Development and Pretesting of a Decision-Aid to Use When Counseling Parents Facing Imminent Extreme Premature Delivery

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Objective To develop and pretest a decision-aid to help parents facing extreme premature delivery during antenatal counseling regarding delivery room resuscitation.

Study design Semistructured interviews with 31 clinicians and with 30 parents of children born <26 weeks' gestation were conducted following standard methods of qualitative research. These characterized perceptions of prenatal counseling to identify information that parents value when making decisions regarding delivery room resuscitation. These parental needs were formatted into a decision-aid. We assessed the primary outcome of how effectively the decision-aid improved knowledge during a simulated counseling session. Two groups of women were studied: parents with a history of prematurity ("experienced") and healthy women without prior knowledge of prematurity ("naïve").

Results Interviewees thought that visual formats to present survival and short- and long-term outcome information facilitated their own preparation, recall, and understanding. Accordingly, we designed a decision-aid as a set of cards with pictures and pictographs to show survival rates and complications. There was significant improvement in knowledge in 13 "experienced" parents ($P = .04$) and 11 "naïve" women ($P < .0001$). Participants found the cards useful and easy to understand.

Conclusions A decision-aid for parents facing extreme premature delivery may improve their understanding of complicated information during antenatal counseling. *(J Pediatr 2012;160:382-7)*.

There is an increasing emphasis on involving patients in treatment decision-making. One consistent theme in the statements of professional societies (eg, the Committee on the Fetus and Newborn of the American Academy of Pediatrics and the Canadian Pediatric Society's Fetus and Newborn Committee) is an emphasis on informed decision making at the limits of neonatal viability and respect for parents' individual preferences.[1-3] However, how to meaningfully implement such policies for individual parents remains unclear. Studies report that parents feel they provide little input in making decisions at delivery and disagree with clinicians' views that parents had given input.[4-6] Moreover, parents and clinicians disagree when asked to recall the actual content of discussions during counseling for extremely low birth weight delivery.[5,7] Finally, studies show physicians are poor judges of parental preferences.[7]

Better ways to communicate complex information to parents facing extreme premature delivery are needed. The Committee on the Fetus and Newborn emphasizes a need for consistency when counseling parents about decision-making.[1] Attempts to create general guidelines for physicians and to simplify parental information suggest that parents view these as useful.[8-10] Decision-aids explain options, quantify potential risks and benefits, and provide structured guidance in deliberation and communication.[11] Benefits of decision-aids include: improved patient knowledge, enhanced active participation in decision-making, and improved agreement between patients' preferences and subsequent treatment decisions.[11-17] Such transparent decision-aids for parents facing delivery of extremely low birth weight infants are not yet available. We aimed to characterize clinicians' experiences with parents of extremely premature infants and the perceptions of parents during antenatal counseling. We then used these results to inform the development and evaluation of a decision-aid for parents facing extreme premature delivery. We hypothesized that participants in a simulated counseling session on the risks of extreme premature delivery would improve their knowledge when using the decision-aid, in inverse proportion to their baseline understanding.

Methods

We followed standard qualitative methods to identify items perceived beneficial to parents to devise a new decision-aid.[18,19] Institutional review board approval at each participating site was obtained.

BPD	Bronchopulmonary dysplasia
IVH	Intraventricular hemorrhage
NDI	Neurodevelopmental impairment
NICU	Neonatal intensive care unit
ROP	Retinopathy of prematurity

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Step 1: Identifying Items for Decision-Aid

Interviews by 1 of 2 trained interviewers (U.G. and S.S.) generated potential items of relevance to counseling. Participants (multidisciplinary clinicians and parents) were recruited between September 2009 and February 2010. A semistructured interview guide was designed for each set of interviews after a review of the literature.[5,20-22] A group of parents (n = 5) and multidisciplinary health care providers (n = 5) assessed face and content validity for interview guides. Clinicians at 3 urban tertiary care hospitals in Philadelphia were asked to attend either a focus group or individual interviews. Clinicians were neonatologists, neonatal fellows, neonatal nurses, and maternal-fetal medicine specialists. Nurses and fellows were interviewed in focus groups of 3 to 5 people. Clinicians were asked to discuss how and what should be discussed during counseling at the limits of viability, and the detail that should be provided.

Parents of infants born before 26 weeks' gestation attending high risk follow-up clinics in Philadelphia were approached for consent. Parents were asked to recall details on their counseling prior to delivery, including how information was presented and how it could have been better.

Interviews were face-to-face and were audio-recorded and transcribed for analysis. Data collection was planned to continue until "saturation," at which no new "statements" or "items" of importance were raised.[18] Transcribed interviews were described first as verbatim "statements" which were then formed into more abstract "items" on the basis of content. Similar "items" were organized into "themes." Two independent reviewers agreed each step using an iterative process, as previously described.[20] Saturation of items was reached after 31 clinician interviews and after 30 parent interviews.

Step 2: Development of the Decision-Aid

Identification of themes identified the issues to be addressed by the decision-aid. Previously reported decision-aids served as prototypes,[17,23,24] which were modified by iterations with a review group (n = 4, 3 neonatologists and 1 social worker). Issues reviewed included format and content.

Step 3: Assessing Usefulness of the Decision-Aid

We next assessed usefulness by conducting a simulated counseling session. The primary outcome was a knowledge assessment. Two groups were recruited: an "experienced" group of parents of infants who had delivered extremely premature and a second group termed "naïve," who were healthy, nonpregnant women, aged 18-35 with no prior history of premature delivery. Subjects were recruited from a high risk follow-up clinic and a women's center at the Hospital of the University of Pennsylvania. Women were approached for consent upon arrival to their clinic appointment. Participants were asked to participate in a simulated counseling session using the decision-aid, from the vantage point of a woman at 24 weeks' gestation and in active labor. They completed a 12-question test to assess their knowledge before and after counseling. In addition, they were asked to evaluate the decision-aid using a 5-question survey and free comments at the end of counseling.

Data Analysis

Because no prior data exist in this population using such a decision-aid, we extrapolated using data from other trials of decision-aids. We assumed a clinically relevant change in knowledge would be at least 30%. We required 10 participants in each group ("naïve" and "experienced") for a power of 90% and an alpha of .05.

The Student *t*-test was used to analyze precounseling and postcounseling test data. Analyses were completed using STATA/IC 10.0 software (Stata Corp, College Station, Texas). $P < .05$ was considered statistically significant.

Results

Step 1: Identifying Items for Decision-Aid

Clinicians. Thirty-one clinicians were interviewed to saturation point: 11 neonatologists, 8 neonatal fellows, 10 neonatal nurses, and 2 maternal-fetal medicine specialists (Table I). These yielded 677 independent statements, which were reduced to 44 unique items. Items probing similar constructs were grouped into 4 themes: communication of information (n = 8 items), framing of information (n = 11 items), factors affecting communication (n = 18 items), and perceptions (n = 7 items). Twenty-four (77%) clinicians thought a visual aid, in the form of a pamphlet, picture, or film, would facilitate counseling and prepare and inform parents. Seventeen of the 21 physicians (81%) thought that exact statistics about survival and outcome should not be used when counseling, though they often used words such as "many" or "about a half," to quantify risk. On the other hand, 80% of nurses thought that most parents want to and should receive statistics. Clinicians thought parents need to hear information on survival, short-term morbidities, and how these morbidities affect long-term outcomes.

Parents. In total, 30 parents were interviewed before saturation of themes was reached (Table II). We identified 689 independent statements pertaining directly to antenatal counseling, decision-making and experiences in the neonatal intensive care unit (NICU). These statements were reduced to 26 unique items. Items were grouped into 7 distinct themes: communication of information to make decisions (n = 5 items), preparation for the NICU (n = 3 items), framing of information (n = 6 items), trust (n = 1 item), factors affecting processing ability (n = 5 items), factors affecting coping ability (n = 3 items), and perceptions (n = 3 items). Of these 7 themes, the first 2 contained concrete information for the development of the decision-aid. Regarding communication of information to make decisions, 17 (57%) of 30 parents would have preferred to receive information in a visual format (pictures, film, written handout). However, 2 (7%) of 30 parents worried that visual images could cause increased stress. Eighteen parents discussed their preference for exact statistics versus generalities about outcomes. Thirteen (72%) of 18 parents wanted to know exact statistics. Ten