

## User-testing of a decision-support tool for parents facing threatened periviable delivery: The Periviable GOALS decision aid<sup>★</sup>



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### ABSTRACT

**Background:** To report user-centered design methods and stakeholder acceptability ratings of the Periviable GOALS (Getting Optimal Alignment around Life Support) decision aid (DA).

**Methods:** ‘Experienced’ and ‘expectant’ mothers engaged in content and design refining sessions. Five videos (10 families) were embedded in the DA to highlight life after delivery. User-testing sessions were conducted with mothers and providers to assess acceptability. End-user testing was conducted with hospitalized women facing potential periviable delivery to assess acceptability and feasibility in the clinical setting.

**Results:** 108 participants engaged in sessions from July 2017–January 2020. Twenty-seven refining sessions resulted in a DA providing survival estimates, neonatal outcomes descriptions, and values clarification exercises. Five white and five black women participated in the videos; six having surviving children (ages 16 months–4 years). Twelve mothers, 16 providers, and six hospitalized women evaluated acceptability. 95.1 % found the content “just right,” 94.9 % rated the videos “good” or “excellent,” and 97.2 % believed GOALS would support families in periviable decision-making.

**Conclusion:** Our results highlight the importance of developing a DA that is acceptable for patient use with direct involvement of stakeholders.

**Practice Implications:** The GOALS DA may prepare families to engage in shared decision-making to facilitate more patient-centered models of periviable care.

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## 1. Introduction

Decision-making surrounding periviable birth (22 0/7–24 6/7 weeks gestation) requires families to face the burden of making “end-of-life” decisions at the very beginning of life [1,2]. Because their brain and lungs are not fully developed by this gestational age, these neonates are unable to survive after delivery without appropriate medical interventions. Outcomes can be poor, resulting in death or survival with significant neurodevelopment impairment [3,4]; thus parents are asked if they want to pursue resuscitation for their child or palliation, also known as ‘comfort care.’ Even if parents choose resuscitation, roughly 40 % of neonates born will die, and, among survivors, roughly half will

suffer moderate to severe disability (e.g. developmental delays, blindness, deafness, cerebral palsy, mental retardation) [5–10].

Decision-making regarding resuscitation versus palliation can be very stressful and complex – not only do parents need to clearly understand the risks, benefits, and potential outcomes of each option, but they must also factor in their personal values into their decision. Expectant parents may have limited awareness of their values in relation to resuscitation and end-of-life decision-making, and may not even consider them until they are faced with the possibility of an extremely premature delivery. Shared decision making (SDM) elicits parents’ values, preferences, and goals as part of their decision-making process. SDM is an optimal approach for supporting families in making these decisions because it fosters dynamic communication between providers and families, engages parents in deliberations, and ultimately gives them the platform to make informed, values-concordant decisions about their child’s treatment [11,12].

While SDM is recommended by the American Pediatrics Association for periviable counseling, our prior studies suggest that current counseling practice is neither shared, well-informed,

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nor patient-centered [13–15]. Due to the possible lack of communication between obstetricians and neonatologists, parents often receive varying outcome estimates and conflicting advice regarding treatment options. Additionally, our work has found that physicians tend to focus on estimates of survival, but infrequently discuss longer term implications of survival with neurodevelopmental impairment. Furthermore, our research has shown that providers lack training in SDM, particularly in eliciting values, preferences, and goals— a critical aspect of periviable decision-making that can have a crucial influence on parents' neonatal treatment decisions [16,17]. Eliciting values from families facing threatened periviable delivery can enhance informed decision making, reduce the likelihood of decision regret, and ultimately, adverse mental health outcomes [18].

In response to the need for resources to support periviable SDM, we employed a user-centered design research methodology partnering with 100 stakeholders, including families, and providers, to develop a novel decision aid (DA) to optimize periviable counseling and neonatal treatment shared decision-making. The International Patient Decision Aid Standards (IPDAS) [19] recommends that, as the targeted end-users, stakeholders should be involved in the design and testing of DAs. One way to effectively meet this recommendation is through user-centered design, a collaborative and intuitive approach to creating DAs. In this study, we detail the transformation of our tool, the Periviable GOALS (Getting Optimal Alignment around Life Support) DA, from a prototype [20] to a functioning DA through two critical stages of user testing – alpha and beta testing. Alpha testing employs stakeholders to partake in the DA refinement process [21] and is an optimal way to obtain direct feedback regarding stakeholders' acceptability. Beta testing allows for 'end-users' to be observed using the tool in a real-world setting in order to assess feasibility, effectiveness, and usability [21,22]. We also describe the development of 'lived experience' videos, which were incorporated to bring the 'statistics to life' at the insistence of patients and family co-designers to enhance understanding, interpretation, and meaning making regarding potential neonatal outcomes. Here, we describe the alpha testing, video development, and beta testing procedures, along with their results for the GOALS DA.

## 2. Methods

This study was approved to be conducted at Indiana University (IU) and the University of California San Francisco (UCSF) (IU IRB protocols# 1606279321 & 1908726844; UCSF IRB protocol# 1620705). Informed consent was obtained from all subjects prior to the start of study procedures.

Our initial design and prototyping efforts have been previously described [20]. Briefly, the design process occurred over the course of five sessions involving over 100 families and providers in patient-advisory panels across both institutions and design research experts. Using design research methods and a "sky's the limit" approach, stakeholders were encouraged to describe what they needed from a tool to help them make decisions related to periviable delivery. This work resulted in a prototype drawing of a mobile app that would include an outcomes calculator, activities to elicit personal values, descriptions of outcomes that may result from neonatal resuscitation and palliation, and 'lived experience videos' to give parents a glimpse of life after a periviable delivery. The videos were designed with the aim of bring the 'jargon and statistics to life' and helping families to understand the range of long-term experiences and the lived reality associated with each of the potential neonatal outcome categories beyond the hospital stay. This was identified as lacking in physician consultation/counseling by experienced parents, who reported that counseling tended to focus in survival, non-survival, and NICU stay. The lived-

experience narratives were utilized primarily to inform (and secondarily to engage), but explicitly not intended to model behavior or persuade [23]. The mobile app would be provided to hospitalized women to enhance periviable SDM by not only supplementing counseling, but also supporting families in making informed, values-concordant treatment decisions. Subsequently, we conducted a series of sessions to refine the prototype (alpha testing), and then programmed and pilot tested the final, functional DST (beta testing).

### Phase 1 Alpha Testing – Part 1: Refining the DA Prototype through Focus Groups

We conducted a series of small focus group sessions from July 2017–January 2019 with English- and Spanish-speaking women who had previously experienced a periviable delivery ("experienced women") and pregnant women within the periviable gestational window (20–26 weeks; "expectant women"). Subjects were excluded if they were under age, did not speak English or Spanish, had never experienced a periviable delivery or were not within the periviable gestational window if currently pregnant. Sessions took place at IU and UCSF and lasted one-hour. Participants received a \$50 gift card upon completion and could attend more than one session, so long as they continued to meet eligibility criteria. Sessions were homogenous (i.e. experienced women only vs. pregnant women) to provide each stakeholder group enough time to address their unique perspectives and specific needs for the tool. Experienced women were identified from participating in the user-centered design study [20] or through perinatal, bereavement, or NICU databases, while expectant moms were recruited at their obstetric appointments or via phone call. Due to the sensitive nature of this work, our team provided resources for support groups for bereaved parents and parents with surviving children. The team also followed protocols to report and refer any disclosures of suicidal ideation to a healthcare provider.

Sessions started with a brief icebreaker. The study team explained the primary goal(s) for that session and asked participants to consider the following while reviewing the prototype: 1) Is it easy to understand and navigate? 2) Is it biased towards one decision or the other? 3) Is it insensitive? 4) Is it supportive? Screenshots from the prototype were presented in a slideshow for the entire group to view, along with an accompanied printed version. Participants noted, circled, or highlighted text that was offensive, confusing, upsetting, or unclear.

Sessions evaluated five critical elements of the prototype: 1) design and color, 2) content related to neonatal outcomes, spectrum of neurodevelopmental disabilities, and comfort care, 3) progression and display of content, 4) graphical representation of outcomes data (e.g., pie charts vs. bar graphs vs. icon arrays) [19], and 5) language and tone used to maximize sensitivity, neutrality, and clarity. The study team used scripted verbal probes ("what do you think is being represented here?", "describe what you would do next") and spontaneous probes ("what about this picture/sentence/etc., makes you feel that way?"). Sessions were facilitated by site PIs (BTE & MK) one of whom is a practicing ob/gyn and health services researcher and the other who is a PhD trained health services researcher. Both have extensive training and expertise in conducting qualitative research. The investigators replicated a user testing procedure previously utilized and published by MK in designing two R01 funded decision-aids to support prenatal genetic testing decision and trial of labor after cesarean decisions. All sessions were audio-recorded and field notes were taken by two observing research staff, all trained in qualitative methods. Notes were collated and shared across teams. Iterative refinements were made in the decision aid based on the presence of recurring feedback, concerns or themes identified from the notation. Using a ping-pong approach, IU conducted a session,

then communicated findings to UCSF, who then conducted a session at their site. Both teams then reconvened via conference call to review notes, and to agree upon the necessary textual/graphical revisions for the software developer to incorporate in the DA. Subsequent sessions were hosted for stakeholders to review those edits and offer new feedback in an iterative refining process. Once no new concerns were raised, the software developers then transformed the DA from a prototype to a working mobile app.

**Incorporating “Lived experience” Videos**

From March-July 2019, a subset of experienced women were filmed and interviewed about their lives following periviable delivery. Five categories of videos were created in consultation with a neonatologist: death following comfort care, death following resuscitation, and survival with mild, moderate, or severe neurodevelopmental impairment. Families were assigned to the appropriate category based on extensive medical record chart review. Research assistants (RAs) used different prompts during the interview based on whether the family was bereaved or had a surviving child (Table 1). Software developers then embedded the videos into the DA. Selected screenshots are presented in Fig. 1.

**Phase 1 Alpha Testing – Part 2: Assessing Acceptability through User-Testing**

While previous alpha testing sessions were structured as informal focus groups, four sessions conducted from August-September 2019 were dedicated to user-testing with women and providers to assess their acceptability of the DA. Eligibility criteria remained the same for women. Maternal-Fetal Medicine (MFM) Specialists and Neonatologists were approached at their weekly

department meetings, in which the research team gave a brief presentation about the study and then invited providers to stay afterward if they wished to participate. Other providers were excluded from participation.

Sessions were homogenous, in which each stakeholder group participated in their own user-testing session. Sessions were conducted at IU and UCSF with expectant and experienced women, and at IU with providers. Participants viewed the DA on electronic tablets and completed a brief, 10-item acceptability questionnaire, a measurement recognized by the Ottawa Decision Support Framework to develop, refine and obtain feedback for decision aids. [24] Descriptive analysis and frequencies were calculated.

**Phase 2 Beta Testing: Assessing Acceptability with Hospitalized End-Users**

Between November and December 2019, IU RAs recruited pregnant women ( $\geq 18$  years) between 22 0/7–24 6/7 weeks gestation who were admitted to labor and delivery for pregnancy complications that posed a threat for periviable delivery, such as rupture of membranes, preterm labor, shortened cervix, pre-eclampsia, and growth restriction. Women underage, incarcerated, medically unstable, or in active labor were excluded. Our aim was to recruit five to six women, which is customary for beta testing. [25]

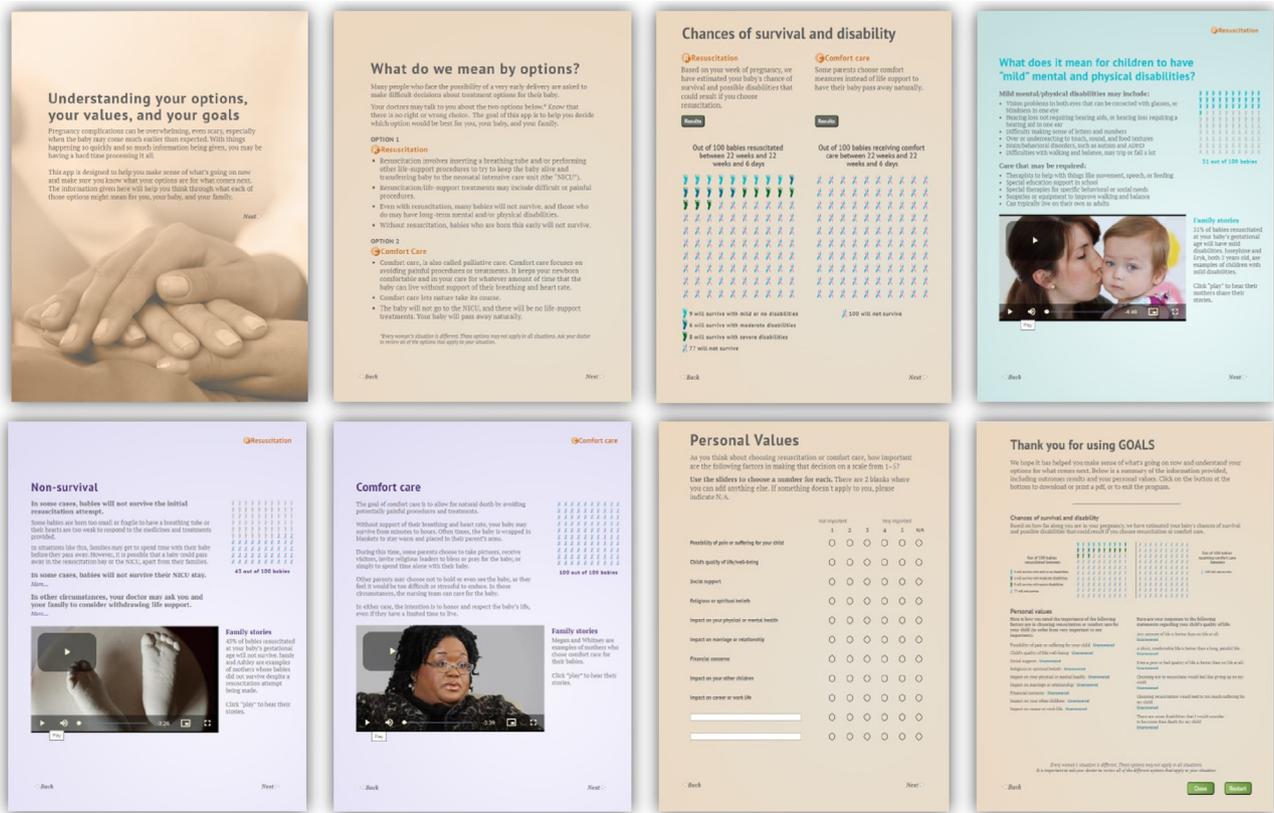
After being counseled regarding their neonatal treatment options, patients were approached by a RA and asked to view the DA in its entirety, including the testimonial videos, and then complete the acceptability questionnaire. [24] Descriptive and frequencies from the questionnaire were analyzed using EXCEL. Participants received a \$75 gift card and a gift bag containing hand

**Table 1**  
Sociodemographics.

	Alpha Testing			Beta Testing
	Provider <sup>a</sup>	Experienced/Expectant woman		Hospitalized woman
	IU N = 16	IU N = 20	UCSF N = 72	IU N = 6
Mean Age,yrs. mean $\pm$ SD	40 $\pm$ 9.0 n (%)	31 $\pm$ 5.6 n (%)	33 $\pm$ 4.5 n (%)	30 $\pm$ 5.5 n (%)
Level of training				
Attending	10 (62.5)	–	–	–
Fellow	6 (37.5)	–	–	–
Race				
African American or Black	1 (6.7)	12 (60.0)	6 (8.3)	2 (33.3)
Asian or Pacific Islander	1 (6.7)	0	27 (37.5)	0
White or European American	13 (86.7)	3 (15.0)	23 (31.9)	4 (66.7)
Latin American or Hispanic	0	5 (25.0)	5 (6.9)	0
Bi-racial	0	0	9 (12.5)	0
Other	0	0	2 (2.8)	0
Relationship Status				
Single/Never Married	4 (27.7)	9 (45.0)	4 (5.6)	1 (16.7)
Married/Partnered	11 (73.3)	11 (55.0)	68 (94.4)	4 (66.7)
Divorced/Separated	0	0	0	1 (16.7)
Education				
Some high school	0	3 (15.0)	0	1 (16.7)
High school	0	9 (45.0)	2 (2.8)	1 (16.7)
Some college	0	4 (20.0)	8 (11.1)	1 (16.7)
College graduate	0	4 (20.0)	29 (40.3)	2 (33.3)
Graduate school	16	0	33 (45.8)	1 (16.7)
Household Income <sup>b</sup>				
<\$24,999	0	6 (30.0)	5 (7.0)	1 (16.7)
\$25,000-\$49,999	0	3 (15.0)	2 (2.8)	1 (16.7)
\$50,000-\$99,999	1 (6.7)	4 (20.0)	8 (11.3)	3 (50.0)
>\$100,000	13 (86.7)	1 (5.0)	55 (77.5)	1 (16.7)
Refused/unknown	1 (6.7)	6 (30.0)	1 (1.4)	0
Health insurance <sup>b</sup>				
Private	–	6 (30.0)	63 (88.7)	3 (50.0)
Public	–	14 (70.0)	7 (9.9)	3 (50.0)
Uninsured	–	0	1 (1.4)	0

<sup>a</sup> 1 provider's demographics were missing at all levels except for the level of training and education.

<sup>b</sup> 1 UCSF experienced/expectant mom missing.



**Fig. 1.** The perivable GOALS Decision Support Tool: Sample Screenshots. A mobile, user-centered design, health tool/application aimed to improve the quality of perivable care by engaging patients and providers in shared decision-making.

sanitizer, lip balm, and lotion, as a show of our appreciation for interviewing during a potentially emotional/stressful experience. Additionally, each RA received 10 -hs of intense training with a trained actress in managing highly emotional circumstances surrounding perivable delivery (e.g. adjusting voice tone, providing space, pausing study procedures, etc.). In extreme cases, the study team was instructed to notify the patient’s providers so that she can receive professional support.

**3. Results**

IU and UCSF conducted a combined total of 31 alpha testing sessions with 92 women (experienced women = 8; expectant women = 84) and 16 providers. Twenty-seven focus groups and four user-testing sessions were conducted.

**Phase 1 Alpha Testing – Part 1: Feedback from Focus Groups**

Most experienced women were recruited at IU, due to an existing partnership from previous work in perivable decision making, while UCSF recruited the majority of expectant women. The majority of the participants were non-white (n = 66, 71.6 %) and married/partnered (n = 79, 85.9 %; Table 1). Their average age was 33 ± 4.9 years. There were clear differences in the sociodemographic characteristics of the participants from each site: 60 % (n = 12) of the IU participants had a high school education or less, while almost all at UCSF had at least some college education (n = 70, 97.2 %). And while 45 % (n = 9) of the IU participants reported an annual household income of less than \$50,000, 77.5 % (n = 55) the UCSF participants had an income of at least \$100,000.

Stakeholders provided substantial feedback regarding the overall design and color of each page, especially the introduction page, which included a brief explanation of the DA’s purpose. They advocated for a background illustration of two holding hands to

symbolize comfort and support, and preferred the image in a soft beige shade instead of grey, associating the former with “warmth” and the latter as too “cold.” Following the introduction page, we added descriptions of “resuscitation” and “comfort care” and the different implications/outcomes associated with each. Stakeholders added a disclaimer as a footnote: “Every woman’s situation is different. These options may not apply in all situations. Ask your doctor to review all of the options that apply to your situation.”

The DA then asks users to enter their gestational age or due date, recognizing that patients may know one but not the other. This entry generates corresponding outcome estimates in the form of icon arrays, designed in response to stakeholders’ request to make statistics “more personal.” Two arrays appear – one presenting the outcomes of resuscitation and the other comfort care. Participants opted for a footprint icon to symbolize survival, with three colors representing the spectrum of disabilities (i.e. mild = light blue, moderate = dark blue, severe = green), and a ribbon icon to represent non-survival.

The next four pages detail the outcomes of resuscitation, starting with mild disabilities and ending with non-survival. “Non-survival” was the term preferred by women over “death.” Each page’s background color corresponds to the spectrum of blue/green colors used in the icon arrays. Finally, “comfort care,” which was preferred over “palliation,” is presented as the last “non-survival” page. The order in which outcomes are presented was a critical decision made by the women, who strongly advocated that outcomes following resuscitation be presented first, followed by comfort care. The last section of the DA includes two values clarification activities that elicit personal values and perspectives based on ‘Key Considerations’ and ‘Gist’ items developed and tested in our prior work. The DA ends with a summary page presenting the outcomes estimates and results from the values

exercises to be printed and shared with providers for further discussion.

Phase 1 Alpha Testing – Part 2: Women & Providers' Acceptability of DA

Twelve women (experienced women = 3, expectant women = 9) and 16 providers (MFMs = 10, Neonatologists = 6) participated in the user-testing sessions (see Tables 2 & 3 ). The DA had high approval amongst women, rating all segments from “good” to “excellent.” Specifically, 83.3 % (n = 10) rated the introductions and definitions, non-survival after resuscitation, comfort care sections “good” or “excellent” (Table 2). Additionally, 91.7 % thought the amount of the information was “just right” and would be useful in helping women make decisions about resuscitation or comfort care (Table 3).

Most providers were white (n = 13, 86.7 %) and averaged was 40 ± 9.0 years old. Similarly to the women, the DA had high acceptability amongst providers. Almost all (n = 15, 93.8 %) found the amount of information to be “just right” (Table 3), 100 % found it useful, and 100 % rated the introductions and definitions pages rating “good” or “excellent” (Table 2). The mild, moderate and severe disabilities (n = 15, 93.8 %; n = 14, 90.5 %; n = 14, 87.6 %,

respectively), non-survival after resuscitation (100 %), and comfort care sections (n = 14, 93.3 %) were rated “good” or “excellent” (Table 2). Notably, half of the providers found the information to be biased toward choosing resuscitation due to the order in which outcomes were presented in the tool. One provider reasoned:

“The most likely outcome, particularly in the very early gestational ages, is that the baby will either pass away or have severe disabilities. I wonder if seeing the information in the order of outcomes might be helpful to patients.” – Provider 6

3“Lived Experience” Videos – Stakeholder Feedback

Ten interviews were conducted and combined into five videos. Two videos were filmed for each outcome category, with attention to having racially diverse families represented in each to mitigate anchoring biases. Half of participants interviewed were white and half were non-white. Six women had surviving children ranging from ages 16 months to four years. Families were asked the same set of questions and their answers were featured back-to-back to highlight both families' experiences. Videos were edited to 3–5 min in length and then embedded into the corresponding outcomes page of the DA. The vast majority of stakeholders

**Table 2**  
GOALS Decision Support Tool: Ratings by Section.

	Provider (alpha testing) N = 16 n (%)	Experienced/ Expectant woman (alpha testing) N = 12 n (%)	Hospitalized woman (beta testing) N = 6 n (%)
<b>Introduction &amp; definitions <sup>a</sup></b>			
Poor	0	0	0
Fair	0	1 (8.3)	0
Good	9 (60.0)	3 (25.0)	3 (50.0)
Excellent	6 (40.0)	7 (58.3)	3 (50.0)
<b>Chances of survival &amp; disability</b>			
Poor	0	0	0
Fair	4 (25.0)	3 (25.0)	0
Good	5 (31.3)	3 (25.0)	2 (40.0)
Excellent	7 (43.8)	7 (50.0)	3 (60.0)
<b>Mild mental &amp; physical disabilities</b>			
Poor	0	0	0
Fair	1 (6.3)	3 (25.0)	0
Good	10 (62.5)	4 (33.3)	3 (50.0)
Excellent	5 (31.3)	5 (41.7)	3 (50.0)
<b>Moderate mental &amp; physical disabilities</b>			
Poor	0	0	0
Fair	2 (12.5)	3 (25.0)	0
Good	10 (65.5)	4 (33.3)	3 (50.0)
Excellent	4 (25.0)	5 (41.7)	3 (50.0)
<b>Severe mental &amp; physical disabilities</b>			
Poor	0	0	0
Fair	2 (12.5)	3 (25.0)	0
Good	11 (68.8)	4 (33.3)	3 (50.0)
Excellent	3 (18.8)	5 (41.7)	3 (50.0)
<b>Non-survival after resuscitation</b>			
Poor	0	1 (8.3)	0
Fair	0	1 (8.3)	0
Good	10 (66.7)	3 (25.0)	3 (50.0)
Excellent	5 (33.3)	7 (58.3)	3 (50.0)
<b>Comfort care</b>			
Poor	0	0	0
Fair	1 (6.7)	2 (16.7)	0
Good	8 (53.3)	3 (25.0)	3 (50.0)
Excellent	6 (40.0)	7 (58.3)	3 (50.0)
<b>Questions about your personal values</b>			
Poor	0	0	0
Fair	2 (13.3)	4 (33.3)	0
Good	10 (66.7)	4 (33.3)	4 (66.7)
Excellent	3 (20.0)	4 (33.3)	2 (33.3)
<b>Videos of women's stories</b>			
Poor	0	0	0
Fair	1 (6.7)	1 (8.3)	0
Good	5 (33.3)	4 (33.3)	3 (50.0)
Excellent	9 (60.0)	7 (58.3)	3 (50.0)

<sup>a</sup> 1 experienced/expectant woman missing.

**Table 3**  
GOALS Decision Support Tool: Ratings for General Characteristics.

	Provider (alpha testing) N = 16 n (%)	Experienced/ Expectant Woman (alpha testing) N = 12 n (%)	Hospitalized woman (beta testing) N = 6 n (%)
The length of the presentation			
Too long	2 (12.5)	2 (16.7)	1 (16.7)
Too short	0	0	0
Just right	14 (87.5)	10 (83.3)	5 (83.3)
The amount of information was:			
Too much information	0	0	0
Too little information	1 (6.3)	1 (8.3)	0
Just right	15 (93.8)	11 (91.7)	6 (100.0)
I found the information to be:			
Slanted towards choosing resuscitation	8 (50.0)	1 (8.3)	0
Slanted towards choosing Comfort Care	1 (6.3)	1 (8.3)	0
Balanced	7 (43.8)	10 (83.3)	6 (100.0)
What did you think of the charts that showed chance of survival and disability for resuscitation and comfort care? Was it:			
Easy to understand	14 (87.5)	10 (83.3)	6 (100.0)
Difficult to understand	2 (12.5)	2 (16.7)	0
What did you think of the summary information sheet? Would it make the decision: <sup>b</sup>			
Easy	5 (35.7)	6 (50.0)	2 (33.3)
More difficult	1 (7.1)	1 (8.3)	1 (16.7)
Neither	8 (57.1)	3 (25.0)	3 (50.0)
Do you think this decision aid would be useful in helping woman make a decision about resuscitation or comfort care?*			
Yes	15 (100)	11 (91.7)	6 (100.0)
No	0	1 (8.3)	0
Do you think we included enough information to help you decide on a treatment for your child? <sup>a</sup>			
Yes	10 (66.7)	10 (83.3)	6 (100.0)
No	5 (33.3)	2 (16.7)	0

<sup>a</sup> 2 providers missing.

<sup>b</sup> 1 provider and 2 experienced/expectant women missing.

expressed satisfaction with the videos’ content and design. All experienced and expectant women were highly satisfied rated the videos “good” to “excellent”.

“Videos give great examples of what experiences are like” – Experienced Woman 2

“I liked it told and showed people who actually had to make a decision and showed the actual child and what problems the child has”- Expectant Woman 6

Similarly, almost all providers (n = 14, 93.3%) rated the videos as “good” or “excellent”.

“Videos are powerful, will be a great tool for reflection, having the statistics on each page was a great reference.” – Provider 11 Beta Testing – Hospitalized Women’s Perspectives of the DA

Six pregnant women who were recruited from October–December 2019. Four were white and two were black, and averaged 30 ± 5.5 years. Four participants had a household income of more than \$50,000.00 and half had less than a college education. DA average viewing time was 24 min and had high acceptability among the users with 100% rating all the sections “good” or “excellent” (Table 2). All participants found the amount of information presented in the DA to be “just right” and “balanced” and thought it would help them make a decision (Table 3). The videos were widely accepted as 100% rated them “good” or “excellent”.

“Good. It showed me each comfort care and resuscitation what the pros and cons are I guess . . . the last page showed me what I wrote down and what I feel.” – Hospitalized woman 1

“Visual chart of stats helpful and values summarized.” – Hospitalized woman 2

## 4. Discussion and Conclusion

### 4.1. Discussion

DA’s are designed to provide decision support, as a complement (not a replacement) to counseling and are useful for facilitating SDM between patients and providers [26,27]. In particular, DAs serve to provide information, realign expectations of outcomes, clarify values, and augment skills in decision-making [28]. Specifically, people exposed to DAs feel more knowledgeable, better informed, and clearer about their values. Furthermore, there is growing evidence that they may improve values-concordant choices [29]. Although a card-based decision aid [27,30,31] exists to inform perivable decision-making, the aid was not developed using design research methodology and does not incorporate values clarification. Thus, to our knowledge, our Perivable GOALS DA is the first digital decision support platform developed for perivable decision making. This platform enables prospective parents to receive consistent, understandable, and up-to-date estimates of morbidity and mortality. By incorporating nationally representative neonatal outcomes from the published literature [3,4], we are able to provide up-to-date estimates of neonatal survival and neurodevelopmental impairment. The digital platform can be reprogrammed as outcomes improve or change over time. Moreover, the outcomes data are converted into pictorial and graphical representations that are more easily understood by patients and wedded with video content that brings the numbers to life.

We set out to program and user-test the Perivable GOALS DA. In our first phase of testing, we engaged more than 90 women who had experienced perivable birth and pregnant women at perivable gestations in a series of focus groups and user-testing

sessions conducted across two institutions to iteratively refine the design elements, content, graphic elements, and overall look, tone and feel of the DA. Upon beta testing the application with ‘end-users’—hospitalized pregnant women experiencing complications that threatened periviable delivery, we found that the women responded overwhelmingly positively to the DA. All of them rated the DA’s sections as “good” to “excellent;” all found the amount of information presented in the tool to be “just right” and “balanced;” and each thought the DA would be useful in helping her make a decision for resuscitation or comfort care.

Patients and providers responded positively to the DA; however, we found the groups differed with regard to their perspectives on how ‘balanced’ the information was presented. While 100% of hospitalized pregnant women found the application to present balanced information, half of the providers felt that the information was slanted towards choosing resuscitation due to the order in which outcomes were presented. This difference of opinion highlights an important element of utilizing a user-centered design approach. The final product designed *with* users/patients, is likely to be different than the product designed *for* patients. Centering patient perspectives yielded distinct insights that shaped tool design. As a team of providers and researchers, we initially wanted to present comfort care first. Experienced and expectant women were adamant that this information would be too difficult to engage with first and foremost and may deter some women from proceeding to utilize the DA. Therefore, the stakeholder engaged process informed the order in which the information was presented to ensure that it would be acceptable and accessible for patient use. That patients’ perspectives would differ from providers’ perspective is not surprising given the literature on their divergent perspectives in periviable counseling [21]. We view it as a strength, and a testament to the importance of patient-centered design, that, though providers voiced concerns about the order effects, patients uniformly experienced the tool as balanced, unbiased, and acceptable. Future studies could alternate the order of presentation to examine order effects on acceptability and decision-making.

The perspectives and preferences of the research team and the patient advisors also diverged with regards to the incorporation of the lived-experience videos. Patient advisors were insistent that there was really no way to understand the decision at hand without bringing the potential outcomes to life for families. They felt that families needed a glimpse into ‘a day in the life’ to understand life *beyond* the hospital, given that most physician counseling focuses on survival and NICU care [32]. As a research team with training in decision science, we were acutely aware of and concerned about the potential biases introduced by testimonial style videos [33]. A systematic review that investigated the effect of narrative information on decision-making found only limited evidence for the influence of narratives on individuals’ decision-making. That said, studies using first-person narratives were more than twice as likely to find an effect. Therefore, authors cautioned investigators about the use of narratives [34]. To mitigate bias, it was important that all possible outcomes be presented and weighted equally, so we chose to make videos to represent all five categories, and to utilize uniform prompts/scripts to ensure that parents covered similar content across outcome categories. Because heuristic processing may cause a patient to pull from past experiences or observations [35], we were particularly concerned that the sociodemographic characteristics of the families featured might cause patients to over (or under) identify with a given speaker or outcome. To mitigate this potential threat of bias, we purposively recruited a diverse parent population, and made two videos for each category, ensuring that more than one race/ethnicity was represented for each category and that a range of socioeconomic status was represented throughout. Further, we

were careful to only discuss the families’ experiences and day-to-day lives, rather than the narrator’s decision-making process in an effort to minimize anchoring or affiliation biases. In this manner, we took extreme caution to avoid modeling behavior or persuading participants [23].

Our study results must be interpreted with certain limitations. First, despite extensive user testing, we recognize that our study sites were limited to two geographic locations, and thus, may not be generalizable to all regions of the country. However, the racial, ethnic, socioeconomic, and geographic diversity represented across these two sites is noteworthy and adds strength to the study. While the alpha testing was conducted in English and Spanish, we do not yet have a functional tool available in Spanish for beta testing. With additional resources we will translate the tool and add closed captioning to the videos. To further mitigate literacy concerns, we will also add the option for voice-over narration. Likewise, the testing, thus far, has not included partners or family members, which will be an important addition in future studies. Finally, as discussed, we recognize that the videos may introduce bias, in particular, some literature suggests that such videos tend to be biased towards more positive depictions for acceptability to parents [29]. However, we have relied heavily on our stakeholders to ensure that the videos are realistic, unbiased, and sensitive. In their absence, parents would be left with no tangible examples or images with which to relate. Our patient stakeholders unequivocally favored presenting lived experiences to bring to life the counseling and data, and to help families make meaning of medical jargon and concepts that are otherwise challenging to understand, particularly for those with lower health literacy.

#### 4.2. Conclusion

Despite these limitations, we believe that this study makes a critically important contribution to the literature on periviable counseling. We describe a novel user-centered design and testing strategy that partners with stakeholders and end-users to design and refine intervention development. As the first decision aid offered on a digital platform, our DA provides a mechanism to update outcome estimates as technology and survival continues to improve. Graphical presentations and lived experience videos aid parents in making meaning of complex content and concepts; and the values clarification exercises may support more values-concordant decision-making. In doing so, the Periviable GOALS DA stands to prepare families and providers for more SDM and more patient-centered models of periviable care.

#### 4.3. Practice Implications

The Ottawa Decision Support Framework [28,36–38] suggests that decisional needs affect decision quality, which in turn affects actions, behavior, health outcomes, emotions, and appropriate use of health services [36,39]. In prior work, we found that the quality of periviable decision-making encounters can have implications for subsequent parental mental health and coping [40]. These data support our overarching hypothesis that decisional quality is associated with subsequent emotional well-being and recovery of parents following periviable delivery. Therefore, our future research will focus on establishing the effectiveness of the Periviable GOALS DA at improving the quality of resuscitation decisions and, in turn, improve parental mental health outcomes. Finally, user-centered design remains underutilized in health care intervention design. User-centered design and ‘design thinking’ are not new [41,42], but their application to the field of health care is a relatively recent development and remains quite novel [43]. Our

findings present this methodology that enhances, and ultimately exceeds, the offerings of more traditional methods of soliciting stakeholder input. We provide a model of partnership and co-design with end-users that can be applied in other clinical context for more robust and sustained stakeholder engagement.

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## CRediT authorship contribution statement

**Brownsyne Tucker Edmonds:** Conceptualization, Formal analysis, Writing - original draft, Funding acquisition. **Shelley M Hoffman:** Data curation, Writing - original draft, Project administration. **Tatiana Laitano:** Data curation, Writing - original draft, Formal analysis. **Kimberly Coleman-Phox:** Data curation, Project administration. **Esperanza Castillo:** Data curation, Writing - review & editing. **Miriam Kuppermann:** Conceptualization, Funding acquisition, Writing - review & editing.

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