



A multi-site pilot study of a parent-centered tool to promote shared decision-making in hypospadias care[☆]

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Summary

Background

Using a user-centered design approach, we conducted a two-site pilot study to evaluate a decision aid (DA) website, the *Hypospadias Hub*, for parents of hypospadias patients.

Objectives

The objectives were to assess the *Hub*'s acceptability, remote usability, and feasibility of study procedures, and to evaluate its preliminary efficacy.

Methods

From June 2021–February 2022, we recruited English-speaking parents (≥ 18 years old) of hypospadias patients (≤ 5 years) and delivered the *Hub* electronically ≤ 2 months before their hypospadias consultation. We collected website analytic data using an ad tracker plug-in. We inquired about treatment preference, hypospadias knowledge, and decisional conflict (Decisional Conflict Scale) at baseline, after viewing the *Hub* (pre-consultation), and post-consultation. We administered the Decision Aid Acceptability Questionnaire (DAAQ) and the Preparation for Decision-Making Scale (PrepDM) which assessed how well the *Hub* prepared parents for decision-making with the urologist. Post-consultation, we assessed participants' perception of involvement in decision-making with the Shared Decision-making Questionnaire (SDM-Q-9) and the Decision Regret Scale (DRS). A bivariate analysis compared participants' baseline and pre/post-consultation hypospadias knowledge, decisional conflict, and treatment preference. Using a thematic analysis, we analyzed our semi-structured interviews to uncover how the *Hub* impacted the

consultation and what influenced participants' decisions.

Results

Of 148 parents contacted, 134 were eligible and 65/134 (48.5%) enrolled: mean age 29.2, 96.9% female, 76.6% White (Extended Summary Figure). Pre/post-viewing the *Hub*, there was a statistically significant increase in hypospadias knowledge (54.3 vs. 75.6, $p < 0.001$) and decrease in decisional conflict (36.0 vs. 21.9, $p < 0.001$). Most participants (83.3%) thought *Hub*'s length and amount of information (70.4%) was "about right", and 93.0% found most or everything was clear. Pre/post-consultation, there was a statistically significant decrease in decisional conflict (21.9 vs. 8.8, $p < 0.001$). PrepDM's mean score was 82.6/100 (SD = 14.1); SDM-Q-9's mean score was 82.5/100 (SD = 16.7). DCS's mean score was 25.0/100 (SD = 47.03). Each participant spent an average of 25.75 min reviewing the *Hub*. Based on thematic analysis, the *Hub* helped participants feel prepared for the consultation.

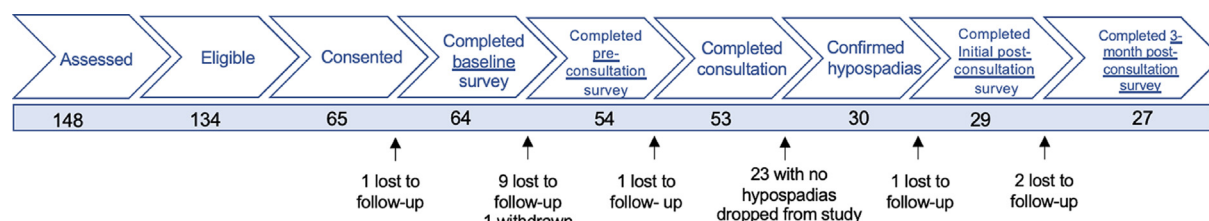
Discussion

Participants engaged extensively with the *Hub* and demonstrated improved hypospadias knowledge and decision quality. They felt prepared for the consultation and perceived a high degree of involvement in decision-making.

Conclusion

As the first pilot test of a pediatric urology DA, the *Hub* was acceptable and study procedures were feasible. We plan to conduct a randomized controlled trial of the *Hub* versus usual care to test its efficacy to improve the quality of shared decision-making and reduce long-term decisional regret.

[☆] The study is registered on [ClinicalTrials.gov](https://clinicaltrials.gov), identifier: NCT05056311.



Summary Figure CONSORT diagram depicting study enrollment and data collection.

Introduction

Hypospadias is one of the most common birth defects in boys (1 in 250 newborns). Left untreated, hypospadias may affect quality of life, cosmetic appearance, urination, sexual function, and fertility. The long-term sequelae, however, may be extremely variable depending on the severity of the condition. Parents are often urged to decide between reconstructive surgery and observation during a consultation with the urologist. These choices have varying clinical outcomes, potential complications, and cost tradeoffs. Currently, parents must make this important, preference-sensitive decision with neither evidence-based guidance nor a clearly superior option. Consequently, 65% of parents who choose surgery for their child experience decisional regret which is strongly associated with preoperative decisional conflict [1]. Further, parents who refuse hypospadias repair for their son experience a higher prevalence and severity of decisional regret; however, the influence of timing of the decisional regret measurement has not been examined [2]. Our team aims to reduce decisional regret by improving information delivery through a shared decision-making (SDM) tool.

SDM is the optimal approach to improve patient knowledge, satisfaction, and engagement for many preference-sensitive urologic and non-urologic conditions [3]. Evidence-based tools that support SDM can reduce decisional conflict and regret by supporting values-based, informed decisions [4]. However, rigorously developed and tested SDM tools for hypospadias management do not exist. Our long-term goal is to improve decision quality for pediatric urology conditions by developing, testing, and implementing support tools that facilitate SDM. We previously developed a web-based hypospadias decision aid (DA), the *Hypospadias Hub (Hub)*, to promote SDM. We applied user-centered design principles to deliver high-quality, balanced information to parents and to help them clarify their values [5–7]. We assessed the *Hub*'s acceptability and usability among parents who previously participated in hypospadias consultations [8,9]. The next step in decision aid assessment is to conduct a pilot test in clinical settings. A pilot study is defined as a "small-scale test" to examine a study's feasibility before conducting a large trial [10]. This is a critical step because the pilot study's results advise the needed modifications to ensure the future study's success [10]. Therefore, the objectives of this two-site pilot study are to assess the *Hub*'s acceptability, feasibility of study procedures, remote usability, and preliminary efficacy among parents who are scheduled for a hypospadias consultation regarding their

sons' hypospadias. We hypothesized that there would be a significant decrease in decisional conflict and increase in decision-relevant knowledge after parents were exposed to the *Hub*.

Materials and methods

Setting, participants and recruitment

From June 2021 to February 2022, research assistants (RAs) called English-speaking parents/legal guardians (≥ 18 years old) of patients (≤ 5 years) who were scheduled for an initial hypospadias consultation within 2 months at two-study sites. We excluded parents/legal guardians < 18 years old, not fluent in English, and no access to an electronic device. We used a purposive sampling strategy to ensure the sample's diversity, prioritizing the recruitment of non-White and Hispanic parents [11].

Overview of data collection

RAs contacted participants via telephone at four time points: baseline (before viewing the *Hub*), after viewing the *Hub* but prior to the consultation (pre-consultation), initial post-consultation, and 3-month post-consultation. At each timepoint an RA administered validated questionnaires (Table 1). During the initial post-consultation, an RA conducted a brief semi-structured, qualitative interview.

Baseline data collection

We collected demographic information, administered a single-item health literacy screener, and asked two questions about treatment preference. [12] We also assessed participants' knowledge relevant to hypospadias decision-making with a Hypospadias Knowledge Assessment, a 6-item, multiple-choice measure with input from health communication experts during the *Hub*'s acceptability/usability testing [8]. Questions covered epidemiology, hypospadias treatment and anesthetic options, typical age at surgery, postoperative recovery and potential long-term effects if left untreated. Lastly, we administered the 16-item Decisional Conflict Scale (DCS), which measures 4-dimensions of decision-making: informed, values clarity, support, and uncertainty [13]. After completing baseline data collection, participants were given access to the *Hub* via a unique login credential.

Table 1 Constructs, measures, and descriptions of their timing.

Construct	Measure and Description	Item Categories	Timing			
			Baseline	Pre-consultation	Initial post-consultation	3-month post-consultation
Demographics	Race, ethnicity, gender, age, marital status, insurance status education, zip code	Varies	X			
Health literacy	Single Item Literacy Screener (SILS): 1-item measure assessing health literacy ("How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?")	Never, Rarely, Sometimes, Often, Always	X			
Decision-relevant knowledge	Hypospadias Knowledge Assessment; 6-item measure assessing of hypospadias knowledge created by the research team	Correctly versus incorrectly answered	X	X		
Decisional conflict	Decisional Conflict Scale (DCS): 16-item measure assessing four dimensions of decision-making: informed, values clarity, support, and uncertainty	0-Strongly agree; 1-Agree; 2-Neither agree nor disagree; 3 -Disagree; 4-Strongly disagree	X	X	X	
Decision aid acceptability	Decision Aid Acceptability Questionnaire (DAAQ): 4-item measure assessing four dimensions of the web-based decision aid: information, length, clarity, balance	All items have 5-points, except clarity has 4-point (Table 3)		X		
Preparedness for decision-making	Preparation for Decision-Making Scale (PrepDM): 10-item measure assessing a parent's perception of how useful the decision aid was and how it prepared him or her to communicate with their provider at a consultation visit	Not at all; 2-A little; 3-Somewhat; 4-Quite a bit; 5-A great deal		X	X	
Shared decision-making	Shared Decision-Making Questionnaire (SDM-Q-9): 9-item measure assessing parents' perception of their involvement in decision-making during the consultations	0-Completely disagree; 1-Strongly disagree; 2-Somewhat disagree; 3-Somewhat agree; 4-Strongly agree; 5-Completely agree			X	
Decisional regret	Decision Regret Scale (DRS): 5-item measure assessing parents' distress or remorse after a healthcare decision	1-Strongly agree; 2-Agree; 3-Neither agree or disagree; 4-Disagree; 5-Strongly Disagree				X
Treatment preference	Questions created by the research team: "Is there a decision to make about whether your son should have surgery for his hypospadias?" and "Do you intend for your child to have hypospadias surgery?"	"Yes", "Unsure", or "No"	X	X	X	

Collection of website analytic data

Participants had unlimited access to the *Hub* and were instructed to view it at least once prior to their urology consultation. Using the *Hub* during the urology consultation was optional. We collected website analytics using an ad tracker called Matomo to record the participant's *Hub* activities prior to the consultation [14].

Pre-consultation data collection

One week after baseline data collection, the RAs called participants for a follow-up survey prior to their urology consultation. An RA confirmed the participant viewed the *Hub* at least once and re-administered the DCS and Hypospadias Knowledge Assessment. The RA also administered the 10-item Preparation for Decision Making scale (PrepDM), which measures participants' perception of how useful the *Hub* was in preparing them to communicate with their provider about their decision about their son's hypospadias [15]. Finally, the RA administered the 4-item Decision Aid Acceptability Questionnaire (DAAQ), which assesses the *Hub*'s length, amount of information, clarity, and balance [16].

Initial post-consultation data collection

Post-consultation, an RA abstracted clinical information from the patient's medical record including whether he was diagnosed with hypospadias, classified hypospadias based on meatal location, and recorded the decision about surgery. Within 5-days following the consultation, an RA contacted *all* participants via telephone. Parents of patients found to have *no evidence of hypospadias* during the exam were dropped from the study and excluded from further analyses. For parents of *confirmed hypospadias patients*, an RA asked about treatment preference, administered validated questionnaires, and conducted a brief, semi-structured qualitative interview. Questionnaires included the DCS, the PrepDM, and the 9-item Shared Decision-Making Questionnaire (SDM-Q-9). The SDM-Q-9 measures participants' perception of their involvement in decision-making during the consultation [17]. The interview inquired how the *Hub* affected their consultation and what factors impacted their decision about their son's hypospadias.

Three-month post-consultation data collection

Three months after the consultation, an RA contacted *all* participants who completed the initial post-consultation survey via telephone. An RA administered the 5-item Decision Regret Scale (DRS), which assesses a participant's regret after making a treatment decision [18]. Also, the RA asked one open-ended question about the participant's decision.

Provider interviews

An RA conducted semi-structured interviews with pediatric urologists to assess whether the *Hub* was used during the visit and how it influenced the conversations with parents.

Website analytics

Using the ad tracker, we collected data points about participants' *Hub* interactions, including number of website visits, average time per visit, number of pages viewed, videos watched, and average view time per video. We analyzed the raw data to identify participants' website engagement trends.

Quantitative analysis

Descriptive statistics were reported for participant demographics and quantitative measures. Total scores on the measures were converted to a 0–100 scale. We performed a two-sided paired t-test comparing the mean total scores on the Hypospadias Knowledge Assessment at baseline and pre-consultation, and further, to evaluate differences in the overall scores for the DCS at baseline versus pre-consultation, and pre-consultation versus post-consultation. We used stratified Mantel-Haenszel [19] with participants as strata, measurement occasion as row variable and outcome as column variable to test for changes in the participant's treatment preference across baseline, pre-consultation, and post-consultation time points. Statistical significance is defined as $p < 0.05$.

Qualitative analysis

The interviews were audio recorded and professionally transcribed. Using NVivo, a qualitative research software [20], we used a thematic analysis to identify themes across all parent interviews. Three research team members triple coded the transcripts and resolved discrepancies by consensus. We also compared the qualitative and quantitative data to further understand how the *Hub* impacted participants' decision-making.

Results

Demographics

Of the 148 parents we contacted, 14 were excluded, 26 declined to participate, and 43 did not respond to further communication with the research team, leaving 65 who consented to participate (48.5% of eligible parents enrolled) (Extended Summary Figure; Table 2). Majority (97%) of participants were women; however, 19% viewed the *Hub* with their spouse/partner prior to the consultation. Exclusion reasons included age < 18 years ($n = 2$), non-English speaking ($n = 4$), no access to a smart phone/computer tablet ($n = 1$), change of pediatric urology practices ($n = 1$), parental report of no hypospadias or uncertainty about the hypospadias diagnosis ($n = 4$), one child who was a ward of the state, and one who already had surgery for hypospadias. Of the 65 participants, 10 were lost to follow-up and 1 withdrew from the study, leaving 54/64 (84.4%) who completed pre-consultation data collection. Of the 54 participants, 9 (16.7%) noted they did not look at the website when an

Table 2 Parent and patient characteristics of study sample.

Participant	Variable	Category	Number (%)
Parent Characteristics	Race	Caucasian/White	49 (76.6%)
		Black	7 (10.9%)
		American Indian/Alaskan Native	2 (3.1%)
		Asian	1 (1.6%)
		More than one race	2 (3.1%)
		Unknown/unreported	3 (4.7%)
		Ethnicity	Hispanic or Latino
		Not Hispanic or Latino	60 (93.8%)
	Gender	Female	62 (96.9%)
		Male	2 (3.1%)
	Age	Mean (SD)	29.2 (5.37)
		Median [Min, Max]	30.0 [18.0, 43.0]
	Marital status	Single	26 (40.6%)
		Married	33 (51.6%)
		Separated	1 (1.6%)
		Divorced	3 (4.7%)
		Widowed	0 (0%)
		Other	1 (1.6%)
		Education	Some high school
	Graduate high school		13 (20.3%)
	Some college		19 (29.7%)
	College degree		22 (34.4%)
	Post-graduate degree		6 (9.4%)
Health Insurance	Public (Medicaid/Children's Special Services/TBC)	28 (43.8%)	
	Private (Anthem/Aetna/TBC)	19 (29.7%)	
	Other insurance type/unknown	9 (14.1%)	
	Self-pay	8 (12.5%)	
	Health Literacy	Never	39 (60.9%)
	Rarely	13 (20.3%)	
	Sometimes	8 (12.5%)	
	Often	2 (3.1%)	
	Always	2 (3.1%)	
	Median income by zip code	Mean (SD)	\$55,900 (18,000)
		Median [Min, Max]	\$51,400 [22,000, 114,000]
Patient/Child Characteristics	Age at consent	Mean (SD)	149 days (197)
		Median [Min, Max]	84 days [7, 1140]
	Meatal location (<i>n</i> = 30 diagnosed with hypospadias)	Glanular (includes Megameatus)	15 (50.0%)
		Distal shaft	10 (33.3%)
		Mid shaft	3 (10.0%)
		Penoscrotal	2 (6.7%)
	Perineal	0 (0.0%)	

RA called about the pre-consultation survey, and 45 (83.3%) shared they had already reviewed the website.

Following the urology consultation, parents of patients with no evidence of hypospadias on exam (23/53; 43.4%) were dropped from the study and excluded from further analyses. Thus, they viewed content that was ultimately irrelevant but none of these parents expressed any concerns during their post-consultation survey. Of the 30 parents of sons with confirmed hypospadias, 29 (96.7%) completed initial post-consultation data collection. Twenty-seven (93.1%) of the 29 parents completed the 3-month post-consultation data collection.

Website analytics

Website analytic data was available for 52/54 (96.3%) participants. Two participants had ad-blocker software on their devices which prevented Matomo from tracking their *Hub* activities. Participants (*n* = 52) used a smartphone (73%), computer (17.3%), computer and smartphone (13.4%) or computer and tablet (2%) to view the *Hub*. During the study period, participants visited the *Hub* 162 times. Most (61.5%) visited multiple times; 23% visited again between the pre-consultation and the urology consultation. The average total time spent on the *Hub* per participant was 25.75 min

(SD = 16.52). The average duration of each visit was 12.75 min (SD = 12.36). The first quartile and third quartile of time spent in minutes is (12.9, 36.2). The interquartile range is 23.23. Participants viewed an average of 7 of the 9 pages across all their visits and more than half of participants (53%) watched at least one testimonial video.

Quantitative results

Decision aid acceptability

After viewing the *Hub*, each participant (n = 54) completed the DAAQ. Most participants thought the website's length (83.3%) and amount of information (70.4%) were "about right." The majority (93.0%) thought that most or everything was clear. Most (70.4%) thought it was completely balanced, 18.5% thought it was slightly slanted and 5.6% thought it was clearly slanted towards surgery; and 5.6% thought it was slightly slanted towards no surgery (Table 3).

Preparation for decision-making

The mean PrepDM score was 82.6 out of 100 (SD = 14.1) (Table 3). Scores ≥ 75 indicate that participants are well-prepared to make decisions after reviewing a decision aid [4].

Decision-relevant knowledge

After viewing the *Hub*, the Hypospadias Knowledge Assessment's mean score (0–100 scale) (54.3 vs 75.6, $p < 0.001$) significantly increased compared to the baseline (Table 3).

Decisional conflict

After viewing the *Hub*, the mean DCS score (0–100 scale) (36.0 vs. 21.9, $p < 0.001$) significantly decreased on the pre-consultation survey. After the consultation, the mean DCS score (21.9 vs. 8.8, $p < 0.001$) significantly further decreased compared to the pre-consultation survey (Table 3).

Perceived involvement in decision-making

The mean SDM-Q-9 score was 82.5 out of 100 (SD = 16.7) indicating a moderate to high degree of perceived involvement in decision-making (i.e., quality of SDM) during the consultation (Table 3) [17].

Decisional regret

The mean DRS score was 25.0 out of 100 (SD = 47.03) indicating extremely low regret (Table 3) [18]. Most participants (74.1%) experienced no decisional regret.

Table 3 Decision aid acceptability and measures of decision quality.

Construct	Scale	Score (%)	
Decision-relevant Knowledge	Hypospadias Knowledge Assessment (0–100)	Baseline/pre-consultation; 54.3 vs 75.6, $p < 0.001$	
Decisional Conflict	Decisional Conflict Scale (0–100)	Baseline/pre-consultation: 36.0 vs. 21.9, $p < 0.001$ Pre-/post-consultation with urologist: 21.9 vs. 8.8, $p < 0.001$	
Decision Aid Acceptability	Decision Aid Acceptability Survey	Balance	0% "much less than wanted" 7.4% "a little less than wanted" 70.4% "completely balanced" 13.0% "a little more than wanted" 9.3% "much more than wanted"
		Length	1.9% "much too long" 3.7% "a little too long" 83.3% "about right" 9.3% "a little too short" 1.9% much too short
		Amount of Information	5.6% "clearly slanted to surgery" 18.5% "slightly slanted to surgery" 70.4% "about right" 5.6% "slightly slanted to no surgery"
		Clarity	0% "clearly slanted to surgery" 29.6% "everything was clear" 63.0% "most was clear" 5.6% some things were clear 1.9% many things were unclear
		Preparation for Decision-making (0–100)	Mean 82.6/100, ± 14.1
		Quality of SDM	Shared Decision-making Questionnaire (0–100)
Decisional regret	Decision Regret Scale (0–100)	Mean 25.0/100 ± 47.03	

Treatment preference

There were no statistically significant changes in participants' treatment preferences between baseline and pre-consultation nor between pre-consultation and post-consultation.

Qualitative results

All participants reviewed the *Hub* prior to the consultation. Only 2 of 29 (6.9%) participants reported using the *Hub* during the consultation. Based on our thematic analysis, the *Hub* helped participants feel informed about hypospadias prior to their consultation, especially regarding the spectrum of hypospadias severity, risks/benefits of surgery, and long-term effects if left untreated (Table 4). The *Hub* addressed their knowledge gaps about hypospadias while the urologist provided personalized information about their son's condition. Participants reported that they focused on the *Hub*'s visual media components including the parent testimonial videos, step-by-step illustrations of hypospadias surgery, and the hypospadias/chordee severity scale. Suggested improvements included additional information about penile torsion/chordee, timing of surgery, pros/cons of surgery, and more testimonial videos of parents who chose observation. Providers were unable to determine which parents reviewed the *Hub*, and they perceived no difference in conversations between participants and non-participants. Further, no provider raised any concerns about the *Hub* significantly impacting their discussion or decision.

Discussion

To our knowledge, this is the first pilot study of a pediatric urology DA. It was critical to pilot test the pre-consultation delivery of the *Hub* prior to conducting a two-arm randomized controlled trial (RCT) testing its efficacy to improve the quality of SDM during hypospadias consultations. First, this study demonstrated the feasibility of recruitment and retention which is a *critically important* step prior to conducting an RCT of an intervention [10,21,22]. Second, the *Hub* was acceptable to parents, increased their decision-relevant hypospadias knowledge, and decreased their decisional conflict.

Most (57%) pediatric SDM interventions are designed for use only before the consultation [23]. Pre-consultation delivery is especially pragmatic in high-volume, pediatric surgical practices with brief, focused visits. Our intervention's goal is to inform parents and clarify their values about the hypospadias decision *before* the urology consultation to increase the likelihood of SDM *during* the visit. We found that pre-consultation delivery facilitated an informed, parental consideration of the relevant issues *before* the consultation, thus allowing parents to synthesize and interpret salient information without the influence of the urologist's potential bias. This is *critically important* because definitive hypospadias management decisions are often made during the initial consultation with the pediatric urologist while parents are still processing emotions/concerns and synthesizing information [7].

Based on our analysis of the website data, we identified specific web pages and content participants viewed, which

provided insight into the issues and concerns that mattered most to them. Participants engaged extensively with our testimonial videos, watching 1.4 videos on average across all visits. Shaffer et al. found that including patient narratives in DAs may enhance individuals' navigation of a health decision and health literacy [24]. Our testimonial video, "No Surgery," was viewed most frequently, which was also popular in previous testing phases [8]. Further, our thematic analysis revealed the testimonials offered participants a balanced presentation of hypospadias decision-making and parental viewpoints. The degree of engagement with the "No Surgery" video illustrates that parents may have unfulfilled informational needs about hypospadias treatment and desire to hear different perspectives. The results of the acceptability questionnaire strengthen this conclusion as most (70.4%) participants found the DA to be completely balanced.

Although we only asked participants to view the *Hub* once, most participants accessed it multiple times and spent an average of 25.75 min on the *Hub* across all visits, indicating extensive engagement. It is no surprise that participants felt the *Hub* helped prepare them for the consultation. Interestingly, only 6.9% of participants used the *Hub* during the visit. Participants found the consultation with the urologist was an important component in their decision-making process and felt prepared for the visit after viewing the *Hub*. Additionally, no participants visited the *Hub* after the clinic visit, suggesting that the combination of the *Hub* and the urology consultation fulfilled their informational needs.

Like previous DA studies, exposure to the *Hub* significantly improved participants' knowledge scores about the condition [4,25,26]. Participants' perception of feeling informed, especially about the risks of surgery, spectrum of severity, and long-term effects if left untreated, was a prominent theme. The perception of feeling informed greatly influenced participants' consultations, which may explain their significant decrease in decisional conflict.

Multiple limitations of our study should be considered. First, we recruited parents of *any* patient referred for a hypospadias consultation despite the presumptive diagnoses of hypospadias being overturned frequently and need for post-recruitment study withdrawal. We believe that alternative strategies (e.g. pre-consultation, video/photographic evaluation of the child's anatomy) would have been technically challenging and unacceptable to parents. Pre-consultation screening could exclude mild hypospadias cases whose families may benefit most from the intervention. Second, due to personal privacy settings on website browsers, we were unable to track two participants' *Hub* activities. Most participants' (96.2%) activities were monitored, and the data indicated a high level of engagement. Third, the study included a small sample size, which is typical for pilot studies; thus, results are not generalizable [10,27]. The small sample size was appropriate for our study's objectives of assessing acceptability, feasibility of study procedures, remote usability, and preliminary efficacy. Also, the small sample size, particularly for post-urologists' assessments, may have precluded the detection of moderate yet clinically meaningful differences. Lastly, we acknowledge that the patient does not have the opportunity to articulate his perspective about hypospadias during the consultation; thus, the patient's

Table 4 Participant quotes about which factors most impacted their decision about their son's hypospadias.

Theme	Definition	Examples	Participant quotes
Reviewing the website beforehand addresses knowledge gaps	Parents identify unfamiliar topic areas about hypospadias which could prompt additional questions or concerns.	Constructing questions to ask doctor at appointment	"I guess doing the research on it ... it helped me make the best decision for it, and I used the website to do most of that research because it was mostly all there." (F, #13)
		Identifying content helps ease and/or facilitate decision	"I'd probably say the website helped me with my options and then talking with family and getting different opinions kind of helped me solidify and then meeting with the doctor made me feel better about that decision." (F, #20) "The website really impacted my decision. I already kind of had my mind made up when I went in there. Just reading about it ... I just want him to be as normal as possible where he won't have any issues later in life." (F, #18)
Feeling informed about hypospadias in general	Parents are knowledgeable and prepared to have a conversation with their doctor after reviewing the decision aid.	Understanding the risks of surgery; spectrum of severity; and long-term effects if left untreated	"The website was extremely helpful because sometimes information can go over your head if you don't work in the medical field. So just having free time to browse the website and hear of others' experiences and all the information there that's in layman's terms before the visit even occurred was very helpful." (F, #4) "Just being able to bring that to the table with the urologist ... just having some information prior to the appointment helped a lot with just the whole experience ... knowing what to ask and terminology and being comfortable with the information." (F, #17) "The website just gave me a lot of basic information to be more prepared to go into the doctor's visit. I don't think it took me in one direction or the other. It just weighed things out." (F, #10) "I did spend a lot of time on the illustrations there ... [the doctor] told me that it was a very mild case. With the pros and cons, we talked about, that helped us decide that at this point we don't feel that we'll get the surgery." (F, #1)
Receiving tailored, personalized information from doctor	Doctors provide supplemental information to explain, clarify, and/or discuss specifics about their patient's condition. Parents have a basic understanding of hypospadias; however, they desire specifics based on their son's case.	Weighing and identifying pros and cons	"The urologist like helped explain more about his specific case. The website told me in general, but the urologist was able to see him and then pinpoint, with his case, the possibilities of what can happen, and I think that really helped." (F, #5)
		Using diagrams/illustrations to explain specifics	"The doctor is very nice. [S/he] explained me everything. [S/he] showed me with the graph and told me if I'm not doing that one, the worse effect on his life.
		Distinguishing differences between mild versus severe cases	

Including partner in the decision-making	Parents who include their partner help facilitate the decision-making process regarding treatment.	Using the decision aid as a conversation guide prior to the clinical visit	So, that's why I chose this option." (F, #7) "I actually had my husband look at the website for him to gather more information. We were able to discuss with each other what our options were. Once we got to the actual appointment, I think we were both on the same page at that point. But hearing it from the urologist, [his/her] thoughts on how to go about it definitely helped make that decision a little easier." (F, #8) "I thought it was extremely helpful, especially for my husband who is not in the medical field. So, he's now very much at ease. He felt like he understood his options. He felt like he was considered in the decision-making, and nothing was over his head. We really appreciated the website." (F, #15) "Me and my husband pretty much came to an agreement during the visit that that's what we wanted to do." (F, #16)
Participating equally in the decision-making process			
Releasing fears or anxiety about the condition and/or treatment option			

preferences are not considered in the decision-making process.

This pilot study provided valuable information regarding recruitment, retention, and standard deviations of our primary outcome (i.e., quality of shared decision-making) that will inform power and sample size calculations for our future RCT [21,22]. The objectives of the future RCT are to test the efficacy of the *Hub* to: (1) improve quality of SDM during hypospadias consultations as measured by parent and observer report, and (2) decrease decisional conflict and regret and increase decision-relevant hypospadias knowledge. We will also assess barriers and facilitators to future implementation of the intervention. We are in the process of creating a culturally adapted, bilingual tool to support SDM for hypospadias with diverse populations, which will be incorporated in the future RCT. This will be a roadmap for future development of patient-centered, culturally sensitive decision support tools for other pediatric urology conditions.

Finally, future studies will include multiple, diverse clinical sites across the United States to better understand the implementation processes of the *Hub* intervention. Ultimately, the intervention's efficacy results will have far-reaching implications across many other preference-sensitive decisions in pediatric urology and other pediatric subspecialties, which will improve child health and quality of life.

Conclusion

This pilot study of the *Hub* intervention demonstrated feasibility of recruitment and retention. The *Hub* was acceptable to participants, and it increased their decision-relevant hypospadias knowledge and decreased their decisional conflict. This pilot study will inform our future randomized controlled trial of the *Hub* versus usual care to (1) compare long-term decisional regret and quality of shared decision-making (SDM) between study groups; and (2) demonstrate that the intervention will have a durable effect and not increase visit times.

Ethical approval statement

This research study was approved by the Institutional Review Boards at Indiana University (#1511846401) and the University of North Carolina at Chapel Hill (#21-0146).

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Conflict of interest

None of the authors have any conflicts of interest to disclose.

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