

Title: Improving Family Meetings in the Pediatric Cardiac Intensive Care Unit

NCT: ID: 15-012274

Document date: 1/17/2023

## Statistical Analysis Plan

Aim 2: Pilot test the co-design-adapted CICU TALC with CICU parents and clinicians to determine:

a) Acceptability of intervention: Hypothesis: Respondents will endorse above a critical threshold of acceptability on satisfaction instruments to 20 clinicians and 23 parents and in semi-structured interviews.

Analytic plan: A constructivist grounded theory approach will guide qualitative analysis of interview transcripts regarding acceptability of the intervention. Descriptive statistics will be calculated for quantitative data from the acceptability survey.

b) Feasibility of enrollment and data collection, and fidelity: Hypothesis: Feasibility will be defined by: i) 30% parental and 50% clinician enrollment and consent rates, and 80% subject retention, and attrition; ii) ability to collect outcomes data from 46 patients (CICU length of stay), from 46 parents and from 50% of eligible team members. and iii) intervention fidelity with 95% of enrolled parents and clinicians receiving parent-directed and team-directed interventions.

Analytic Plan: Data completeness and accuracy will be monitored. I will calculate descriptive summaries including means and standard deviations for continuous variables, and proportions for categorical variables. As appropriate for pilot trials, analyses will focus on estimating proportions of binary feasibility and fidelity endpoints and constructing 95% CIs. Analyses of parent-reported outcomes will primarily be descriptive. Means and standard deviations along with 95% confidence intervals will be calculated.

c) Impact of CICU TALC on CICU parent and team behavior in family meetings. Hypothesis: the intervention will increase parent speaking time by 60%, elicitation of parental concerns to 40%, and response to parental emotion by 30%. I will audio record 230 CICU family meetings occurring before CICU TALC is initiated and 230 after initiation and use quantitative methods to measure pre-vs-post differences in a) speaking time of parents and physicians; b) elicitation of parental concerns; and c) response to parental emotion.

### Analytic Plan:

- Speaking time will be analyzed by comparing the change in the number of words spoken by physicians versus parents speak in pre- and post-CICU TALC meetings using generalized linear regression with binomial link function controlling for the length of the meetings. Means and standard deviations will be calculated for the tool and t-tests will determine if significant differences exist for the two groups pre and post-CICU TALC.
- Elicitation of parental concerns and empathic response to parental emotion will be determined through quantitative coding. Each skill will be analyzed separately, using the cutoffs to identify skill proficiency as used by Back. Univariate relationship pre/post intervention by outcomes (Table 1)
  - If the outcomes (skills acquisition scores) are continuous and satisfies the normality assumptions, then t-tests will be appropriate to compare pre – intervention and post –intervention changes.

- If outcomes are continuous but not normally distributed, then a Wilcoxon Rank sum test will be appropriate to compare pre –intervention and post –intervention changes.
- If outcomes are binary (high vs low), then chi-square/fishers exact tests will be appropriate to compare pre –intervention and post –intervention changes.
- Similar statistical analysis will be performed to compare pre –intervention and post –intervention changes overall and for each type of participant.
- Analyses will be presented at the meeting-level as well as the participant-meeting level. Participant-meeting level data will be stratified by physician-type pending  $\geq 5$  participants in the pre- and post-intervention groups for each type.
- Relationship pre/post intervention by outcomes adjusted for participant and meeting level characteristics
  - If sample size allows and there are significant univariate associations, we will utilize mixed effect regression models to explore the relationship between the intervention and outcomes, first controlling for--gender and years of experience and accounting for correlation of repeated measurements within participants. If sample size allows, we will include other characteristics including number of participants at the meeting, proportion of speaking time by participant type, etc