
Title	Decision Making Support for Parents and Caregivers
IRB Number	Pro00111995
CRU/Department/Division/Center	Department of Pediatrics
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1. Study Overview

Background/Introduction

The study is a single arm intervention trial for assessing the feasibility and acceptability a decision guide for parents of critically ill infants.

Study Objectives, Aims, and Hypotheses

Primary/ Secondary Outcomes	Aim/Objective	Hypothesis
Primary	Compute enrollment rate.	We expect the proportion of enrolled infants to be at least 50%.
Primary	Compute complete data collection rate.	We expect the proportion of enrolled families with data collected to be at least 80%.
Secondary	Describe decision aid acceptability, stratified by parent and clinician.	Descriptive objective, no hypothesis testing
Secondary	Describe pre- and post- parent psychological distress, stratified by parent.	Descriptive objective, no hypothesis testing
Secondary	Describe pre- and post- decision (as appropriate) outcomes, stratified by parent.	Descriptive objective, no hypothesis testing
Sample description	Describe infant characteristics, parent demographics, and clinician demographics.	Descriptive objective, no hypothesis testing

2. Study Population and Data Source

Study Design

- Single arm design, study team will deliver a tool to be used by parent(s) to help guide them in decision making
- Tool includes a brief introduction to the tool and decision-making, a values clarification exercise, and a question prompt list
- Study will include: critically ill infants, their parent(s), and clinicians

Inclusion Criteria

- Infant inclusion criteria will include
 1. Age < 1 year
 2. Admission to a critical care unit
 3. Anticipated major decision

Exclusion Criteria

- Parent exclusion criteria will include 1) age < 18 years, 2) hearing or speech impairment, and 3) non-English speakers.

Data Acquisition

- Data source: REDCap
- REDCap project name and ID: Decision Making PID 14854

3. Outcomes, Exposures, and Additional Variables of Interest

Outcomes

Outcome	Definition/Descriptions	Variables and Source
Enrollment rate	Percentage of eligible infants enrolled.	screening log
Complete data collection rate	Complete data collection defined as all eligible infant, parent, and clinician data points collected for a given case; data points for which the participant withdrew prior to relevant data collection excluded	data collection log
PrepDM score	The preparation for decision making (PrepDM) scale evaluates parents' perceptions of how useful the decision aid was in preparing them to communicate with their child's health care team and make a decision. The 10-item survey uses a 5-point Likert scale. In accordance with the user manual and other studies, we will convert item responses to integers from 1 to 5, calculate the average, subtract 1 from average, and multiply by 25 to give a final score from 0 to 100. Higher scores indicate a higher perceived level of preparation for decision making.	prepdmscore (to be derived) <i>Components:</i> decision_present, decision_prep, consider_pros_cons, importance_pros_cons, depends_values, organize_thoughts, decision_involvement, questions_to_ask, discuss_values, prep_future_convos

Found this decision guide to be helpful		guide_helpful
would recommend this decision guide to other parents making decisions about their child's health care		rec_to_parents
would use this decision guide again if I need to make future decisions about my child's health care		would_use_again
Promis t-score	We will measure scores for the following PROMIS domains: Short Form v2.0 Physical Function 4a, Short Form v1.0 Emotional Distress - Anxiety 8a, Short Form v1.0 Emotional Distress - Depression 8a, Short Form v1.0 Fatigue 4a, Short Form v1.0 Sleep Disturbance 4a, Short Form v2.0 Ability to Participate in Social Roles and Activities 4a, Short Form v1.1 Pain Interference 4a, and Numeric Rating Scale Pain Intensity 1a. The default calibration sample will be used for all scores.	stress_promis_tscore (to be derived)
Family satisfaction in the intensive care unit (FS-ICU)	The decision making subscale of the FS-ICU is a 10-item survey that measures family surrogates' satisfaction with the decision making process in the ICU using 5-point Likert-type response formats. Families are asked to rate their satisfaction with communication from the health care team, the quality of the information they received, and how included and supported they felt in making medical decisions. In accordance with the survey's user manual and other studies, we will convert all item responses to integers from 0 to 4, calculate the average, and multiply by 25 to give a final score from 0 to 100. Aligning with prior studies from our group and others, a subscale score ≥ 75 will indicate a high level of satisfaction with decision making.	fs_icu (to be derived)

Decisional regret score	The DRS is a 5-item survey that measures remorse or distress following a health care decision. Parents are asked to rate their agreement level with statements that express the presence or absence of regret, with 5 response options ranging from “strongly agree” to “strongly disagree.” In accordance with the survey’s user manual and other studies, we will convert all item responses to integers from 0 to 4, calculate the average, and multiply by 25 to give a final score from 0 to 100. Aligning with prior studies from our group and others, a score >25 will indicate a high level of decisional regret.	<p>drs_score (to be derived)</p> <p><i>Components:</i></p> <p>drs_decisions, drs_regret, drs_again, drs_harm, drs_wise</p>
Decisional conflict score	The DCS is a 16-item survey that measures parents’ state of uncertainty about making health care decisions. Parents are asked to rate their agreement level with statements that relate to 5 domains of decisional conflict: being informed, support, effective decision making, uncertainty, and values clarity. In accordance with the survey’s user manual and other studies, we will convert all item responses to integers from 0 to 4, calculate the average, and multiply by 25 to give a final score from 0 to 100. Aligning with prior studies from our group and others, a score >25 will indicate a high level of decisional conflict.	<p>dcs_score (to be derived)</p> <p><i>Components:</i></p> <p>hard_v2, unsure_v2, clear_v2, awarechoice_v2, benefits_v2, risks_v2, advice_v2, importbene_v2, importrisk_v2, riskbenefit_v2, pressure_v2, amount_v2, informed_v2, selfdecision_v2, stick_v2, satisfied_v2</p>
Feeling heard and understood (FHAU) score	The 4-item FHAU scale measures parents’ experience of feeling heard and understood by their infant’s health care team using 5-point Likert-type response formats. In accordance with the user manual and other studies, we will use “top box scoring” for each item that defines “completely true” (i.e., the top box response) as passing, where 1 = passing and 0 = not passing. For each individual, we will average the number of top-box responses (up to 4) to estimate their proportion of Feeling Heard and Understood. We will also use descriptive statistics to calculate the total number of participants who responded “completely true” or “very true” for each item.	<p>fhu_score (to be derived)</p> <p><i>Components:</i></p> <p>heard_understood, interests_first, interests_first, understood_values</p>

4. Statistical Analysis Plan

Feasibility

The primary outcome will be intervention and study feasibility, defined *a priori* as 1) enrollment rate of $\geq 50\%$ of eligible infants and 2) complete data collection rate of $\geq 80\%$.

Enrollment rate will be computed as the number of infants enrolled divided by the number of eligible infants screened. Complete data collection will be defined as all eligible infant, parent, and clinician data points collected for a given case; data points for which a participant withdraws prior to relevant data collection will be excluded.

Decision aid acceptability, Psychological stress, and Decision outcomes

Secondary outcomes include 1) parent and clinician acceptability of the tool, 2) preparation for decision-making, as measured by the Preparedness for Decision-making Scale (PrepDM), and 3) parent psychological distress, as measured using the PROMIS. Parent and clinician acceptability will be measured using self-report questions. Additional measured outcomes include parent decisional conflict, regret, and satisfaction. Decisional conflict and regret will be measured by the Decisional Conflict Scale (DCS) and the Decisional Regret Scale (DRS). Satisfaction with decision-making was measured using the Family Satisfaction-ICU decision-making subscale.

Decision aid acceptability will be summarized separately by parent, mother and father, as well as clinician. Pre- and post-intervention parental psychological stress and decision outcomes will be described for self-identified mothers and fathers separately.

Categorical characteristics will be summarized as frequency and percent, continuous characteristics will be summarized as mean, standard deviation, median, Q1, Q3, and range. A list of all reported variables can be found in the table shells in **section 5**.

5. Appendix. Planned table shells:

Table 1. Infant Characteristics	
Characteristic	Median (Range) or n (%)
Infants enrolled (n=)	
Gestational age at birth, weeks	
Age at enrollment, days	
Sex, Female	
Medical condition	
Prematurity (<37 weeks)	
Seizures	
Genetic diagnosis	
Congenital heart disease	
Neurologic diagnosis	
Interventions (%)	
Mechanical ventilation	
Surgical feeding tube placement	
Palliative care consult	
Tracheostomy placement	
Length of hospital stay, days	
Location at enrollment	
NICU	
PCICU	
PICU	
Death during study enrollment	

Table 2. Parent Characteristics	
Characteristic	Median (Range) or n (%)
Parents enrolled (n=)	
Age, y	
Gender, Female	
Race and ethnicity	
African American	
Asian	
Hispanic/Latinx	
White	
More than one race	
Other/not reported	
Level of education	
Less than high school	
High school/GED	
Some college	
Bachelor's degree	
Associate's degree	
Graduate or professional degree	
Annual household income	
Less than \$25,000	
\$25,000-\$34,999	
\$35,000-\$49,999	
\$50,000-\$74,999	
\$75,000-\$99,999	
\$100,000-\$149,999	
Greater than \$150,000	
Not reported	
Decision Guide Use	
Shared with clinical team	
Used in family conference	

Table 3. Clinician Characteristics	
Characteristic	Median (Range) or n (%)
Clinicians enrolled (n=)	
Age, y	
Gender, Female	
Race and ethnicity	
African American	
Asian	
Hispanic/Latinx	
White	
More than one race	
Other/not reported	
Years in practice	
Specialty	
Neonatology	
Pediatric critical care	
Pediatric neurology	
Pediatric cardiology	
Neurosurgery	
Other	
Social work	
Nursing	
Decision Guide Acceptability	
Found it to be helpful	
Would recommend to parents	
Would use again in future	

Table 4. Decision Aid Acceptability			
Acceptability measure	Mothers	Fathers	Clinicians
Found to be helpful			
Would recommend to other parents/patients			
Would use in the future			

Categorical variables display n for Agree/Strongly agree.

Table 5. Preparedness for Decision Making			
	Mothers	Fathers	Clinicians
PrepDM score			
PrepDM items (n agree or strongly agree, %)			
Helped recognize that decision needs to be made for child			
Prepared me to make decision for child			
Helped me think about the pros and cons of each treatment option			
Helped me think about which pros and cons are most important			
Helped me know that the decision depends on what matters most to me			
Helped me organize my thoughts			
Helped me think about how involved I want to be in making decisions			
Helped me identify questions to ask my child's doctor			
Prepared me to talk to my child's doctor about what matters most to me			
Prepared me for future conversations with my child's doctor			

Median (IQR) and n (%) for continuous and categorical variables, respectively. Categorical variables display n for Agree/Strongly agree or Quite a bit/A great deal

Table 6. Parent well-being (PROMIS measure)										
		Baseline			Post-Intervention			Difference (Post - Pre)		
Score	Response	Baseline Mother	Baseline Father	Baseline All Participants	Post-Intervention Mother	Post-Intervention Father	Post-Intervention All Participants	Post - Pre Mother	Post - Pre Father	Post - Pre All Participants
PROMIS: Ability to Participate in Social Roles and Activities										
PROMIS: Emotional Distress – Anxiety										
PROMIS: Emotional Distress – Depression										
PROMIS: Fatigue										
PROMIS: Pain Intensity										
PROMIS: Pain Interference										
PROMIS: Physical Function										
PROMIS: Sleep Disturbance										

Median (IQR) and n (%) for continuous and categorical variables, respectively.

Table 7. Decisional conflict, decisional regret, decision-making satisfaction, and feeling heard and understood.										
		Baseline			Post-Intervention			Difference (Post - Pre)		
Score	Response	Baseline Mother	Baseline Father	Baseline All Participants	Post-Intervention Mother	Post-Intervention Father	Post-Intervention All Participants	Post - Pre Mother	Post - Pre Father	Post - Pre All Participants
Decisional Conflict score										
Effective Decision										
Informed										
Support										
Uncertainty										
Values Clarity										
Decisional Regret score										
Family Satisfaction-ICU score										
Feeling Heard and Understood score										

Median (IQR) and n (%) for continuous and categorical variables, respectively. Categorical variables display n for Agree/Strongly agree or Quite a bit/A great deal.