Engaging Families to Improve Care of Patients with Hypospadias: Decision Aid Pilot Testing

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1.0 Background & Rationale

Parents faced with surgical decisions for their children encounter irreversible choices with potentially lifelong consequences. They must balance tradeoffs between disease outcomes, surgical treatment success, and side effects given that no single management strategy will achieve all of a patient's or parent's goals. Therefore, decisional conflict may arise, manifesting itself through patients' or parents' verbalizing uncertainty, expressing concerns about outcomes, wavering between choices, delaying decisions, questioning their personal values, being preoccupied with the decision, or expressing emotional distress.[1] To date, few studies have examined parental decision-making for pediatric surgery or decisional conflict/regret regarding these decisions.[2-6] The objective of this 5-year project is to use a multi-modal approach to develop a decision aid that will deliver clear, accurate parent-informed material about hypospadias. The goals of this research are to empower parents to make informed decisions about surgery for their children and improve their level of satisfaction with the decision afterwards. The central hypothesis is that decision aids developed using parent-centered research strategies can successfully reduce decisional conflict by better informing the surgical decision-making process.

2.0 Research Aims

AIM 1 (Year 1): Utilize patient-centered design research methods to explore: a) the parental decision making process regarding hypospadias repair, including identifying parental attitudes, perceptions, and informational needs, and b) outcomes of importance to parents of children with hypospadias.

AIM 2 (Year 2): Assess qualitatively providers' attitudes about shared decision-making and use of a decision aid (DA) for hypospadias, including feasibility and utilization in the context of a clinic visit.

AIM 3 (Years 3 and 4): Create a decision aid and postoperative outcome measurement tool for use by parents facing decisions regarding hypospadias repair and by those who have elected repair, respectively, based on the factors identified in Aims 1 and 2 of the study.

AIM 4 (Years 4 and 5): Conduct a pilot field test (pre-test/post-test) of the decision aid in the clinical setting and conduct a preliminary psychometric assessment of the patient-centered outcome measurement tool.

3.0 Pilot Testing Objectives

The primary purpose of the pilot field test is to determine the feasibility and acceptability of implementing the decision aid (DA) in the clinical setting and to measure its efficacy for our key outcomes. To determine feasibility, our primary outcomes are: (1) percent of eligible parents screened; (2) percent of eligible parents enrolled, and (3) percent of parents retained in the study. To determine acceptability, our primary outcome is to assess the DA's content, length,

clarity, and balance of information. Our secondary outcomes include knowledge of treatment options, knowledge of hypospadias, choice predisposition, decisional conflict, decisional regret, shared decision making, and preparation for decision making. We will also qualitatively examine urologists' views about the DA's applicability in their practice context, DA's perceived efficacy in assisting parents to arrive at a treatment-related decision, and perceived barriers and facilitators to DA implementation.

4.0 Criteria

4.1 Inclusion Criteria

Parents: 18 years of age and older of sons (ages up to 5 years) with hypospadias, or a tentative hypospadias diagnosis and/or referral to urology for hypospadias and are planning to attend the urology appointment; able to consent and do interview in English; aware that there is an issue with the child's pee hole; and, have access to a reliable internet and smart phone, tablet, or computer to view the website (DA). The child/patient will be scheduled to see a urologist but must not have seen the urologist at the time of enrollment. (Parents ideally have not yet made a final decision about surgery at the time of enrollment.)

To assure representation in our parent sample, we will attempt to recruit samples that include mothers, fathers, diversity in patient/parent race and ethnicity, education/socioeconomic status, health literacy and possibly device used to access the website (e.g. computer, phone).

Providers: general pediatrician or general pediatric nurse practitioner; pediatric urologist or pediatric urology nurse practitioner.

4.2 Exclusion Criteria

Parent Pilot Testing: If, during the recruitment call the parent states they are not aware of any issue with the child's pee hole, not simply unaware of the term hypospadias, then the parent would be excluded. If, at the clinic visit, the urologist decides that the patient does not have hypospadias, then the parent will be notified that she/he will be withdrawn from the remaining data collection points as they are no longer in a decision-making process about surgery. If we fill target groups (to balance parents' gender, race, or ethnicity), we may exclude some parents in order to have a balanced sample.

For all potential participants (except providers), the PI may use discretion if a medical (or other) condition makes a patient or parent inappropriate to enroll in a study activity.

All participants: Non-English speaking or illiterate. All activities will require a discussion and/or completion of written activities that require English competency.

5.0 Study Design

We will use a multi-modal, parent-centered approach to develop a decision aid that will deliver clear, accurate parent-informed material about distal hypospadias surgery. The decision aid will undergo three sets of testing and iterative re-designs. The study's current phase, pilot testing, involves field testing of the website by parents of boys with hypospadias and by providers (e.g. pediatric urologists).

6.0 Enrollment

6.1 Parents/Patients

We will identify new patients via urology clinic schedules (patients diagnosed with hypospadias and/or received a referral for hypospadias). Providers may also refer patients and parents to the research team. Recruitment of parents for pilot testing will take place via a phone with caller ID, in person/in the clinic, U.S. mail, email, and/or text message. First, a well-trained research assistant will introduce him/herself. For example, "I am a research assistant working with Dr. Katherine Chan who is a pediatric urologist at UNC Chapel Hill. I am located at IU School of Medicine and we are partnering with her team at UNC on this research. I'm calling to invite you to review a tool to help parents and physicians make decisions about surgery." If the parent expresses interest, the RA will then review the study procedures and goals with parents verbally in person, over the phone and/or by text. Over the phone, the research assistant will offer to send a copy of the consent documents via email. Parents will have the opportunity to ask questions and further consider participation. Those who choose to enroll will provide verbal consent, which will be documented by the research assistant in the REDCap database (on a secure departmental server).

6.2 Providers

Medical providers (including pediatric urologists, general pediatricians or general pediatric nurse practitioners, pediatric urologists or pediatric urology nurse practitioners) will be invited to participate via email, in person, or over the phone. A research assistant will present and explain the Study Information Sheet to the provider. Then, the provider will have the opportunity to ask questions and further consider participation. Those who choose to enroll will provide verbal consent, which will be documented by the research assistant in the REDCap database.

7.0 Study Procedures

7.1 Parent Pilot Testing of Decision Aid

Research assistants will collect data from parents at four time points, twice before and twice after their son's first visit with a pediatric urologist/pediatric urology nurse practitioner for a potential or actual diagnosis of hypospadias. The questions will address website usability,

feedback on content, usefulness in decision-making, and basic demographic questions. Data will be collected via phone interview with a research assistant. Interviews may be recorded and professionally transcribed for analysis. Reminders will be sent to parents between the four time points regarding looking at the website and the upcoming data collection calls. We anticipate that each data collection point will require 10-30 minutes for parents to complete. We will also use a website plug-in to track any analyze how parents move through the website. We plan to interview 10-25, but no more than 40 parents (n=40) who complete all timepoints of the study.

7.2 Post-Pilot Testing and Debriefing with Providers

Urology providers permission to approach their individual patients will be requested on a rolling basis during the enrollment portion of the study. If the provider allows approach, and consent is given, the provider will be notified their patient's parent has consented and will be reminded of the upcoming consented patient appointment. Research assistants and/or the PI will conduct interviews with urology providers. Interviews will occur after a provider has interacted with parent participants at their child's clinic visit for hypospadias. We will assess the providers' views of the applicability of the decision aid in the practice context, perceived efficacy of the tool in assisting parents to arrive at a treatment-related decision, and perceived facilitators to decision aid implementation. We will also collect any feedback on the content and layout of the decision aid website. We anticipate that interviews will be 10-30 minutes long and may be recorded and professionally transcribed for analysis. We will also use a website plug-in to track and analyze how providers move through the website. We plan to interview 5-10 providers.

8.0 Study Calendar

Parent Pilot Test Data Collection Schedule	
Baseline (T1)	• Demographics/Health Literacy (8 questions) • Decisional Conflict Scale (DCS) (16 questions) • Decision-Specific Knowledge Test (6 questions) • Treatment Preference/Awareness of Decision (2 questions) Recommendation: Have any of your child's healthcare providers already made a recommendation about your son's hypospadias? If so, what was the recommendation? (1 question)
Pre-consultation, 1 week after baseline (T2)	• Website Viewed (3 questions) o Did you have time to look at the website o Did you view the website with anyone else? o Did you view the website on a smart phone, tablet, or computer? • Treatment Preference/Awareness of Decision (2 questions) • Decisional Conflict Scale (DCS) (16 questions) • Decision-Specific Knowledge (6 questions)

	• Decision Aid Acceptability Questionnaire (4 questions) • Preparation for Decision Making Scale (10 questions)

Initial post-consultation, within 48 hours of urology visit (T3)	• Treatment Preference/Awareness of Decision (2 questions)
	• Decisional Conflict Scale (DCS) (16 questions)
	• Shared Decision Making Questionnaire (SDM-Q-9) (9 questions)
	• Preparation for Decision Making Scale (PrepDM) (10 questions)
	• Open-ended questions (3 questions)
	  ○ What most impacted your decision during/after your visit with the urologist?
	  ○ How did you use the decision aid during your visit with the urologist?
	  ○ Is there anything we didn't cover that you would like to share?

3-month post-consultation (T4)	• Decision Regret Scale (5 questions)
	• Open-ended questions (2 questions)
	  ○ What do you wish you would've known when you were making the decision?
	  ○ Is there anything that we didn't cover that you would like to share?

9.0 Reportable Events

We will assess for adverse events (AE) and actively monitor for a security breech or protocol deviations that might affect the confidentiality or privacy of the sensitive data we store, manage and analyze. If there are any AEs identified, we will report these to the Institutional Review Board (IRB) within the required timeframe.

10.0 Data Safety Monitoring

There will be regular review meetings that will occur, at a minimum, quarterly throughout the year. The study team will review current accrual, data management concerns, and data analysis/interpretation.

11.0 Study Withdrawal/Discontinuation

If a parent or provider wishes to withdraw from the study, s/he may inform the research assistant or PI at any point and s/he will be withdrawn from the study immediately. If the consented parent did not attend the urology visit or if the study team is unable to reach the parent or unable to collect Timepoint 2 before the urology visit occurs, then the parent will be withdrawn. Additionally, if the urologists recommends no surgery, in typically mild cases, then the parent may be withdrawn. Parents may be notified of withdrawal by email, text, or phone call.

12.0 Statistical Considerations

To inform sample size calculations and feasibility for a larger trial, we will analyze data as in a larger study and generate estimates of variance and correlation.[9] We will check all quantitative data for departures from normality and analyze it with descriptive statistics. We will compute measures of central tendency and dispersion for continuous variables, and frequencies and proportions for categorical variables.

To examine the effect of the DA on decisional conflict and knowledge, we will examine differences between pre- and post-intervention measures (i.e. the decisional conflict scale and the decision-specific knowledge test) using paired t-tests or Wilcoxon signed-rank tests for all continuous measures.

As this protocol focuses on appropriateness, acceptability and pilot testing of the DA, no sub-analyses are planned. We will plan to undertake examination of the influence of participant characteristics in future studies.

We will analyze all transcribed qualitative data, including parent participant and provider follow-up interviews, using inductive thematic qualitative content analysis.[7,8] The frequency, extensiveness, and specificity of comments will guide data categorization into recurrent themes.[7,8] We will alter and refine these themes through a recursive process from the data to analyst-generated categorical and conceptual definitions. The qualitative results are considered to be tertiary/exploratory as the findings provide additional context to the quantitative scores. The qualitative results are not primary or secondary outcomes of this study.

13.0 Statistical Data Management

Primary data for surveys and interviews will be collected, managed, and stored electronically in REDCap and/or the secure department server. During data collection, any questions or concerns will be flagged in the REDCap database for PI review. Additional quality assurance steps will include: testing of database by study team prior to moving to production mode and extraction and cleaning of data that will be used for analysis every two months.

14.0 Privacy/Confidentiality Issues

This study presents a minimal risk of loss of confidentiality. Efforts will be made to keep personal information confidential. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Participant identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. Participants will have the option to pass/skip any questions or activities that they do not want to answer or participate in. Any study data used for dissemination, publications, or the decision aid will be de-identified with the exception of the parent testimonial videos.

15.0 Follow-up and Record Retention

The study will continue through December 2023. After that, records will be retained for the minimum time allowed by law and then de-identified or destroyed.

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17.0 Appendix

To assess the quality of the decision-making process and the impact of the decision aid, we will utilize these scales:

- **Decisional Conflict Scale (DCS).** DCS is a validated scale that has been extensively studied and consists of 10 statements and 5 response categories ranging between 0 (no decisional conflict) and 100 (extremely high decisional conflict).
- **Decision-SpecificKnowledge**. We used data from Aims 1 and 2 to inform the development of a questionnaire to determine decision-specific knowledge of hypospadias treatment options/outcomes. We decided a priori that a score of 80% must be attained on this questionnaire as an indicator of being "informed."
- **Hypospadias Treatment Preference/Awareness of Decision***.* Parents will be asked whether they intend to have their child undergo hypospadias surgical repair and whether they are aware that there is a decision to be made.
- **Decision Aid Acceptability Questionnaire**. We will also assess the acceptability of the DA using a tool similar to the Decision Aid Acceptability Questionnaire. Questions will elicit feedback on amount of content, clarity, and helpfulness of the DA, acceptability of format and whether the information was presented in a balanced and fair manner.
- **Preparation for Decision Making Scale (PrepDM).** This 10-item scale assesses a patient's perception of how useful a decision aid is in preparing the respondent to communicate with their practitioner at a consultation focused on making a health decision.
- **Shared Decision Making Questionnaire (SDM-Q-9):** This is a 9-item self-report instrument developed to measure the process of SDM as perceived by the patient. The scale has high internal consistency, high item discriminations, and showed high face and factorial validity.
- **Decision Regret Scale:** The Decision Regret Scale measures distress or remorse after a health care decision. We will perform an early assessment of DR in this study with plans to re-assess the long-term level of regret in a future randomized controlled trial.