Evaluating the Use of a Decision Aid for Parents Facing Extremely Premature Delivery: A Randomized Trial

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Objective To assess decisional conflict and knowledge about prematurity among mothers facing extreme premature delivery when the counseling clinicians were randomized to counsel using a validated decision aid compared with usual counseling.

Study design In this randomized trial, clinicians at 5 level III neonatal intensive care units in the US were randomized to supplement counseling using the decision aid or to counsel mothers in their usual manner. We enrolled mothers with threatened premature delivery at $22^{0/7}$ to $25^{6/7}$ weeks of gestation within 7 days of their counseling. The primary outcome was the Decisional Conflict Scale (DCS) score. One hundred mothers per group were enrolled to detect a clinically relevant effect size of 0.4 in the Decisional Conflict Scale. Secondary outcomes included knowledge about prematurity; scores on the Preparedness for Decision Making scale; and acceptability.

Results Ninety-two clinicians were randomized and 316 mothers were counseled. Of these, 201 (64%) mothers were enrolled. The median gestational age was 24.1 weeks (IQR 23.7-24.9). In both groups, DCS scores were low (16.3 ± 18.2 vs 16.8 ± 17, $P = .97$) and Preparedness for Decision Making scores were high (73.4 ± 28.3 vs 70.5 ± 31.1, $P = .33$). There was a significantly greater knowledge score in the decision aid group (66.2 ± 18.5 vs 57.2 ± 18.8, $P = .005$). Most clinicians and parents found the decision aid useful.

Conclusions For parents facing extremely premature delivery, use of a decision aid did not impact maternal decisional conflict, but it significantly improved knowledge of complex information. A structured decision aid may improve comprehension of complex information. *(J Pediatr 2019;209:52-60)*.

Trial registration Clinicaltrials.gov: NCT01713894.

Parents may not understand nor recall discussing their options for resuscitation when facing extremely premature delivery.[1] A shared decision model may assist parents facing decisions on the resuscitation of periviable infants born at 22 to 25 weeks of gestation.[2-4] However, how best to meet the needs of expectant parents and guide shared decision-making in this clinical context is unknown.[5] Most parents want to receive information to enable good decision-making and request discussions on anticipated survival and long-term outcomes.[6-12] Some parents want more than statistical information on gestation-specific morbidity and mortality outcomes during the antenatal consult.[13-15] For some parents, information on how they can participate in the care of their child in the neonatal intensive care unit is important.[16] Parents also want sensitivity, compassion, and attention to their goals tempered by honesty about medical uncertainty.[1,6,12,13,17-19]

The American Academy of Pediatrics emphasizes an individualized and family-centered approach to antenatal counseling.[2] Guidelines and calculators may minimize site variation in approaches to counseling and help to individualize information on extreme prematurity.[20,21] Whether providing outcome data enables shared decision-making in antenatal discussions remains uncertain.[1,22] Decision aids are tools to inform about potential outcomes and risks and benefits.[23] They supplement face-to-face discussions between clinicians and patients to encourage shared decision-making. A Cochrane review of 105 randomized trials showed that, across several diseases, patients counseled with decision aids display lower decisional conflict when compared with those who received usual care.[24] Decision aids also improved knowledge, clarified healthcare values, and enabled patients to take a more active role in decision-making.[24]

We systematically developed a decision aid for antenatal counseling at 22-25 weeks of gestation after eliciting information from parents about their experiences.[10] The resulting 6-card decision aid conformed to many criteria outlined by the International Patient Decision Aids Standards Collaboration (**Figure 1**) and was validated in a separate cohort.[10,23] It is an inexpensive tool that facilitates communication even when limited time is available for counseling should the mother present in active labor. The decision aid provides survival and outcome data, which can be individualized to the circumstances. It informs and supports decision making without endorsing a particular option. It is presented to help parents evaluate their preferences with the support of a counselor. The objective of this randomized study was to determine whether

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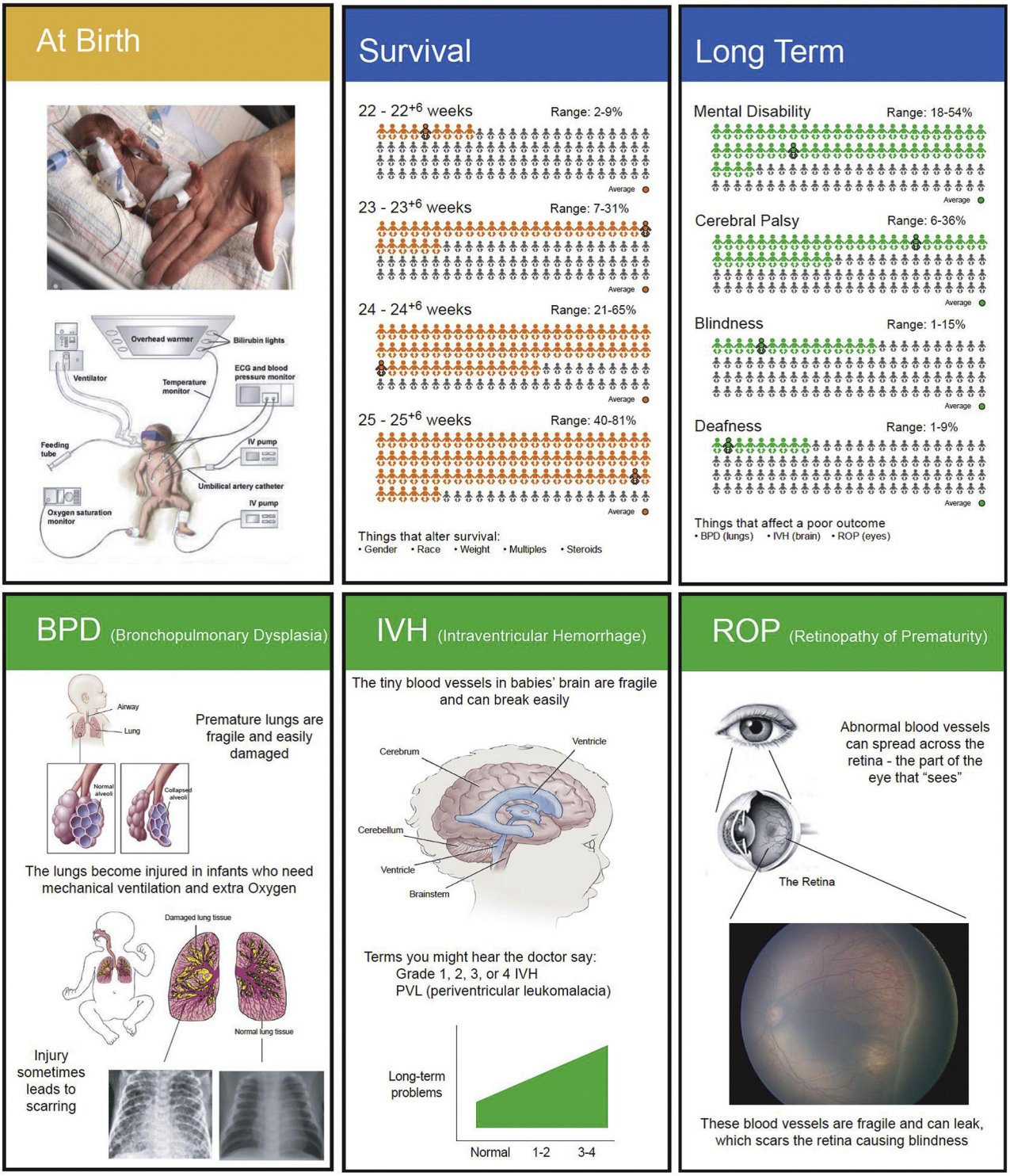

Figure 1. Decision aid for counseling parents facing extreme prematurity. *BPD*, bronchopulmonary dysplasia; *IVH*, intraventricular hemorrhage; *ROP*, retinopathy of prematurity.

parents facing extreme premature delivery between 22 and 25 weeks of gestation experience reduced parental decisional conflict when receiving antenatal counseling using a decision aid as compared with routine antenatal counseling.

Methods

This prospective, randomized controlled trial was conducted from May 2013 to August 2017 at 5 tertiary care centers in the

US following institutional review board approval at each site. The trial was registered at clinicaltrials.gov (NCT01713894). Written informed consent was obtained before enrollment of each counseled mother and her counseling clinician. Using a random number generator, we randomized clinicians (attending neonatologists, neonatology fellows, neonatal nurse practitioners, and physicians' assistants) who provide antenatal counseling to supplement counseling using the decision aid (intervention) or to provide their usual routine counseling (control). No crossovers were allowed; each clinician conducted all eligible consults as randomized for the entire study. Clinicians randomized to the intervention arm were trained by the principal investigator on the use of the decision aid. Randomized clinicians used the decision aid to supplement discussions and were not asked to memorize a script. Clinicians randomized to the control arm were asked to complete their consults in their usual manner. None of the sites in this study had any tools already in use for counseling. Within 7 days of counseling, mothers were enrolled into the study. Mothers were included if they were older than 18 years of age; between 22 and 25 completed weeks of gestation; and had a primary language of English. Mothers were excluded if there were known fetal anomalies or for intrauterine fetal demise before counseling. Baseline demographic information was obtained for enrolled clinicians and mothers.

The primary outcome was decisional conflict using the Decisional Conflict Scale.[25] Decisional conflict is a state of uncertainty about the course of action to take when making choices involving risk or uncertainty of outcomes. This 16-item, validated instrument measures a person's uncertainty in making a decision, the modifiable factors contributing to uncertainty, and the overall effectiveness of decision-making. Decisional conflict scores range from 0 to 100. Lower scores indicate lower decisional conflict. We measured decisional conflict after counseling was completed.

Secondary outcomes were measured after enrollment following antenatal counseling for threatened extremely preterm birth. Secondary outcomes were as follows: (1) Understanding of the complications of extreme prematurity, measured using a 47-question true/false knowledge test. (2) Preparedness for decision making, as measured with the 7-item preparedness for decision making scale. Scores range from 0 to 100. Greater scores indicate the individual feels prepared to make a decision.[26] (3) Acceptability survey to assess mothers' perceptions of the counseling they received. (4) Clinicians in the intervention arm were asked to complete a 5-point survey on the effectiveness of the decision aid after each consult regardless of whether the mother was successfully enrolled in the study.[27] (5) Both enrolled mothers and clinicians were asked to identify maternal preferences about resuscitation before and after counseling. (6) Enrolled mothers were given the opportunity to provide additional free-text responses about their counseling experience.

Clinicians in the intervention arm reported whether they had used the decision aid as instructed during counseling. They also were asked to document the amount of time spent on a consult. Mothers were also administered the Newest Vital Sign Instrument. This widely used validated tool assesses health literacy, where a score ≥4 (of 6) indicates adequate health literacy.[28]

We hypothesized that parents who received standardized data on short- and long-term sequelae of extreme prematurity with a validated prenatal decision aid would have lower decisional conflict compared with parents who received current routine counseling.

Sample Size and Data Analysis

In the absence of previous studies, we estimated the effect of a neonatal decision aid on decisional conflict. In adult medicine studies, the decisional conflict scale discriminates between different interventions with an effect size of 0.2-1.2 for the total scale.[29] O'Connor recommend basing sample sizes on detecting a minimal clinically relevant effect size of 0.3-0.4.[29] Using an effect size of 0.4, for a 2-sided alpha of 0.05 and power of 80%, 96 mothers were needed per group. We compared the observed primary outcome rates between groups using a hierarchical linear model. This model took into account the number of consults that each counselor contributed to the total. An a priori subgroup analysis of parents who were counseled at 23 and 24 completed weeks of gestation also was conducted. Data were analyzed on the basis of intention to treat. A P value $< .05$ was considered significant. Qualitative thematic analysis of maternal free-text responses identified items valued for decision-making about delivery room resuscitation. Line-by-line coding of the comments was performed by 2 independent investigators, who agreed on each step of the analysis using an iterative process. Identified items were subsequently grouped into themes; ambiguities and inconsistencies were resolved through discussion with other team members.

Results

Figure 2 shows the flow of participants through the study. Of the 92 clinicians randomized, 12 in the routine counseling group and 19 in the decision aid group did not complete any consults in the gestational age window during the study period. Six of the 102 consults of enrolled mothers in the decision aid group were conducted without the use of the decision aid. Reasons given were misplacement (n = 1); clinician did not feel it was clinically appropriate to use (n = 3); or no reason was documented (n = 2). Results for these 6 mothers were included in the decision aid arm for analysis. Of the 316 mothers counseled, pregnancy outcome data were available for 262. One hundred fifty-four of the 262 counseled mothers (58.8%) delivered at ≤25 completed weeks of gestation. Of the 201 mothers enrolled, 52 (52.5%) in the routine counseling arm and 71 (69.6%) in the decision aid arm delivered at ≤25 weeks' gestational age.

There were no significant demographic differences between the 2 parent groups (Table I). The median gestational age of those counseled was 24.1 weeks (IQR 23.7-24.9). Mothers had a health literacy score ≥4 (70.6%),

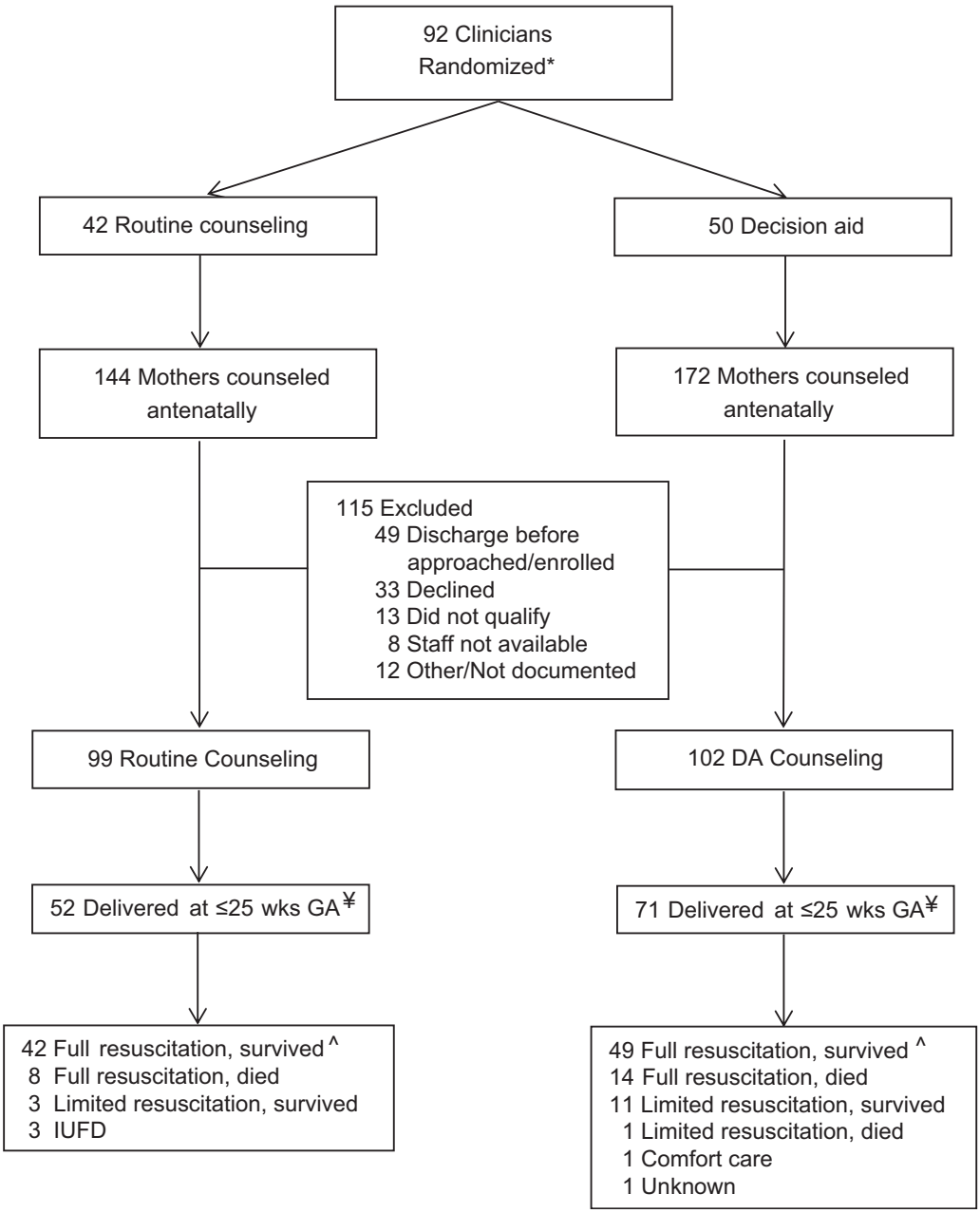

Figure 2. Flow diagram. *Of the 92 clinicians randomized, 12 in the routine counseling and 19 in the decision aid group did not perform any consults during the study. ¥Gestational age at delivery was unknown for 9 mothers in the routine counseling group and 2 mothers in the decision aid group.^Survival defined as survival to hospital discharge. Four sets of twins delivered in the routine counseling group and 1 set of twins, 1 set of triplets, and 1 set of quadruplets were delivered in the decision aid group. *DA*, decision aid; *GA*, gestational age; *IUFD*, intrauterine fetal demise.

indicating a minimum of adequate health literacy. There were no significant differences between the 2 groups of randomized clinicians (**Table I**). Both groups had equal proportions of attending physicians and fellows enrolled. The 9 enrolled neonatal nurse practitioners did not conduct any consults during the conduct of the study.

For the primary outcome, mean decisional conflict scores were low in both the decision aid (n = 96, 16.3 ± 18.2) and routine counseling arms (n = 95, 16.8 ± 17, $P = .97$). There was no significant difference in decisional conflict scores between the 2 groups.

For the secondary outcomes, knowledge scores in the decision aid group (n = 98, 66.2 ± 18.5) were greater compared with the routine counseling group (n = 96, 57.2 ± 18.8, $P = .005$). The mean preparedness for decision-making score was high in both the decision aid (n = 96, 73.4 ± 28.3) and

Table I. Maternal and clinician self-reported demographics

Demographics	Routine counseling N = 99	Decision aid N = 102	*P* value
Maternal			
Age, y ± SD	29.3 ± 5.9	29.5 ± 6.0	.688
Race/ethnicity, n (%)			.416
Black	49 (49.5)	49 (48.0)	
White	38 (38.4)	44 (43.1)	
Hispanic or Latino	7 (7.1)	3 (2.9)	
Asian	0 (0)	2 (2.0)	
Other	5 (5.1)	4 (3.9)	
History of premature delivery: yes, n (%)	30 (30.3)	21 (20.6)	.114
Gestational age at time of counseling, wk			.664
22	8 (8.1)	8 (7.8)	
23	29 (29.3)	31 (30.4)	
24	34 (34.3)	42 (41.2)	
25	27 (27.3)	21 (20.6)	
Marital status, n (%)			.555
Single	34 (34.3)	35 (34.3)	
Living with partner	18 (18.2)	15 (14.7)	
Married	46 (46.5)	48 (47.1)	
Divorced	1 (1.0)	4 (3.9)	
Education, n (%)			.989
Less than high school	8 (8.1)	7 (6.9)	
High school	34 (34.3)	32 (31.4)	
2-y college/technical school	24 (24.2)	26 (25.5)	
4-y college	22 (22.2)	24 (23.5)	
>4-y college/graduate school	11 (11.1)	12 (11.8)	
Adequate health literacy, n (%)	65 (65.7)	77 (75.5)	.126
Clinician	n = 42	n = 50	
Age,*y ± SD	41.4 ± 11.6	37.5 ± 10.4	.061
Female, n (%)	30 (71.4)	33 (66.0)	.532
Race/ethnicity,*n (%)			.88
White	29 (69.0)	32 (64)	
Black	1 (2.4)	1 (2)	
Hispanic or Latino	1 (2.4)	2 (4)	
Asian	4 (9.5)	7 (14)	
Other	2 (4.8)	1 (2)	
Marital status,*n (%)			.142
Single	4 (9.5)	11 (22)	
Married	33 (78.6)	31 (62)	
Divorced		1 (2)	
Position,*n (%)			.542
NICU Attending	15 (35.7)	14 (28)	
NICU Fellow	17 (40.5)	25 (50)	
NNP/PA	5 (11.9)	4 (8)	
Years of experience,†n (%)	16.7 ± 10.9	12.7 ± 9.1	.278

NICU, neonatal intensive care unit; *NNP*, neonatal nurse practitioner; *PA*, physician assistant.
*Missing data for n = 5 in routine and n = 7 in decision aid groups.
†Years of experience for attending neonatologists and NNP/PAs.

the routine counseling arms (n = 95, 70.5 ± 31.1, $P = .33$). Mothers in both groups felt the amount of information they received was just right and found the information easy to understand (**Table II**; available at www.jpeds.com). Mothers in both groups understood most or all of the information they received, and for a majority, the information they received was new. Clinicians in the decision aid group counseled a total of 172 women with the decision aid, including women who were not enrolled in the study. For these, there were 137 (79.7%) clinician acceptability surveys completed. Most clinicians in the decision aid group thought the decision aid was of use to patients (**Table III**; available at www.jpeds.com). The perceived benefits ranged from understanding the risks associated with prematurity, allowing more involvement in decision-making and making a more informed decision, and improvement in the way time was spent during the consult. A majority of clinicians in the decision aid group felt the decision aid was easy to use, easy to understand, and compatible with how counseling should be done. Clinicians did not think using the decision aid would save them time. This was corroborated by the average times spent counseling, which with the decision aid was 36.9 ± 13.8 minutes as compared with 32.1 ± 12.2 minutes for counselors in the control arm of the study ($P = .003$).

For the subgroup analysis of parents (decision aid, n = 73; routine counseling, n = 63) who were counseled at 23 and 24 completed weeks of gestation, results were similar to the overall study results. Decisional conflict scores were low in both groups (decision aid: 15.9 ± 15.6 vs routine: 13.4 ± 15.6, $P = .26$). Knowledge scores were significantly greater in the decision aid group compared with the routine counseling group (64.8 ± 19.2 vs 57.2 ± 17.7, $P = .02$). Preparedness for decision-making scores were high in both groups (decision aid: 73.9 ± 27.1 vs routine: 70.0 ± 31.0, $P = .39$).

We investigated whether clinicians accurately identified maternal preferences for resuscitation before and after counseling. In total, 127 of 198 (64%) enrolled mothers stated they had already formed a preference regarding resuscitation before counseling; of these, 110 (86.6%) wanted full resuscitation. Clinicians stated that 78 of 184 (42%) enrolled mothers had a precounseling preference regarding resuscitation. Of these, they thought 73 (94%) wanted full resuscitation. Of the 127 mothers who confirmed they had a precounseling preference regarding resuscitation, clinicians misidentified 72 of them (56.7%) as not having a preference. Postcounseling, 167 of 201 enrolled mothers (83%) stated they wanted full resuscitation—almost unchanged to their precounseling preferences. Clinicians stated that 132 of 201 enrolled mothers (65.7%) wanted full resuscitation. Of the 167 mothers who wanted full resuscitation, clinicians misidentified 54 (32%) as undecided or preferring comfort care or limited intervention.

Of 201 enrolled mothers, 136 provided free-text comments: 79 in the decision aid group and 57 in the routine counseling group. Three major themes emerged (**Table IV**). First, some mothers expressed a desire for a tailored approach to antenatal consultation. Second, the theme of clinician sensitivity addressed the importance of giving parents hope, thoughtful timing of consultation, and recognition/support of parents' emotional state. Last, the theme of shared decision-making included the importance of trust, failure to present options, problems with parent engagement, and values mismatch. Seventy-nine of 102 parents who received counseling with the decision aid provided additional free-text comments about the decision aid itself. Seventy-three found the visual depiction of the information helpful and 24 specifically commented on the benefit of providing a visual

Table IV. Items valued by parents in antenatal consultation identified in free-text comments

Theme/subthemes	Study arm	Parent free-text
Tailored information		
Right amount	Standard counseling	"I scheduled a tour of this hospital because I am dealing for the first time with the possibilities of having a severely premature infant. The staff provided me with detailed information regarding the risks, medical interventions that could/could not be provided at the various gestational stages for me to make a decision as to the level of care I would like to receive for my child. I am very pleased with the knowledge and information that has been provided, that has assisted me in making an informed decision."
Too much/confusing	Standard counseling	"All of the information was very informative, but particularly for me, comparison to something a little more understandable would've been helpful."
Too little	Decision aid	"It might have been useful to me to have seen some stats for older premature babies (26-28 wk, 29-32 wk, etc) since it is unknown when I'll actually deliver. Otherwise, the NICU doctor did a great job explaining all of the process and answering my questions."
Different focus	Decision aid	"The info presented in the [Decision Aid] were mostly geared to woman that had ruptured membranes at about 24 weeks of gestation. My situation is extremely different because my water broke at 16 weeks. I would like to see visuals that are more befitting to my unique situation."
Clinician sensitivity		
Good hope/comfort/optimism	Decision aid	"I liked the [Decision Aid] cards. It gives you hope. I really appreciate that. I know if one week passes, another week, my chances are better. The cards stick in mind. When it's just talking it doesn't make sense. It's not just something coming out of her head. She really knows the information."
Poor hope/comfort/optimism	Standard counseling	"I would only suggest that although it's about the baby, to try to take the mom's feelings into consideration just a little more. I felt like my feedback was all negative without any reassurance of something positive:(still loved him though!)"
Timing of consultation	Decision aid	"I was VERY upset when the NICU [Physician Assistant] came to Labor & Delivery when I first arrived. It's the WRONG time. At least give the nurses time to get the patient situated especially if contractions have died down, before hurling words at them like 'resuscitation' and 'decision making'. That was the worst possible time to discuss that."
Recognition/support of parent emotions	Standard counseling	"I suggest that there be a support person present to assist the patient with emotional support and the partner is not available. Counseling services should be made available so patients can express their emotional concerns after dealing with the medical pros and cons."
Shared decision-making		
Presentation of options	Standard counseling	"For me, the downplay of the extreme negative effect was helpful. I was stressed out enough and knowing there some hope got me through. I would have appreciated a bit more info on the fact there was an option of care. I did not realize there were levels of choice—comfort measures vs full revival, etc, when discussing. I thought it was more the doctors would automatically do whatever they could to keep the baby alive and if something changed, we would make the decision at that time."
Parent engagement	Standard counseling	"Engage with the parent how much they want to know. Personally, I agreed out of fear and didn't say anything."
Values mismatch	Standard counseling	"On our first visit before the cerclage the first option presented was about terminating the pregnancy. I don't feel, emotionally, that was beneficial to our decision. It was more of a knife being turned as opposed to helping us realize the gravity of the situation."
Trust/honesty	Decision aid	"There is no ideal easy time. Sitting close, eye contact, honesty, and urgency. I love the way it happened."

representation of statistical information; one found it more confusing. A few mothers (n = 7) did not find the decision aid beneficial, and 2 reported negative perceptions. Mothers in both groups noted the importance of engaging diverse learning styles; and many commented on the benefit of using a visual aid or handout.

Discussion

This randomized controlled trial of a previously validated decision aid for resuscitation decisions at the margin of gestational viability systematically evaluated the effects of a decision aid on parental decision conflict and knowledge, as well as mothers' attitudes about counseling and preparedness for decision making. Although the decision aid did not significantly impact our primary outcome of decisional conflict, it improved knowledge scores. A majority of mothers in this cohort had already come to a decision about resuscitation before counseling. Clinicians were unable to consistently identify which mothers had already made resuscitation decisions. Finally, mothers in the decision aid group found the visual representation of information useful, but mothers in both groups desired a tailored approach to counseling and recognition of their emotional needs.

We hypothesized that the decision aid would reduce maternal decisional conflict and improve preparedness for decision-making at the margin of gestational viability, but we found no improvements in either, whether for the whole cohort or in a subgroup analysis. In both the decision aid group and the routine counseling groups, decisional conflict was low and preparedness for decision-making was high. Our hypothesis stemmed from literature on the impact of decisions aids in randomized trials in other clinical settings, such as women facing cancer treatment options and patients with chest pain presenting to the emergency department. In these patients, lower rates of decisional conflict were found in groups counseled with decision aids as compared with usual counseling.[24] Only limited data exist on decisional conflict in parents facing extreme prematurity. In a small group of parents (n = 20), Moore et al found an elevated median decisional conflict score of 50 (IQR 32-70) before antenatal counseling at 23 weeks of gestation.[30] The majority of parents in that cohort were female (55%), married (60%), and well educated (60%). Following counseling with a decision aid,

the median decisional conflict score decreased to 0 (IQR 0-18). However, they did not have a control group for comparison.

There are a number of potential explanations for our findings. It is likely that our results were impacted by the demographics of the women enrolled. Lower health literacy may affect patients' decision-making abilities. A systematic review of patient decision aid trials showed that lower health literacy was associated with lower patient health knowledge and greater decision uncertainty and regret.[31] In this study, a majority of the mothers enrolled were well educated and health literate. Moreover, a majority of these mothers had already formed precounseling preferences regarding resuscitation. There is evidence that individuals bring well-articulated preferences regarding resuscitation to decision-making.[32] Because many mothers in our study had already formed clear preferences, it is possible that they had low decisional conflict before randomization. Alternatively, it is possible that many of these mothers, free of labor, never perceived themselves at risk for premature delivery. Approximately 43% of mothers who were not enrolled were missed because they were discharged free of labor, before they could be approached for enrollment. In addition, 39% of the mothers enrolled did not proceed to deliver at ≤25 completed weeks of gestation. In settings such as oncology, decision aids help patients decide between interventions that are definitely indicated. However, mothers in our study were not certain that a premature delivery would occur. It is possible that even mothers who ultimately delivered at ≤25 completed weeks of gestation remained hopeful during counseling that delivery would not occur and therefore did not have decisional conflict.

Nonetheless, the decision aid did significantly improve maternal knowledge scores compared with the control group. In other clinical settings ranging from parents facing decisions about prenatal screening to patients with cancer facing different medical and surgical treatment options, randomized studies show that decision aids consistently improve knowledge and accuracy of risk perceptions.[33-42] There was no correlation between improved knowledge scores and decisional conflict. Potentially, the construct of decisional conflict is distinct from knowledge, and changes in one may not influence the other.

Mothers and clinicians in the decision aid arm of the study had positive feelings about the decision aid. Similarly, studies evaluating the use of a decision aid for different cancer screening and treatment found that patients counseled with a decision aid felt more satisfied with their decision and the decision-making process as compared with routine counseling.[43,44] Among clinicians, favorable attitudes toward the decision aid point to a subjective sense by antenatal counselors that a structured approach to counseling such as one using a decision aid is better than unstructured routine counseling for margin-of-viability decision making. It may also suggest clinicians' perceptions of their own limitations to effectively convey complex information, elicit values, or support decision-making without the benefit of a decision aid. We demonstrated high preparedness for decision-making in most participants, which may indicate adequate counseling by clinicians in both groups. We did not evaluate potential differences in clinicians' perceptions of the decision aid by age or years of experience. It is possible that the overall positive acceptance of the decision aid is driven by younger, more inexperienced clinicians.

The themes we identified in mothers' comments agree with previous studies and further inform how clinicians should approach the antenatal consultation encounter.[1,10,12,16,22] In this study, many mothers in the decision aid arm found graphic outcome statistics understandable, and many in routine counseling suggested a visual aid would have helped them. This supports that clinicians should explore parents' desire for information and tailor counseling to parental needs.[5] For some parents, shared decision-making involves personalized information including amount and type and not just an enumeration of risks.[15] A systematic review of parent communication needs suggests that the quality of the consult when facing extreme prematurity is not solely data driven but is also dependent on the way in which it is provided.[16] In this study, mothers noted other aspects of the consultation influential to their experiences, suggesting that clinicians should individualize counseling regarding timing, support for parent emotions, and provision of hope. Likewise, many opportunities to improve parents' participation in shared decision-making were identified, including clearer communication of the decision and options, parent engagement, and elicitation of values.

Clinicians failed to consistently identify both whether mothers had predetermined preferences about resuscitation, and the nature of those preferences. Zupancic et al described this malalignment: clinicians could not accurately identify the 45% of parents who felt strongly about their decision-making autonomy.[45] We found 64% of mothers had precounseling preferences, where counseling supplemented by a decision aid may not have been useful. Some clinicians argue that neonatologists should first actively treat and only then seek consent to withdraw in adverse conditions.[46,47] However, this does not account for the parents who ultimately decide to forgo resuscitative efforts—an equally acceptable parental value and preference. For the 36% of mothers in this study who had no pre-formed preference, the antenatal consult is potentially beneficial. And, counseling supplemented with a decision aid, tailored to the informational needs of the mother could be helpful. Default intervention does not leave room for shared decision-making and parental autonomy. Misunderstanding mothers' expectations about goals of consultation (anticipatory guidance vs decision-making) may contribute to patient dissatisfaction and vital miscommunication about resuscitation plans.

We acknowledge limitations. First, decisional conflict was not measured before the counseling session. This was to avoid adversely influencing mothers' perceptions during counseling. Second, clinicians within each site were randomized to minimize potential bias from variation of patient

populations by site. However, contamination of counseling methods was possible because those randomized to routine counseling may have become aware of the decision aid. This may have affected their approach to counseling. Third, we did not assess clinicians' perceptions about resuscitation and counseling at the limits of gestational viability. Religious and cultural differences may influence clinician/patient interactions.[48-50] Clinicians navigate between what is best for an infant and what is best for a family, and their feelings about either.[46,51] We did not ask participating clinicians or parents to identify their religious or spiritual preferences. As discussed previously, some physicians believe that proactive perinatal management should be the standard of care for all extreme premature deliveries.[47] It is possible that clinicians' own biases may have influenced their counseling, thereby influencing mothers' perceptions and decisions. Finally, clinicians in this study may have had a strong interest in periviability counseling, which led to their participation in this study and overall good communication with mothers in both groups. Nonetheless, we demonstrate that a practical and inexpensive tool to support the counselor in providing individualized antenatal counseling at the margin of gestational viability improves maternal knowledge and is acceptable to clinicians and patients. Although a majority of mothers had already come to a decision about resuscitation before counseling, for those mothers who have not decided, counseling supplemented by a decision aid may be useful. The decision aid provides a way to present accurate and consistent information, facilitates a dialogue between mothers and clinicians to elicit mothers' values, and is a step toward a shared process of decision-making. ■

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Table II. Maternal acceptability survey responses

Responses	Routine counseling n = 96	Decision aid n = 94
Describe the amount of information you received: (just right)	76 (79.2)	80 (85.1)
The way in which the information was presented was too complicated (disagree/strongly disagree)	78 (81.2)	70 (74.5)
How easy was the information to understand? (moderately/very easy)	70 (72.9)	80 (85.1)
How much of the information did you understand? (most/all)	87 (90.6)	89 (94.7)
How much of the information was new to you?	56 (58.3)	55 (58.5)

Values are noted as n (%).

Table III. Clinician acceptability survey responses for all mothers counseled with the decision aid, n = 137

To what extent did the decision aid:	Quite a bit/a great deal n (%)
Help your patient understand the risks associated with extreme prematurity?	97 (70.8)
Help your patient be as involved in the decision-making process as she desired?	85 (62)
Help your patient make a more informed decision?	83 (60.6)
Help you to more fully understand the issues that are most important to your patient?	59 (43)
Help you tailor your counseling to your patient's preference for decision participation?	65 (47.4)
Improve the way time was spent during the consultation?	90 (65.7)
Please show your opinion of the decision aid:	**Agree/strongly agree**
The cards were easy for me to use	115 (83.9)
The cards were easy for me to understand	135 (98.5)
It will be easy for me to experiment with using the cards	123 (89.8)
The results of using the cards will be easy to see	71 (51.8)
Using the cards is better than how I usually go about helping patients decide their options	97 (70.8)
This counseling strategy is compatible with the way I think things should be done	121 (88.3)
Compared with my usual approach the cards will result in my patients making more informed decisions	101 (73.7)
Using the cards will save me time	65 (47.4)
The cards are a reliable method of helping patients make decisions about extreme prematurity	108 (78.8)
Pieces or components of the cards can be used by themselves	135 (98.5)
This type of counseling strategy is suitable for helping patients make value-laden choices	123 (89.8)
This counseling strategy complements my usual approach	125 (91.2)
Using the cards does not involve making major changes to the way I usually do things	108 (78.8)
There is a high probability that using this strategy may cause/result in more benefit than harm	111 (81)

Values are noted as n (%).
Total number of mothers counseled with decision aid by clinicians, n = 172. Data missing, n = 35.