Study Protocol: Decision Making Support for Parents and Caregivers

Study Site:
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Study Title: Decision Making Support for Parents and Caregivers

Short Title: Decision Making Support

Study Objective.

To determine the feasibility and acceptability of a tool to support decision making for parents of critically ill children.

Study Overview.

The feasibility study will use a single-arm design. All critically ill infants for whom a serious decision is anticipated will be screened for enrollment. We will enroll up to 40 infants, their parent(s), and their clinician(s). A study team member will deliver the tool, discuss its use with parents, and answer parent questions as they arise. We will survey parents at baseline. Parents and clinicians will be surveyed and interviewed after utilizing the tool.

Measures.

Prior to implementation of this decision aid in a prospective randomized trial, we must first determine whether 1) study procedures are feasible and 2) the intervention is acceptable to parents and clinicians.

Feasibility will be defined as 1) enrollment rate of ≥ 50% and 2) complete data collection rate of ≥ 80%. Parent and clinician acceptability will be measured using self-report survey measures, adapted from prior work. Additional outcomes will include preparation for decision making, parent decisional conflict, regret, and satisfaction, perception of feeling heard and understood, and psychological distress. Preparation for decision making will be measured using the PrepDM. Decisional conflict and regret will be measured by the Decisional Conflict Scale (DCS) and the Decisional Regret Scale (DRS); perception of feeling heard and understood will be measured by the Feeling Heard and Understood Scale (FHAU); parent psychological distress will be measured using PROMIS-29.

Data collection.

The infant's chart will be reviewed and relevant data extracted. We will also document recruitment feasibility data. Parent baseline surveys will include demographic information and measures of psychological distress. Post-intervention surveys will be given to parents and clinicians following use of the tool. Clinician surveys will include measures of decision aid acceptability. Parent surveys will include measures of decision aid acceptability, decisional satisfaction, conflict and regret, perception of feeling heard and understood, preparation for decision making, and psychological distress.

Parents and clinicians will be invited to complete semi-structured interviews, with content targeting acceptability of the decision aid. Survey data will be collected and stored via REDCap. Qualitative data will be analyzed using NVIVO.

Study participants.

Study participants will include infants, parents, and clinicians. Study team members will screen unit lists for potential eligible patients.

Infant inclusion criteria will include 1) age < 1 year, 2) admission to a critical care unit, and 3) an anticipated serious health care decision, defined as 1) a decision about

initiating, not initiating, or withdrawing life sustaining treatment or chronic life-sustaining treatment (e.g. tracheostomy) and/or 2) a decision about major surgery and/or medical therapy.

All parents of eligible infants will be considered for inclusion. Parent exclusion criteria will include 1) age < 18 years, 2) hearing or speech impairment, and 3) non-English speakers.

All clinicians of eligible infants will be considered for inclusion.

Subject Recruitment and Compensation.

We anticipate up to 40 infants, 60 parents, and 40 clinicians will be enrolled in this study.

Patients and parents: We will recruit from the Duke Intensive Care Nursery, Pediatric Intensive Care Unit, and Pediatric Cardiac Intensive Care Unit.

A study team member will communicate with the unit about 1) eligible patients and 2) approaching the family about their willingness to speak with research staff about the study. A waiver of HIPPA authorization has been requested to allow identification of prospective participants. A member of the study team will approach eligible families to introduce the study to the family. For infants enrolled, parents will be compensated $100 for completion of all study procedures. Clinicians will be compensated $50 for completion of all study procedures.

Study Intervention.

The intervention includes a paper-based decision support tool. This decision guide includes content related to decisional awareness, values clarification, and a series of question prompts. This intervention will be introduced to participants by a study team member, who will remain available with parents as they review and complete the tool. The tool asks parents to consider which values matter most to them and to identify questions they would like to ask the clinical team. Following completion of the tool, a study team member will ask parents if they would like their answers shared with their clinical team. If the parent would like to share their responses, the study team member will share a copy of parent responses with clinicians caring for the patient and their family.

Risk-benefit assessment

Benefits. There will be no direct benefits to the participants in the study. The potential benefit to future parents and clinicians is substantial because of the potential for this study to lead to the development of interventions to improve shared decision making for infants and children with life-threatening conditions. Therefore, the risks of this study, which we anticipate to be minimal, are reasonable in relation to its anticipated benefits.

Adverse events. The principal investigator or the clinical study staff will record and follow all adverse events that occur. Data describing adverse events will be collected and reported to the IRB.

Confidentiality and data security. We believe this study poses minimal risks to participants. See additional sections for procedural information concerning data storage, privacy, confidentiality, and safety monitoring.

Parent distress. It is possible that intervention delivery or study procedures, including participant interviews, could increase parent distress. Previous research has shown that

interviews do not increase grief, and that families are glad to have participated in studies involving interviews about highly emotional topics. We will use several strategies to minimize the possibility of increasing distress, including 1) keeping the interview flexible so that when emotional responses such as anger or crying occur, the interviewer may offer rest breaks and direct the interview in and out of the sensitive area, and 2) providing immediate therapeutic intervention when needed. A study team member with interview experience or the study PI will perform the interviews. Should a parent become upset during an interview or survey completion, the study team member collecting the data will allow the parent to stop and encourage them to talk about their feelings. If a parent remains upset, the research staff member will stay with the parent and help them to contact the social worker or a community mental health professional about their concerns. As part of routine clinical care, a social worker is assigned to each patient and family. After each parent interview, parents will be reminded that if they have concerns they wish to discuss, they can contact their social worker, hospital chaplain or personal clergy, or community mental health professional. The parents will be given information on how to contact other resources if necessary or, if they prefer, the research staff will contact a professional for them. For concerns or questions about the study, parents will be given phone numbers for the investigators.

Parent burden. We anticipate that tool completion will require 15-20 minutes of participant time. Parent interviews are expected to last approximately 30-45 minutes. Clinician interviews are expected to last approximately 15 - 30 minutes. This time commitment may be a burden for some participants.

Data and safety monitoring

We believe this study will infer minimal risk to participants. Interval data analysis will be performed midway through study completion. Data monitoring, including ensuring audio-recordings are transcribed in a timely manner, will be confirmed monthly by the principal investigator and/or study coordinator. For the audio recordings, we will use a Duke-approved transcription service. For the purposes of our study, “de-identification” will involve the removal of all identifiers outlined by the HIPAA privacy rule. Qualitative software will be used to analyze de-identified transcripts.

Analysis files will be permanently stored on the Duke Server. During the analysis phase, de-identified analysis files may additionally be stored on Duke Box or a Duke University or Duke Health System computer, and uploaded to the Duke server daily.

Consent process.

The consent process will be completed by the principal investigator, clinical research coordinator, or clinical research specialist on the study team. There is no time limit to the consent discussion. We are open to answering any potential questions that may arise when we present the study information to parents or clinicians.

The consent process will occur in the Neonatal Intensive Care Unit, the Pediatric Intensive Care Unit, or the Pediatric Cardiac Intensive Care Unit. The parent/legal guardian may be consented over the phone or by using an e-consent. The phone consent process will take place in those situations where attempts to find families in the neonatal intensive care unit have failed. With the use of phone consent or an e-consent all efforts will be made to provide a copy of the consent to parents either by fax or email before reading the consent. A telephone script will be used to introduce the study and then the consent form will be read to the parent or sent via email as an e-consent.

To mitigate the risk of loss of confidentiality, all patient and clinician data will be fully de-identified, with a participant ID number assigned in the place of any identifiers. This ID number will be linked to identifying information only in a secure, separate file for the duration of the study period and analysis, to allow follow-up clinical information to be collected as needed.

Participants can contact the PI or members of the study team with any questions that arise. In addition, given that this study has multiple points of contact, participants will have additional opportunities to raise questions throughout the study period.

We will maintain a high level of sensitivity to passive refusal, so prospective participants who do not show active interest will not be enrolled in the study.

Privacy and confidentiality.

All patient and physician data will be de-identified, with a participant ID number assigned in the place of any identifiers. This ID number will be linked to identifying information only in a secure, separate file for the duration of the study period and analysis, to allow follow-up clinical information to be collected as needed. All recordings will be transcribed and de-identified.

Audio-recordings, transcriptions, and other data will be securely stored on a Duke server accessible to the research team. Audio recordings will be reviewed by a Duke-approved transcription service to de-identify audio recordings. Paper documents will be kept in a locked cabinet in an access controlled area.