-9	7.67	1.49	0	.167	.833
Q14. Medications to reduce a child's anxiety are typically administered 10-30 minutes prior to surgery.	1-9	7.33	2.29	.083	.083	.833
Q15. All medications are dosed appropriately, based on the pediatric patient's weight	2-9	8	2	.083	.083	.833
Q16. The PDA should include a more detailed description of circumstances in which an IV may be inserted (e.g. age, size, illness).* [n= 11; missing response]	6-9	7.82	0.94	0	.182	.818
Indeterminate Consensus						
Q4. Not all children require medications to reduce preoperative anxiety. About 50% of children in the United States receive medication to reduce preoperative anxiety.	1-8	5.92	2.02	.167	.25	.583
Q13. Opioids, like fentanyl, are other medications that can be given preoperatively to provide pain control and sedation. This decision aid should include information on opioids	1-9	5.50	2.57	.25	.417	.33

Section 2: Associated Factors						
Strong Consensus						
Q17. Targeted child-life sessions tailored to a child's developmental needs is a very successful non-pharmacological strategy to address preoperative anxiety.	1-9	8	2.27	.083	.083	.833
Q18. Play therapy prior to parental separation is useful to decrease preoperative anxiety	2-9	7.67	1.97	.083	.083	.833
Q19. Distraction in the form of tablet computer devices that have games or videos are a successful way to decrease preoperative anxiety	3-9	7.75	1.74	.083	.083	.833
Q22. Immersion into the perioperative experience in the form of OR tours, introduction to supplies including masks, IV supplies, and role-playing peri-operative processes can help decrease preoperative anxiety	6-9	7.75	1.23	0	.25	.75
Indeterminate consensus						
Q20. Transporting a child in a toy car or wagon can help decrease preoperative anxiety.	4-9	6.33	1.80	0	.583	.417
Q21. Music therapy is a successful and realistic way to decrease preoperative anxiety	5-9	6.42	1.44	0	.667	.333
Section 3: Risks						
Strong Consensus						
Q23. Children between the ages of 1-5 years old have the highest risk of experiencing increase preoperative anxiety	1-9	6.67	2.09	.083	.167	.75

Q24. Children with particular personality traits that include negative emotionality, increased intensity of reactions, and inhibited temperament (shyness/withdrawal) have a higher risk of experiencing increased preoperative anxiety.	1-9	7.08	2.40	.083	.167	.75
Q25. Children with experience of previous numerous or negative medical encounters have a higher likelihood of experiencing increased preoperative anxiety	1-9	7.92	2.22	.083	0	.917
Q26. Children with psychological, developmental or behavioral disorders have a greater risk for preoperative anxiety	2-9	7.08	2.22	.083	.167	.75
Q27. Children with parents who have a high level of anxiety during the perioperative period have a higher likelihood of experiencing increased preoperative anxiety.	2-9	7.75	1.92	.083	0	.917
Q28. Midazolam, when administered in appropriate weight-based doses for preoperative anxiety control, causes minimal drowsiness, breathing, and heart problems.	4-9	7.42	1.55	0	.25	.75
Q29. Midazolam, when administered orally leaves a bitter taste in the mouth, and when given nasally can produce irritation, discomfort, and burning	3-9	8.17	1.62	.083	0	.917
Q30. There is a risk of paradoxical reaction with administration of midazolam, where some children become agitated rather than mildly sedated	5-9	8.08	1.04	0	.083	.917
Q31. The occurrence of allergic reactions to midazolam are very rare (less than 0.02%). Clinical signs of an allergic reaction to midazolam include a skin rash, swelling around the mouth/face, difficulty breathing, wheezing, increased/decreased heart rates, and low blood pressure.	3-9	7.58	1.75	.083	0.83	.833

Q32. Increased preoperative anxiety leads to maladaptive negative physical and psychological behaviors that continue to affect the child post-operatively.	2-9	7.08	1.98	.083	.25	.667
Q33. Unmanaged preoperative anxiety can increase the likelihood for future inability to cope with additional medical encounters	6-9	8	.91	0	.083	.917
Q34. Unmanaged preoperative anxiety can lead to poor post-operative pain control. * [n= 11; missing response]	4-9	7.27	1.42	0	.182	.818
Indeterminate consensus						
Q35. Untreated preoperative anxiety can lead to increased risk of emergence delirium	4-9	6.75	1.59	0	.417	.583
Q36. Pharmacological treatment of preoperative anxiety may increase the risk of delayed PACU discharge.	3-9	6.75	1.83	.083	.333	.583

Note. N = 12. * Indicates survey questions where one respondent did not answer; N=11

Table 3

Results of Delphi Survey 2

Results From Development of a Decision aid for Preoperative Anxiety Survey 2: Section 1 – Re-test of indeterminate items

Survey 2 Items (by Question Number [Q] and Consensus)	Distribution of ratings %	
	Yes	No
Section 1: Re-test Yes/No		
Strong Consensus		
Q2. Transporting a child in a toy car or wagon can help decrease preoperative anxiety.	.875	.125
Q3. Music therapy is a successful and realistic way to decrease preoperative anxiety	1.0	0
Q4. Untreated preoperative anxiety can lead to increased risk of emergence delirium.	1.0	0
Q5. Pharmacological treatment of preoperative anxiety may increase the risk of delayed PACU discharge	.75	.25

Indeterminate Consensus			
Q1. Opioids, like fentanyl, are other medications that can be given preoperatively to provide pain control and sedation. This decision aid should include information on opioids	.50		.50

Results From Development of a Decision aid for Preoperative Anxiety Survey 2: Section 2 –

Additional Likert Scale Items

Survey 2 Items (By Question Number [Q] and Consensus)	Range	Mean	SD	Distribution of ratings % 1-3	4-6	7-9
Section 2: Additional Items						
Strong Consensus						
Q7. An alternative to midazolam as premedication includes dexmedetomidine – administered orally or intranasally	7-9	8.38	.7	0	0	1.0
Q10. Some special circumstances may require the use of Ketamine administered via an injection (in the arm or leg) or through an IV	8-9	8.63	.48	0	0	1.0
Q11. Ketamine may cause increased salivation, involuntary eye movements and agitation	4-9	7.63	1.41	0	.125	.875
Q13. The combination of ketamine and midazolam may prolong recovery and discharge times	7-9	8.25	.66	0	0	1.0
Q14. In some circumstances an IV is placed pre-operatively and pre-medications can be given through the IV	8-9	8.75	.43	0	0	1.0
Q15. An IV placement may be preferred in children of older age and with increased peri-operative risks including malignant hyperthermia, high risk of aspiration, and perioperative respiratory adverse events	8-9	8.63	.48	0	0	1.0

Q16. Placement of an IV can be a stressful event. Clear communication with your child, activities for distraction (play, toys, videos) and/or a topical anesthetic can help make the process more comfortable	8-9	8.88	.33	0	0	1.0
Indeterminate Consensus						
Q8. Dexmedetomidine produces similar preanesthetic sedation to midazolam, but is more successful at decreasing postoperative pain	5-9	6.75	1.48	0	.5	.5
Q9. Dexmedetomidine when administered in appropriate weight-based doses for preoperative anxiety control causes minimal drowsiness, breathing and heart problems.	1-9	6.25	2.59	.125	.375	.5
Q12. Ketamine can be administered with other agents to reduce the effects listed above	5-8	6.38	1.41	0	.5	.5

Results From Development of a Decision aid for Preoperative Anxiety Survey 2: Section 3 – Design of PDA

Survey 2 Statement Items	Distribution of ratings %	
	Yes	N
Section 3: Design of PDA Yes/No		
Q18. The decision aid should use visual formats to reduce format bias	1.0	0
Q19. The decision aid should use multiple colors	1.0	0
Q20. The decision aid should consider the numeracy and graph literacy of the audience	1.0	0
Q21. The patient decision aid should use plain language and should be written at a level no higher than 8th grade	.875	.125
Q22. The decision aid should use a readability formula to ensure a defined comprehension level is achieved	1.0	0
Section 3: Design of PDA Multiple Choice Options	Consensus Answer	
Q23. The decision aid format should be	Single- sided	
Q24. The font on the decision aid should be	Calibri	

Q25. Color template for the decision aid should be

Table 4
Results of Delphi Survey 3
Results From Development of a Decision aid for Preoperative Anxiety Survey 3: PDA Draft Feedback

Survey 3 Items (By Question Number [Q] and Consensus)	Distribution of ratings %			Free Text Comments
	Y	N	M	
Section 1: PDA Feedback Yes/No/Maybe				
Q1. Does the decision aid describe treatment choices supported by current best evidence?	1.0	0	0	None
Q2. Does the decision aid contain essential information for decision-making?	.80	0	.20	M: "There needs to be an added side effect for oral versed and that there is a chance the patient will wake up crankier than normal. Parents need to be aware of this so that they are prepared in PACU if they are told that is a normal side effect."
Q3. Is the decision aid well organized?	.80	0	.20	M: "It is quite busy. Instead of boxes and bubbles, maybe a story board style or algorithm/pathway style for determining what (if anything) a child need for support." M: "Very busy and initially overwhelming to look at."
Q4. Does the decision aid present information in an unbiased manner?	.90	0	.10	None

Q5. Does the decision aid present information clearly and concisely that is not too complex for decision makers?	.60	.10	.30	Y: “But too much. Remember these caregivers have their own anxiety as well.” N: “It is quite busy. Instead of boxes and bubbles, maybe a story board or algorithm/pathway style for determining what (if anything) a child needs for support.” M: “Some words like “immersion” may be too complex for understanding.”
Q6. Do you think this decision aid will help parents feel empowered to participate in the decision-making process?	.90	0	.10	None
Q7. Do you think this PDA will be useful in your practice?	.80	0	.20	Y: “If the display is more user friendly.” Y: “With the adding of that side effect from oral versed.” M: “Needs to be provided to the “right type of parent.” i.e., information seeking/English speaking.”
Q8. Is there anything you wish you could change about the decision aid?				“No, love the layout. It’s not too busy and the colors are appealing.” “I think it would be good to put somewhere on it that the decision to use these medications is at the discretion of anesthesia... maybe where the alternatives is. I could see a family asking for one of these medications (i.e. Ketamine) when it would not be appropriate for that pt.”

“The FIRST page is nice. I would say you could remove the 40-60% visual of a child holding a balloon. That is distracting. The middle MAP is nice. I think it should be larger. I'm not sure I understand what this means. "they have a tendency towards negative affect and intense reactions" Maybe reword this. I love the options section. The SECOND page is very busy. I think it would be clearer as an algorithm (similar to a PALS card) or a story board that shows the heading and then options thereafter. The IV statement should be at the top then the options under it so the family understands if they don't have to prep for an IV maybe they can use the non-pharm options. Reading about the IV first sets them up to prepare for specific comfort measures their child could need thereafter”

“There needs to be an added side effect for oral versed and that is there is a chance the patient will wake up crankier than normal. Parents need to be aware of this so that they are prepared in PACU if they are told that is a normal side effect.”

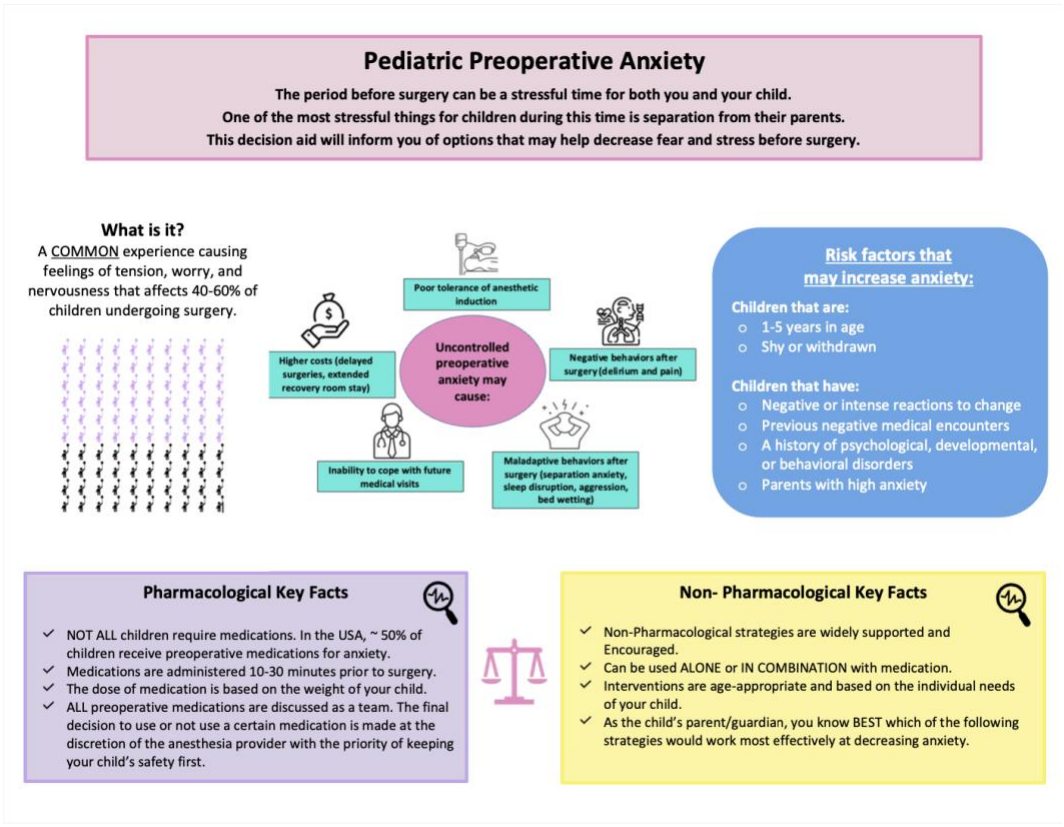
"In the IV bubble the AGE needs to be erased. Our OHSU policy is ONLY based on weight. Positioning for comfort needs to be included in "How we DECREASE anxiety for PIV placement". "Preoperative Tours" needs to be removed from distraction options. "Distraction" is all things "Play Therapy/Immersion and PREPARATION needs to be the top header instead of "Distraction". A CLS is and can be involved with ALL patients vs. just those just "at risk.”

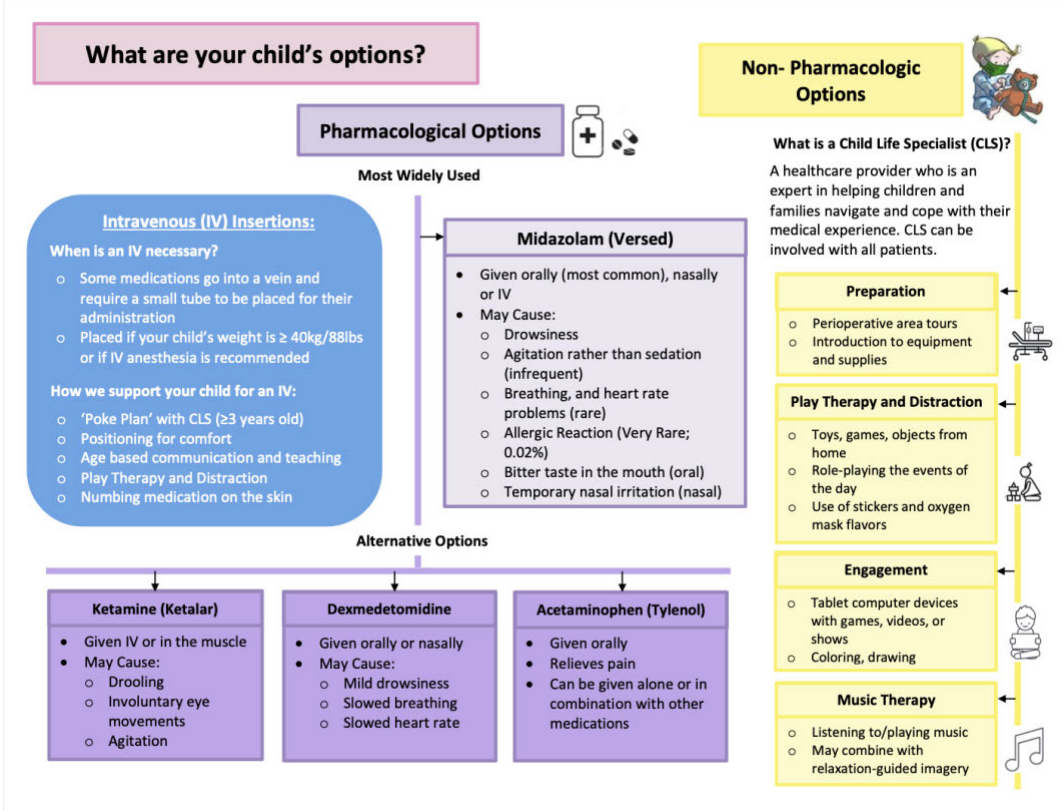
Appendix J

Timeline for Survey Distributions: Delphi Phase 1, 2, PDA Draft

	Initial Notification	Reminder 1	Reminder 2	Deadline
Delphi Phase 1: Survey 1	5/2/22	5/10/22	5/13/22	5/16/22
Delphi Phase 2: Survey 2	6/1/22	6/9/22	6/27/22	7/1/22
PDA draft survey	8/22/22	9/8/22	9/14/22	9/16/22

Appendix K


Pediatric Preoperative Anxiety
The period before surgery can be a stressful time for both you and your child.
One of the most stressful things for children during this time is separation from their parents.
This decision aid will inform you of options that may help decrease fear and stress before surgery.
What is it?
A COMMON experience causing feelings of tension, worry, and nervousness that affects 40-60% of children undergoing surgery.
Poor tolerance of anesthetic induction
Higher costs (delayed surgeries, extended recovery room stay)
Uncontrolled preoperative anxiety may cause:
Negative behaviors after surgery (delirium and pain)
Inability to cope with future medical visits
Maladaptive behaviors after surgery (separation anxiety, sleep disruption, aggression, bed wetting)
Risk factors that may increase anxiety:
Children that are:
1-5 years in age
Shy or withdrawn
Children that have:
Negative or intense reactions to change
Previous negative medical encounters
A history of psychological, developmental, or behavioral disorders
Parents with high anxiety
Pharmacological Key Facts
NOT ALL children require medications. In the USA, ~ 50% of children receive preoperative medications for anxiety.
Medications are administered 10-30 minutes prior to surgery.
The dose of medication is based on the weight of your child.
ALL preoperative medications are discussed as a team. The final decision to use or not use a certain medication is made at the discretion of the anesthesia provider with the priority of keeping your child's safety first.
Non- Pharmacological Key Facts
Non-Pharmacological strategies are widely supported and Encouraged.
Can be used ALONE or IN COMBINATION with medication.
Interventions are age-appropriate and based on the individual needs of your child.
As the child's parent/guardian, you know BEST which of the following strategies would work most effectively at decreasing anxiety.


What are your child's options?
Pharmacological Options
Most Widely Used
Intravenous (IV) Insertions:
When is an IV necessary?
Some medications go into a vein and require a small tube to be placed for their administration
Placed if your child's weight is ≥ 40kg/88lbs or if IV anesthesia is recommended
How we support your child for an IV:
'Poke Plan' with CLS (≥3 years old)
Positioning for comfort
Age based communication and teaching
Play Therapy and Distraction
Numbing medication on the skin
Midazolam (Versed)
Given orally (most common), nasally or IV
May Cause:
Drowsiness
Agitation rather than sedation (infrequent)
Breathing, and heart rate problems (rare)
Allergic Reaction (Very Rare; 0.02%)
Bitter taste in the mouth (oral)
Temporary nasal irritation (nasal)
Alternative Options
Ketamine (Ketalar)
Given IV or in the muscle
May Cause:
Drooling
Involuntary eye movements
Agitation
Dexmedetomidine
Given orally or nasally
May Cause:
Mild drowsiness
Slowed breathing
Slowed heart rate
Acetaminophen (Tylenol)
Given orally
Relieves pain
Can be given alone or in combination with other medications
Non- Pharmacologic Options
What is a Child Life Specialist (CLS)?
A healthcare provider who is an expert in helping children and families navigate and cope with their medical experience. CLS can be involved with all patients.
Preparation
Perioperative area tours
Introduction to equipment and supplies
Play Therapy and Distraction
Toys, games, objects from home
Role-playing the events of the day
Use of stickers and oxygen mask flavors
Engagement
Tablet computer devices with games, videos, or shows
Coloring, drawing
Music Therapy
Listening to/playing music
May combine with relaxation-guided imagery